2021

Feasibility of Innovative Model of Medical Abortion Service Provision in Georgia

CLINICAL STUDY REPORT

PROJECT “IMPROVING ACCESS TO ABORTION IN GEORGIA”

Contents

Background

In Georgia, the medical abortion regimen involves three in-person visits. During their first visit, women undergo ultrasound and physical examination to assess eligibility for medical abortion, determine gestational age, and receive information and counseling about medical abortion and contraception options from abortion provider. If eligible for medical abortion, women must undergo a five-day waiting period and then return to the clinic to obtain medical abortion pills from the provider. Though not required in the national guidelines, approximately two weeks after ingesting mifepristone, providers recommend a third in-person visit to confirm abortion completion (Dr. George Tsertsvadze, personal communication, 2020).

Most international recommendations do not require multiple in-person visits to complete a medical abortion. The World Health Organization recommends a single in-person visit unless symptoms indicate the need for an in-person follow-up. Mandatory waiting periods between counseling and ingestion of mifepristone are medically unnecessary. In addition, waiting periods intrude on provider-patient relationship, and introduce an additional barrier to obtaining medical care as well as making extra trips to the clinic can be a significant financial and logistical burden.

Various medical abortion service delivery models that aim to eliminate medically unnecessary in-clinic visits have been piloted and evaluated. These models include mailing of medical abortion pills and the use of multi-level urine pregnancy tests to assess abortion outcome at home. Recent research demonstrates that mailing medical abortion pills is feasible and satisfactory to women. Unlike high-sensitivity urine pregnancy tests, multi-level urine pregnancy tests reliably assess abortion outcome as early as one week after mifepristone ingestion, and is recommended to be used up to 63 days since the last menstrual period. In addition, some providers in Georgia have experience using the MLPT for early medical abortion.

The goal of this study was to pilot and evaluate a simplified medical abortion service delivery that will reduce the number of in-person visits to only one visit for diagnosis and counseling. Five days later, provider will mail the medical abortion pills and two multi-level urine pregnancy tests (MLPT) to women. To account for the waiting period, the eligible upper gestational level was limited to 58 days since the last menstrual period. This pilot study was carried out by Tanadgoma and Healthy Life in partnership with Gynuity Health Projects.

Objective

The goal of the pilot study was to obtain data on the safety, feasibility, and acceptability of a service delivery model that reduces the number of medically unnecessary in-person visits.

Measures for safety objective:

- Adverse events attributable to the simplified medical abortion service
- Abortion outcomes

Measures for feasibility objective:

- Interest in the simplified medical abortion service
- Challenges of mailing abortion pills to women, such as number of lost and delayed packages

Measures for acceptability objective:

- Women's and provider satisfaction with the service delivery model
- Distance and cost associated with women's travel to the clinic
- Cost savings associated with using a reduced-visit model
- Satisfaction with MLPT for home based follow-up
- Amount women are willing to pay for MLPT if it were available, and comparison of women's willingness to use MLPT 7 days after taking mifepristone to the willingness to use high-sensitivity pregnancy test (HSPT) 4 weeks after taking mifepristone.

Study population

Women 16 years or over presenting seeking first trimester medical abortion at participating study sites were participants of the study.

All women must have met the following criteria to participate in the study:

- Have an ongoing pregnancy of 58 days gestation or less at the time of the initial in-person visit
- Are eligible for medical abortion according to study provider's assessment
- Able to receive physical mail
- Have access to a phone
- Be willing and able to consent to participate in the study
- Be willing to follow study procedures

Sample size and location of research

120 women were enrolled at three study sites, Gagua Clinic in Tbilisi, Batumi Medical Center in Batumi, and Clinic Elite in Zestafoni. The sample was based on the number of medical abortions performed at each study site and financial limitations.

Study procedures

Initial visit, day 1

Women with pregnancies of 58 days or less who contacted the study site and were eligible for medical abortion according to the provider were offered information about the study, they were given informed consent form to read and sign. Enrollment log documented number of women who were interested in participating in the study. Study staff documented those women who were not interested in participation in the study and the reason for refusal in the refusal log.

