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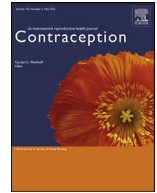
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Original Research Article

Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models

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ABSTRACT

Objective: To demonstrate the effectiveness of medication abortion with the implementation of telemedicine and a no-test protocol in response to the COVID-19 pandemic.

Study design: This is a retrospective cohort study of patients who had a medication abortion up to 77 days gestation at the University of Hawai'i between April and November 2020. Patients had the option of traditional in clinic care or telemedicine with either in clinic pickup or mailing of medications. During this time, a no-test protocol for medication abortion without prior labs or ultrasound was in place for eligible patients. The primary outcome was the rate of successful medication abortion without surgical intervention. Secondary outcomes included abortion-related complications.

Results: A total of 334 patients were dispensed mifepristone and misoprostol, 149 (44.6%) with telemedicine with in-person pickup of medications, 75 (22.5%) via telemedicine with medications mailed, and 110 (32.9%) via traditional in person visits. The overall rate of complete medication abortion without surgical intervention was 95.8%, with success rates of 96.8, 97.1, and 93.6% for the clinic pickup, mail, and clinic visit groups, respectively. Success for those without an ultrasound performed prior to the procedure was 96.6%, compared to 95.5% for those with ultrasound. We obtained follow-up data for 87.8% of participants.

Conclusions: Medication abortion was safe and effective while offering multiple modes of care delivery including telemedicine visits without an ultrasound performed prior to dispensing medications.

Implications: Incorporating telemedicine and a no-test protocol for medication abortion is safe and has the potential to expand access to abortion care. All care models had low rates of adverse events, which contradicts the idea that the Risk Evaluation and Mitigation Strategy increases the safety of medication abortion.

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1. Introduction

The COVID-19 pandemic greatly impacted the delivery of healthcare services. Healthcare providers and healthcare systems made rapid shifts from face-to-face medical visits to telemedicine, even for non-COVID positive patients [1]. This rapid increase in the use of telemedicine services since the start of the pandemic has been well accepted, with one retrospective study showing significantly higher patient satisfaction with telemedicine visits compared to in-person visits [2]. Although the body of evidence sur-

rounding the implementation of telemedicine during the pandemic is still growing, early studies have demonstrated its utility in providing safe and satisfactory care to patients.

Prior to the COVID-19 pandemic, several medication abortion delivery models already included telemedicine. Clinic-to-clinic telemedicine models, which incorporate preabortion testing at a clinic remote from where the mifepristone provider is located, a videoconference with the provider, and dispensing abortion medications at a remote site, demonstrated no difference in rates of adverse events, ongoing pregnancy, or blood transfusion compared to in-person visits [3, 4]. Gynuity Health Project's TelAbortion study, in which patients received mifepristone and misoprostol via mail after a telemedicine visit, also demonstrated high abortion completion and low complication rates [5]. In addition, patients and

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providers have found these telemedicine models to be acceptable and satisfactory forms of care delivery [4–6].

Hawai'i has the unique geographic challenge of being comprised of many islands with abortion care only offered on Oahu, Hawai'i Island, and Maui. This challenge was exacerbated by the pandemic, since the prepandemic practice of having patients fly in for a visit now has the added risk of COVID-19 exposure, plus varying limitations and quarantine requirements for interisland travel. In an effort to respond to the COVID-19 pandemic, our clinic expanded use of telemedicine and also adopted a new no-test medication abortion protocol for eligible patients while continuing to offer in person face-to-face visits for medication abortion. The no-test protocol is based on evidence demonstrating that preabortion testing with labs and ultrasound can often be safely omitted for many patients, thus eliminating the need for any in person visit prior to receiving a medication abortion [7]. With appropriate counseling from a clinician, much of the medication abortion process can be managed independently by patients, including confirmation of pregnancy, self-administration of medications, and management of side-effects [8]. Our clinic now offers a variety of models for medication abortion including traditional in-person visits and telemedicine visits with medications dispensed from clinic or by mail, while utilizing a no-test medication abortion protocol for eligible patients. The objective of this study was to describe our experience with these delivery models operating simultaneously.