After receiving information and counseling about medical abortion and the study including instructions on how to use the MLPT, women signed standard form consenting to abortion services and the study informed consent form. Following data were collected: participant characteristics, medical and obstetric history, methods used to date the pregnancy, travel time, associated costs, and distance to the study site, time off from work/school, obligations at home, childcare arrangements, and reasons for interest in participating in the study. The study clinicians recorded mailing address and contact information, and together with the woman, decided on the date when the package was to be mailed, which would be at least 5 days or longer after the initial visit. Study provider also discussed symptoms that indicate the need for in-person visit and location of medical centers where emergency care could be obtained. Study provider also discussed follow-up plan, which includeed provider phone call to the participant to review medical history and abortion symptoms, and collecting results of the MLPT.

Mailing of the medical abortion pills and MLPT, day 5 or later

On the date agreed by the provider and participant but least five days after signing informed consent form, study staff contacted the woman to confirm that the woman does not have symptoms of miscarriage and wants to have the abortion. If the woman wished to continue, study provider provided additional counseling on medical abortion, confirmed follow-up plan, including date and time of follow-up call, and reviewd the woman's mailing address. Study staff then prepared a study package. The study package included:

- home study card with instructions on how and when to take the medical abortion pills, field where woman can record date and time of mifepristone and misoprostol ingestion, field where woman can record when she took first and second MLPTs and the results of the tests, symptoms when to seek emergency care, date and time of follow-up phone call
- mifepristone and misoprostol
- instructions on how to use the MLPT
- two MLPTs

Study staff recorded the tracking number for the package in the enrollment log.

Performing MLPT and taking medical abortion pills

Woman was instructed to take 200 mg mifepristone and the first MLPT when she received the package as long as her gestational age was no more than 63 days. Twenty-four to forty-eight hours later, the woman was instructed to take 800 mcg misoprostol buccally. The woman was then instructed to perform the second MLPT one week after mifepristone administration. If the result of the second MLPT was the same or higher than the first MLPT, woman was instructed to contact the study clinic immediately. Date and time of mifepristone ingestion and when MLPTs were taken was recorded by the woman.

If the woman's gestational age was 64-70 days at receipt of the study medications, she was instructed to take the medical abortion pills per national abortion guidelines and return to the clinic for in-person follow-up one week after taking mifepristone. If the first MLPT did not work, woman was instructed to

take the mifepristone and misoprostol as were instructed by a study staff and return to the clinic for in-person follow-up. If the second MLPT malfunctioned, women was recommended to return to the clinic for in-person follow-up. For women with gestational age more than 70 days upon receipt of study package was instructed to return to the clinic for surgical termination according to the national protocols.

Follow-up call, day 14 after initial visit or later

Follow-up phone call was arranged after one week of taking mifepristone. During the phone call, study provider conducted standard post-abortion interview that included a symptom checklist which ascertained the need for follow-up care, and collected results of the MLPTs. The following data were collected: date and time of mifepristone and misoprostol ingestion, route of misoprostol ingestion, level of bleeding, adverse events, treatment sought for care related to the abortion, and test results from the MLPTs. Based on the information collected, the study provider evaluated whether the woman needed in-person care at the study site or another medical center.

If the woman was required to seek additional in-person treatment due to ongoing pregnancy, incomplete abortion, infection or heavy, prolonged or irregular bleeding the study provider informed where and how to receive it. Reasons for treatment, type of treatment, and final abortion outcome were collected. If during the in-person visit it was determined that abortion was complete, the woman exited/completed the study.

Exit interview

Once the abortion was determined to be complete either by phone or during in-person visit, the study provider conducted an exit interview to gather feedback on the service. Data collected included: satisfaction with the simplified medical abortion service and MLPT, difficulties in obtaining study package and additional treatment, perceived cost savings resulting from participating in the study, and preference for alternative model of follow-up with the use of an HSPT four weeks after taking mifepristone.

Loss to follow-up

Study staff contacted every woman prior to sending the study package. Staff made at least three attempts to contact her using as many modalities as were allowed by the woman and by the study site's privacy policies. After the study package was sent, study staff made at least three attempts to contact the woman using as many modalities were allowed by the woman for at least four weeks after the study package was mailed. Once four weeks had passed since the last contact attempt, the woman was considered lost to follow-up.