2. Methods

2.1. Medication abortion protocol

We conducted a retrospective cohort study of patients seen via multiple care models between April 1, 2020 and November 30, 2020 during the COVID-19 pandemic in Hawai'i. Our primary objective was to describe our experience with medication abortion when multiple medication abortion service delivery models were offered to patients. The primary outcome we sought to describe was successful medication abortion, defined as medication abortion completed without any need for surgical intervention. We also described the proportion of patients who had an incomplete abortion (retained gestational sac or tissue without viable pregnancy), ongoing pregnancy (continued viable pregnancy after taking medications), took additional misoprostol beyond what was initially dispensed, received a blood transfusion, or sought care in an emergency room (ER) for an abortion-related concern.

Our family planning clinic is an academic practice with two locations on Oahu and one on Hawai'i Island, with centralized scheduling for abortion care. After April 1, 2020, patients contacting the clinic selected a medication abortion service delivery model depending on their clinical presentation, telemedicine capability, geographic location, and personal preferences, with some limitations. These options are outlined in Table 1. We also continued to offer surgical abortions throughout this time period. Eligibility determination (clinical history, assessment of gestational age) and counseling were conducted either in-person or via telemedicine using synchronous Zoom videoconferencing. Mifepristone consent forms were signed either in person or via telemedicine with an electronic consent. Patients who participated in the TelAbortion Project could have medications mailed to any address in Hawai'i. We also mailed medications to non-study patients under the U.S. District Court for the District of Maryland ruling that temporarily put a hold on the Risk Evaluation and Mitigation Strategy (REMS) in person dispensing requirement during the pandemic.

Patients who had a known last menstrual period (certainty within 1 week) that gave them a gestational age of 11 weeks or less, had regular periods and did not have any risk factors for ec-

topic pregnancy (prior ectopic pregnancy, tubal surgery, intrauterine contraception use at the time of conception) or symptoms of ectopic pregnancy (vaginal bleeding or pelvic pain in the past week) could forgo an ultrasound. If any of these criteria were not met or the patient desired an ultrasound, we referred the patient for an ultrasound prior to dispensing medications, or performed it while the patient already was in clinic. TelAbortion patients were required to have an ultrasound or pelvic examination performed before being mailed medications.

We provided medication abortion up to 77 days gestation. All patients were dispensed 200 mg mifepristone and 2 doses of 800 mcg misoprostol. We counseled patients to take oral mifepristone followed in 24 to 48 hours by 800 mcg misoprostol, either buccally or vaginally. If they did not start bleeding within 24 hours of their first dose of misoprostol, we advised that they take a second dose of 800 mcg misoprostol. For pregnancies at 63 to 77 days, we instructed patients to take a second dose of 800 mcg misoprostol four hours after the first dose. We required documentation of Rh type for patients above 70 days gestation and administered Rh-immune globulin either at our clinic or a location closer to the patient if more convenient.

Standard follow-up was a telemedicine visit by videoconference or telephone 1 to 2 weeks after ingestion of mifepristone and a high sensitivity urine pregnancy test taken 4 weeks after mifepristone, followed by a phone call from clinic staff. We dispensed urine pregnancy tests with the medications. We also offered patients the option of having an ultrasound at any convenient clinic 1 to 2 weeks after mifepristone ingestion or obtaining serial serum human chorionic gonadotropin (hCG) levels, particularly if they were going to be traveling out of state or desired a long-acting reversible contraceptive method sooner than 4 weeks after the abortion. If the initial telemedicine follow-up visit was concerning for ongoing pregnancy based on provider judgment of the lack of appropriate bleeding or continuation of pregnancy symptoms, we scheduled the patient for an ultrasound. Likewise, if a urine pregnancy test remained positive 4 to 5 weeks after the abortion, patients were advised to have a serum hCG or ultrasound. Patients could contact our on-call physicians at any time with issues or go to their local emergency room.

2.2. Data abstraction and analysis

We performed a retrospective chart review of all patients who initiated a medication abortion visit from April through November 2020. Authorization to perform a chart review was obtained from the Western Institutional Review Board. We excluded patients who were not dispensed the medications.

Researchers independently abstracted de-identified data from patient charts into a secure Qualtrics XM (Qualtrics, Provo, UT) database. We reviewed clinical notes, demographic data, lab results, outside provider notes, and emergency department records. Electronic medical records from the largest health systems in the state were accessible for review when assessing outcomes. We collected data on demographics, payor type, medical history, gestational age, testing done prior to the abortion, medications provided, medications taken, abortion outcome, and complications. If a patient had more than one medication abortion during the time period, we included all encounters. We reported gestational age at the time of dispensing medications based on either ultrasound dating if available or last menstrual period (LMP).

Successful medication abortion was determined by patient history, urine pregnancy tests, serum hCG, and/or ultrasound. Since our last patient included in the database received their medications by November 30, 2020, all patients were followed for at least 8 weeks to confirm abortion outcomes prior to chart abstraction.

Table 1
Service delivery models for medication abortion care at the University of Hawai'i between April and November 2020

Date initiated	Service delivery model	Additional information
April 1, 2020	In Clinic Visit + Pick Up – Ultrasound for gestational age dating only if indicated – In-Person Visit Dispensed Mifepristone and Misoprostol from the office during their visit	Was the standard model prior to April 2020 with ultrasound routinely performed
April 1, 2020	Telemedicine Visit + Pick Up – Ultrasound for gestational age dating only if indicated – Telemedicine Visit Dispensed Mifepristone and Misoprostol from office on Oahu or Hawai'i Island after their visit	Interaction in person typically lasted less than 5 minutes with a medical assistant dispensing medications.
Program began in 2016, ongoing on April 1, 2020	Telemedicine + Mail (TelAbortion Project) – Ultrasound for gestational age dating for all patients – Telemedicine Visit Dispensed Mifepristone and Misoprostol by mail	Only eligible up to 70 days gestation. Details described in previous publication [5].
October 1, 2020	Telemedicine + Mail – Ultrasound for gestational age dating only if indicated – Telemedicine Visit Dispensed Mifepristone and Misoprostol by mail	We mailed medications to patients who did not participate in the TelAbortion study under the US District Court ruling. Patients decided on this option if they wished to forgo an ultrasound or did not want to participate in a study.

Descriptive statistics were performed using SPSS Version 27 (IBM, Armonk, NY). We included all patients seen for medication abortion in our practice during the study time period. Pearson's chi-squared tests were used for the primary outcomes but no significant difference in outcomes based on method of dispensing mifepristone or if ultrasound was completed were noted, so they are not displayed.

3. Results

From April through November 2020, we dispensed mifepristone and misoprostol for 334 medication abortions, with a total of 330 unique patients. Patients did not vary demographically based on mode of dispensing medications, except by island where they lived, as shown in Table 2. Four patients (1.2%) had an early pregnancy loss, four (1.2%) stated they were terminating the pregnancy because of maternal health, and one individual stated the pregnancy had resulted from rape.

Figure 1 shows the breakdown of the different methods of receiving care, with two thirds completing a telemedicine visit and one third going to clinic. Of the 223 (66.8%) patients who had an ultrasound performed, 139 (62.3%) were performed prior to presenting to our clinic, 51 (22.9%) were performed for routine gestational dating after presenting to our clinic, 19 (8.5%) were required due to unsure LMP, and 14 (6.3%) due to a history of or symptoms concerning for ectopic pregnancy, 7 of whom had a prior ectopic. Two hundred and thirteen patients (63.8%) had a known Rh type prior to the abortion, either present in their medical records

(173, 81.2%), self-reported (24, 11.3%), or ordered specifically for the abortion (16, 7.5%). Patients chose their route of misoprostol administration, with 148 (51.6%) choosing buccal, 93 (32.4%) vaginal, and 46 (16.0%) not reported.