Any attempts to contact the woman were documented in the Enrollment log.

Non-participant women cost survey

Study staff documented those women who were not interested in participation in the study and the reason for refusal in the refusal log. Women who were not interested in participation in the study, and consented to participate in the costing survey, were interviewed by the study team member. The latter conducted short interviews with them at initial visit, five days later when they returned to the clinic to obtain medical abortion pills and during the third visit. The interviews covered questions about costs associated with women's travel to the clinic and medical abortion service.

Provider satisfaction

Site staff maintained a log of any problems with implementing this simplified medical abortion service. When the study was terminated at each site, Tanadgoma conducted interviews with staff to collect data on what did and not work well, how the process could be improved, and whether this service delivery model could be implemented at the national level.

Serious Adverse Events

Study staff collected data on serious adverse events experienced by women while participating in this study. A serious adverse event was defined as one causing:

- Hospitalization or prolonged hospitalization;
- Permanent or serious disability;
- Additional threat to life; or
- Death.

A probable relationship with the study drug was not necessary to trigger a reporting obligation of a serious adverse event (e.g. car accidents had to be reported if they reached the attention of the investigator). All serious adverse events must have been reported by the investigator within 48 hours of her/his becoming aware of them to Tanadgoma and Healthy Life. This reporting could be done by telephone, fax or email. The report of a serious adverse event had always to be followed by a detailed written report containing patient information, description of the event or problem, relevant laboratory results, and information pertaining to pre-existing medical conditions. Each study site was supplied with standardized SAE forms to complete as needed.

When reporting a serious adverse event to the coordinator, the on-site investigator was obliged to protect the woman's confidentiality by excluding names or addresses. The unique subject code should be used in the report and the investigator should have retained the code to facilitate verification of data by the study coordinator or drug regulatory authority. The name of the investigator reporting the serious event should have been stated.

Data collection and analysis of results

Data collection took place from April, 2020 to March, 2021. Data were entered into SPSS database by study staff in Tbilisi. The data were kept and used by Tanadgoma, Healthy Life, Gynuity, and site investigators. The site investigators worked together to analyze the results of the study.

Univariate analyses was used to calculate the following statistics:

- Participant characteristics, such as demographics, obstetric and medical history
- Interest in the simplified medical abortion service, including continuing abortion treatment after initial consultation
- Distance and cost associated with women's travel to the clinic
- Abortion outcomes
- Additional treatment sought before or after follow-up
- Adverse events attributable to the simplified medical abortion service
- Challenges of mailing medical abortion pills such as lost or delayed packages
- Women's and provider satisfaction with the service delivery model
- Cost savings associated with using a reduced-visit model

Results of the study

Among the 122 women who enrolled in the study, the mean gestation age was 38 days (range 21-54 days) based on the last menstrual period (table 1). Gestational age was determined by ultrasound (96.7, n=118), LMP (42.6%, n=52), and/or clinical exam (27.0%, n=33). About half the women did not have previous medical abortion (66.9%, n=81) and most completed at least high-school level education (99.2%, n=119). On average, women lived 10.4 kilometers (range 0-100 kilometers) from the study site and required an average of 28 minutes (5-90 minutes) to travel to the study site (Table 1, participant characteristics). Also, 46.7% of the participants missed household duties, and out of them 41.8% sought assistance for missed obligations.

The top three reasons for choosing participation in the study were fewer clinic visits/less travel to the study site (64.8%, n=79), greater comfort (63.1%, n=77), and lowered travel costs (29.5%, n=36, Table 2, reasons for interest in the study).

After the 5-day waiting period, two women decided to continue their pregnancy and elected not to receive study medications by mail. One woman did not return follow-up call and was considered lost-to-follow-up, and one woman returned to the clinic prior to the follow-up call. Most women (98.3%, n=118) were successfully contacted by phone two weeks after taking mifepristone and nine (7.5%) returned to the study site for in-person visit upon request by the physician (4.2%, n=5) or request by the patient (3.3%, n=4, Figure 1, participant flow chart).