The primary and secondary outcomes are presented in Table 3. Seven patients who were dispensed medications reported that they did not take them and were excluded from analysis of the outcomes. Twelve of 287 patients with follow up data underwent uterine aspiration, giving an overall rate of successful medication abortion of 95.8%. If 100% success is assumed for those without follow up data, 315 out of 327 (96.3%) had a successful medication abortion. If failure is assumed for all those without follow up, 275 out of 327 (84.1%) would have been successful. Of the 12 aspiration procedures done, there were three ongoing pregnancies, four incomplete abortions with a gestational sac present, four procedures for heavy bleeding and/or retained tissue, and one patient who changed her mind after taking mifepristone and desired a surgical abortion rather than taking misoprostol. The subgroups did not have any significant difference in the primary outcome.

Rates of follow up are presented in Table 4, with patient history obtained from over three-quarters of patients, followed by urine pregnancy test results, ultrasound, and serum hCG levels. The mean time from dispensing to taking medications was 1.8 ± 2.6 days and the mean interval from dispensing medications to obtaining the first follow up information was 19.0 ± 12.7 days. There were significant differences in these intervals between the cohorts as expected due to the specifics of each delivery model.

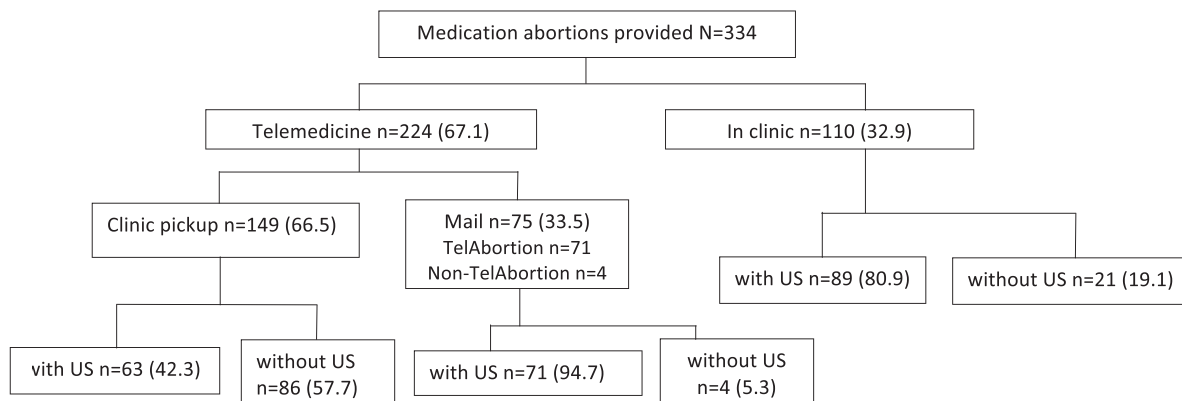


Fig. 1. Methods of providing medication abortion to patients at the University of Hawai'i between April and November 2020. US, ultrasound

Table 2

Demographic characteristics of patients who were dispensed mifepristone and misoprostol for a medication abortion through the University of Hawai'i between April through November 2020. Displayed as n (%) unless otherwise indicated

Characteristics	All Participants (N = 334)	In clinic (n = 110)	Telemedicine + pickup (n = 149)	Telemedicine + mail (n = 75)
Age (y), mean (SD)	27.8 (6.4)	28.1 (7.0)	27.3 (6.3)	28.5 (5.6)
Gravidity, mean (SD)	2.9 (2.0)	2.8 (1.8)	2.8 (1.9)	3.1 (2.3)
Parity, mean (SD)	1.0 (1.3)	1.1 (1.2)	0.9 (1.1)	1.3 (1.6)
Prior abortion	115 (34.4)	36 (32.7)	47 (31.5)	32 (42.7)
Prior medication abortion	44 (13.2)	11 (10.0)	20 (13.4)	13 (17.3)
Race/ethnicity ^a				
Filipino	44 (13.2)	9 (8.3)	18 (12.1)	17 (22.7)
Japanese	27 (8.1)	13 (11.9)	9 (6.0)	5 (6.7)
Other Asian	32 (9.6)	12 (10.9)	10 (6.7)	10 (13.3)
Black	12 (3.6)	6 (5.5)	5 (3.4)	1 (1.3)
Hispanic	29 (8.7)	11 (10.0)	10 (6.8)	8 (10.7)
Native American	7 (2.1)	3 (2.8)	1 (0.7)	3 (4.0)
Native Hawaiian	71 (21.3)	21 (19.3)	27 (18.1)	23 (30.7)
Pacific Islander	15 (4.5)	5 (4.5)	4 (2.7)	6 (8.0)
White	97 (29.0)	30 (27.3)	24 (16.1)	43 (57.3)
Unknown	81 (24.6)	25 (22.9)	56 (37.6)	1 (1.3)
Island ^b				
Oahu	196 (58.7)	87 (79.1)	108 (72.5)	1 (1.3)
Hawai'i	71 (21.3)	21 (19.1)	41 (27.5)	9 (12.0)
Kauai	58 (17.4)	1 (0.9)	0 (0)	57 (76.0)
Lanai	3 (0.9)	0 (0)	0 (0)	3 (4.0)
Maui	4 (1.2)	1 (0.9)	0 (0)	3 (4.0)
Molokai	2 (0.6)	0 (0)	0 (0)	2 (2.7)
Payment method ^a				
Private insurance	128 (38.3)	45 (40.9)	56 (37.6)	27 (36.0)
Medicaid	118 (35.3)	35 (31.8)	48 (32.2)	35 (46.7)
Paid by patient	110 (32.9)	30 (27.3)	47 (31.5)	33 (44.0)
Site abortion fund	8 (2.2)	0 (0)	0 (0)	8 (10.7)
Gestational age when dispensing medications				
Less than 49 d	130 (38.9)	49 (44.5)	51 (34.5)	30 (40.0)
49–62 d	165 (49.4)	55 (50.0)	75 (50.3)	35 (46.7)
63–77 d	39 (11.7)	6 (5.5)	23 (15.4)	10 (13.3)

^a Multiple options could be selected for these questions so percentages do not equal 100%.

^b Significant difference of mode of dispensing medications by island ($p < 0.001$)

Table 3

Medication abortion outcomes for patients who obtained a medication abortion via the University of Hawai'i with an in clinic visit or with telemedicine followed by clinic pickup or mailing of medications, with or without ultrasound prior

	n ^a	Gestational age (days, median [IQR])	Follow up data obtained	Medication abortion completion without surgery	Complications		
					Additional misoprostol ^b	Blood transfusion	ER visit ^c
All patients	327	52 [45–58]	287 (87.8)	275 (95.8)	4 (1.4)	2 (0.7)	11 (3.8)
In clinic	110	50 [45–57]	94 (85.5)	88 (93.6)	1 (1.1)	0 (0)	2 (2.1)
Telemedicine + pickup	145	51 [46–59]	124 (85.5)	120 (96.8)	1 (0.8)	2 (1.6)	5 (4.0)
Telemedicine + mail	72	50 [44–59]	69 (95.8)	67 (97.1)	2 (2.9)	0 (0)	4 (5.8)
With ultrasound	219	52 [45–59]	199 (90.9)	190 (95.5)	3 (1.5)	1 (0.5)	9 (4.5)
Without ultrasound	108	48 [44–55]	88 (81.5)	85 (96.6)	1 (1.1)	1 (1.1)	2 (2.3)

^a Excludes 7 participants who were dispensed the medications but did not take them: 3 who were mailed medications and 4 who picked up the medications from clinic.

^b Additional misoprostol beyond the 8 tablets dispensed routinely.

^c ER visit = emergency room visit for any abortion-related concern.

Table 4

Follow-up methods used by 327 patients who received medication abortion care at the University of Hawai'i between April and November 2020

Mode of follow up	Total (n = 327)	In clinic (n = 110)	Telemedicine + pickup (n = 145)	Telemedicine + mail (n = 72)
Patient history	253 (77.4)	85 (77.3)	112 (77.2)	56 (77.8)
Ultrasound	66 (20.2)	28 (25.5)	23 (15.9)	15 (20.8)
Serum hCG	19 (5.8)	5 (4.5)	5 (3.4)	9 (12.5)
Urine pregnancy test	156 (47.7)	40 (36.4)	69 (47.6)	47 (65.3)
No follow up	40 (12.2)	16 (14.5)	21 (14.5)	3 (4.2)

hCG, human chorionic gonadotropin.