One hundred nineteen women were included in outcome analysis. The majority of women (95.8%, n=114) had a complete abortion; for most (91.3%, n=109) the abortion outcome was confirmed by a

decreased level of human chorionic gonadotropin (hCG) hormone as assessed by the multi-level pregnancy test and the review of symptom checklist (Table 3, abortion outcome). There were no serious adverse events in this study. Of the 119 women who were successfully contacted after the study package was mailed, only 10 (8.4%) returned to the clinic for an in-person visit either upon request by the study provider or woman's preference.

Study participants were able to follow the study regimen; all participants took the first MLPT prior to taking mifepristone, and all participants took mifepristone before 64 days LMP, which was the upper gestational limit in this study. Furthermore, most participants (99.2%, n=188) took misoprostol within 24-48 hours after taking mifepristone as scheduled together with the study provider, and most (99.1%, n=99.1) took the follow-up MLPT 6 or more days after taking misoprostol (Table 6).

On average, study package containing study medications and the two MLPTs was received 1.3 days (range 0.0-5.0 days) after the study provider's phone call to the participant to confirm their decision to proceed with the abortion procedure (table 5). Few participants (5.9%, n=7) reported delays in receiving the study package; nevertheless, all were able to take mifepristone before 64 days LMP. The majority of the participants (95.8%, n=114) were contacted on the scheduled follow-up call.

Most participants reported high rates of satisfaction with the medical abortion service offered through this study. All participants reported feeling very satisfied or satisfied with new service delivery model, the vast majority (89.9%, n=107) would recommend this service to a friend, and most would choose a same service if it were available in the future (87.4%, n=104, table 4). In addition, our study participants also reported self-perceived cost savings by participating in this study. Since the vast majority required only one in-person visit, the top cited savings were transportation (89.1%, n=106) and forgoing fees for the follow-up visit (74.8%, n=89, data not shown).

Conclusions

1. The novel model of Medical Abortion service is safe and effective option
2. Women can check the abortion status at home based on symptoms and the test results
3. Remote delivery of medical abortion allows the healthcare system to meet patient requirements, especially in hard-to-reach populations and areas where there is no experienced physician available
4. Remote support for medical abortion helps doctor in COVID-19 times and allows MA services to be flexible enough in order to reduce the spread of the virus

This study demonstrates that remote administration of medical abortion is safe, feasible, and acceptable to women. The vast majority of study participants had a successful medical abortion without an additional intervention performed by a provider. There were no adverse events reported in this study.

All participants were able to follow study protocol as discussed with the study provider, the majority were able to receive study medications by mail without significant delays, and the majority reported high satisfaction with the service.

- To 99% - taking postage of MA pills and pregnancy tests at home is very acceptable, or acceptable
- To 97% - using pregnancy test for follow-up at home is very satisfying, or satisfying
- 100% - satisfied, or very satisfied with the new model of service delivery

Our results are similar to findings of other research studies on telemedicine medical abortion (Grossman, 2011; Grossman, 2017; Aiken, 2021).

Our study found that the majority of participants (91.6%,) were able to reduce in-person visits to the clinic from three to one, with the added benefit of cost savings associated with in-person visit such as transportation and visit fees. Also, the study found that this model reduces logistical burden as almost half of the women who missed their obligations sought assistance. In the Republic of Georgia, a medically unnecessary 5-day waiting period requires multiple trips to the clinic to assess eligibility for medical abortion and obtain abortion medications. Telemedicine medical abortion allows for the mandated 5-day waiting period while reducing in person visits and associated costs. By incorporating telemedicine services in national abortion protocols in the Republic of Georgia, providers have the potential to offer more convenient and woman-centered services, thus further increasing satisfaction with the procedure and minimizing the intrusion on the provider-patient relationship.

Study limitations

The present study has several limitations. We did not collect data on the costs associated with in-person abortion and therefore, cannot ascertain cost benefits to women for choosing telemedicine medical abortion. In addition, we did not collect data on the costs incurred by providers when offering telemedicine medical abortion. In the Republic of Georgia, fees for abortion services are paid by the patient and a reduced in-person visit schedule may result in lower income to providers. In addition, we were unable to follow-up patients after their abortion. It is possible that women presented to providers who were not involved in the study to confirm abortion completion. Lastly, the majority of our study population completed at least high-school level education and study findings may not be generalized to the general population.

This study demonstrates that telemedicine medical abortion is safe, effective, and feasible, and has the potential of making medical abortion services more comfortable and patient-centered in settings where waiting periods are mandated. Study findings should encourage health experts in the Republic of Georgia to incorporate telemedicine medical abortion services in the national abortion guidelines and decrease the burden on women by decreasing the number of medically unnecessary in-person visits to the clinic.

Data tables

Table 1. Participant characteristics

	N=122
Age, mean (range)	30.5 (19-44)
Gravidity, mean (range)	4.6 (0-17)
Parity, mean (range)	1.8 (0-6)
Previous MA*	0.5 (0-9)
GA in days, mean (range)*	37.7 (21-54)
Highest education level completed, n (%)	
Primary	1 (0.8)
Highschool	55 (45.1)
University	66 (54.1)
Residence, n (%)	
City	83 (68.0)
Village	39 (32.0)
Distance to clinic, km, mean (range)	10.4 (0-100)
Travel time to clinic in minutes, mean (range)	28 (5-90)

*n=121, missing response (1)

Table 2. Reasons for interest in study *(choose up to 2)*

	N (%)	N=122
1	Less travel/clinic visits	79 (64.8)
2	More comfortable	77 (63.1)
3	Less travel costs	36 (29.5)
4	Allows flexibility in schedule	24 (19.7)
Other*		
	Want to try MLPT	2 (1.6)
	Allows self-assessment of abortion outcome	3 (2.5)
	Will miss less work/school	7 (5.7)
	Free of charge service	16 (13.1)

Table 3. Abortion outcome

N (%)	N=119
Abortion outcome	
Complete abortion	114 (95.8)
RPOC	5 (4.2)
Additional miso for RPOC	*1 (0.9)*
Manual removal of RPOC	*1 (0.9)*
MVA for RPOC	*3 (2.6)*
Final abortion outcome confirmed with MLPT or patient symptoms alone	109 (91.3)
# In-person visits	10 (8.4)
# Provider referred after call	5

# Unscheduled, patient initiated	4
# Visits prior to FU call	1

Lost to follow-up (1)

Table 4. Satisfaction

N (%)	N=119
Acceptability of receiving medications and MLPT at home?	
Very acceptable	83 (69.7)
Acceptable	35 (29.4)
Neutral	1 (0.8)
Prefer same service delivery model, if needed	
Yes	104 (87.4)
No	1 (0.8)
Don't know	14 (11.8)
Would recommend this service delivery model to a friend	
Yes	107 (89.9)
Don't know	12 (10.1)
Overall satisfaction with the new service delivery model*	
Very satisfied	73 (61.9)
Satisfied	45 (38.1)

Lost to follow-up (1)

*Response missing (1) [ID 123]

Table 5. Service delivery/feasibility

	N=119
Time (in days) between initial visit and receipt of study package, mean (range)	5.8 (4.0-9.0)
Time between mailing package and receiving package	1.3 (0.0-5.0)
Time between scheduled FU call and actual FU call	0.1 (-1.0-3.0)
Provider spoke to patient 1 day before scheduled FU time, n (%)	1 (0.8)
Provider spoke to patient at the scheduled FU time, n (%)	114 (95.8)
Provider spoke to patient ≥1 day after scheduled FU time, n (%)	4 (3.4)
Reported problems receiving package, n (%)	7 (5.9)

Lost to follow-up (1)

Table 6. Adherence to study protocol

N (%)	N=119
Took 1st MLPT before taking mife	119 (100)
Took mife <64 days LMP	119 (100)
Took miso 24-48 hours after mife*	118 (99.2)
Took 2nd MLPT 1 week after taking mife**	
<6 days after mife	1 (0.9)
≥6 days after mife	116 (99.1)

Lost to follow-up (1)

* [ID 237 did not take miso per protocol]

**n=117, response missing (1); patient came to clinic before FU call (1) [ID 237]

Figure 1. Participant flow chart