Displayed as n (%) with a denominator of the number who were dispensed the medications and did not have evidence that they chose not to take the medications. Patients often followed up by >1 method.

4. Discussion

This retrospective cohort study demonstrates high medication abortion effectiveness amongst people using telemedicine with medications dispensed in clinic or by mail, as well as traditional in person care. The medication abortion success is comparable to previously published data of people dispensed mifepristone in clinic [9, 10]. The 87.8% follow up rate is higher than many prior observational studies of medication abortion [11, 12]. We were able to access the records of the major medical systems in our state so even if the patient did not complete their follow up visit, we were able to obtain information about any visits within those systems. Therefore, it is highly unlikely that the sensitivity analysis scenario where all patients who did not follow up required a surgical procedure is true.

Rates of abortion success are similar for all methods of dispensing mifepristone and misoprostol. They are also similar for those who did and did not have an ultrasound performed prior to the abortion. A limitation of this study is that our patient population was relatively small and unsuccessful medication abortions are rare, so we were underpowered to make groupwise comparisons. No differences between groups were noted for the primary outcome, although the in clinic group trended towards lower success.

Complications were rare with only 2 patients requiring a blood transfusion, 4 who received additional misoprostol and 11 who went to an emergency room. We did not find any hospital admissions, missed ectopic pregnancies, unrecognized ongoing pregnancies, expulsion of a fetus at an advanced gestational age, infections, or hysterectomies. Given that all 3 groups had similar, low rates of adverse events, this does not support that the REMS increases the safety of medication abortion.

Telemedicine is an acceptable option for patients, with 60% of patients living on the islands with all options available using it. Although individuals generally were offered all the options for receiving care, some did not have a choice. Patients reporting an unsure LMP or who needed an interpreter were directed to in person care, whereas individuals living on islands other than Oahu or Hawai'i Island were preferentially offered medication abortion by mail since it would be more complicated for them to arrange a flight to our clinic. Sixty-two patients living on islands without abortion providers were able to have an abortion without flying to a different island. During this pandemic, both spending time at a healthcare facility and traveling puts patients at higher risk of being exposed to COVID-19. Telemedicine with either a quick in clinic pickup or mailing of medications decreases this risk of COVID-19 exposure and transmission.

It is important to highlight that technological barriers to using telemedicine may exacerbate existing health disparities rather than decreasing disparities by increasing access [13, 14]. This can lead to intervention-generated inequalities, widening the gap between those who own a device with videoconferencing capability, are comfortable using that technology, and have access to the internet versus those who do not have these resources. The same people who have access to technology are also likely to be more educated with more social and economic resources, reinforcing the already better health outcomes of this group [15]. In addition, interpreter services may not be as readily available for use in telemedicine, impacting the options available for those with low English proficiency [13]. A third of our patients still came to clinic, demonstrating that it is still important to offer a clinic option for those who have limited technology access, screen in to requiring an ultrasound, or prefer a face-to-face interaction.

This study provides evidence from a practical approach to incorporating telemedicine and eliminating routine testing from medication abortion care. Multimodal care delivery is feasible and did not decrease the safety and effectiveness of medication abortion compared to studies of patients receiving their care in clinic. There remains a role for in clinic care for a certain proportion of patients, such as those who face intervention-generated inequalities. More work should explore ways of reducing technological barriers, such as for our patients on islands with no local abortion provider who would otherwise take on the added burden of flying to a different island. However, our current model demonstrates that using a combination of methods to reach patients is safe and effective and allows us to tailor our care to our patients' specific circumstances and preferences.

Conflict of Interest

All authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. Dr. Kaneshiro receives research support from ContraMed Pharmaceuticals (Sebela Pharmaceuticals), Gynuity Health Projects, and the National Institutes of Health. She is a consultant for UpToDate.

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