

Review

Medical Abortion using Mifepristone and Misoprostol Drugs

Svetlana Radeva^{1,3*}, Zhivko Zhekov^{2,3}

Abstract

¹MU Varna, Department of health care

²MU Varna, Department of Obstetrics and gynecology

³Specialized Obstetric and Gynecological Hospital Varna

*Corresponding Author's E-mail:
sv.radeva@abv.bg

A comparative analysis of medicated abortion (Mifepristone and Misoprostol) in outpatient and inpatient conditions during the drugs for abortion trimester of pregnancy was performed: in terms of effectiveness, early and late complications. More and more women around the world are choosing a medical abortion. Medical abortion is safe and effective and has been used around the world for decades. The method is associated with less costs, without detachment from the work environment and does not aggravate the costs of hospital stay and treatment. Abortion pills - Mifepristone and Misoprostol are approved by the U.S. Food and Drug Administration for terminating a pregnancy up to 10 weeks, but in some countries they are also used later without the need for a doctor's visit. A systematic review of publications on the topic in the scientific database. Many countries restrict access to abortion, including the pill. This means that how you access this care may depend on where you live. induced Many countries restrict access to abortion, including the pill. This means that the way access to this care can depend on where a woman lives, so she needs an urgent procedure. There are few studies of medicated abortion at home, because either Prima is not documented or is not made available to a medical person. Most of the data are from medical practices and centers where patients are prescribed medicines for home use. Medical abortion in outpatient and inpatient conditions is of high efficiency and safety. Overall, the rates of complete abortions are 95-98.0%, and the incidence of serious complications is less than 1.0%. By gestational age: completed abortion - in 57-63 days (8-9 gw.)-average 95.0%; for 64-70 days (9-10 gw, average 93.0%. The number of continued pregnancies also does not differ significantly (for 57-63 days – an average of 3.0%; for 64-70 days – an average of 3.0%). Both methods have a high acceptability-an average of 88.0%. Through telemedicine, the time to receive the service is shorter by approximately 4.0 days. From 5.0% to 15.0% of women self-identify their gestational age incorrectly! Lower education, younger age, and pregnancy after 20 weeks are significantly associated with a preference for face-to-face communication and medicated abortion in stationary conditions. Medical abortion is considered very safe. It is estimated that only 2% of these abortions lead to complications, and most of them are minor. Self-induced abortions with pills available through telemedicine were not associated with higher risks of complications compared to pills prescribed by a doctor. Abortion with tablets avoids anesthesia and surgery (curettage), as well as the associated risks. The procedure has a high success rate – about 96%.

Keywords: First Trimester, Medical Abortion, Mifepristone and Misoprostol, telemedicine

INTRODUCTION

Abortion is the most common gynecological procedure - over 56 million per year worldwide (Gemzell-Danielsson and Lalitkumar, 2008; Royal College of Obstetricians and

Gynaecologists, Best practice in abortion care, 2022), with only 10.0% to 15% of all abortions occurring in the second trimester (Georgiev et al., 2018). Worldwide,

there is a trend of expanding medicated abortion (MA) indications during the drugs for abortion trimester, incl. in outpatient conditions. There is no established protocol for the safe termination of pregnancy during the Ambulatory trimester. As the main method of providing this service is accepted the use of telemedicine. In a modern sense, the concept of telemedicine has existed since 1924 when it appeared in the United States in a radio news article, with a picture on the cover of a doctor examining a patient and sending his results over the radio. The first demonstration was made in 1951 at The New York World's fair. It is believed that the term telemedicine was introduced into the medical literature in 1974. with the publication of R. G. Mark (Georgiev et al., 2018).

According to other sources, it was first recorded in 1970, he used the term in the publication (Strehle et al., 2006). Telemedicine is a way of providing health services in which providers (consultants) and clients are separated by distance (WHO-Abortion care guideline, 2022). This interaction can take place in real time (synchronously), e.g. by phone or video. But it can also occur asynchronously when a request is sent and the answer is provided later, e.g. by e-mail or text / voice / audio message (WHO-Abortion care guideline, 2022).

Telemedicine counseling allows women to do Medical abortion (depending on the stage of pregnancy) in their own home with remote support from the abortion provider. They do not need personal contact with the provider. There is no need to visit the abortion clinic before then, unless there is a reason for doing so: uncertain date of Mifepristone and Misoprostol - last Menstrual cycle; risk of ectopic pregnancy; complex medical conditions.

Telemedicine is gaining popularity as a service for the provision of Medical abortion and in many countries legally organized practices for its application are sought. The use of telemedicine as part of the abortion service also has historical precedent. Women in Northern Ireland used telemedicine for early and outside legal circumstances and outside the health system for almost a decade before its use was legislated.

The Medical abortion tablets were provided by members of feminist websites who provided them with detailed information on how to use them and what effects to expect from women. A number of more recent studies have found that many of their experiences are similar to those managed through England's National Health Service (NHS) (NIACT, 2021).

The aim of this review is to conduct a comparative analysis of medical abortion in inpatient and outpatient settings during the drugs for abortion trimester of pregnancy: in terms of effectiveness, early and late complications, using the electronic resources of information in the last 10 years.

Material a systematic review of publications on the topic in the scientific database.

METHODS AND METHODOLOGY

Documentary-scientific publications on the topic; retrospectively-conducted own observation.

RESULTS

Medical abortion in outpatient conditions-effectiveness and complications

10-12 g.w.: A systematic review of nine prospective comparative cohort studies involving 4,522 women up to 56 days (8 g.w.) from pregnancy, it was shown that the incidence of full abortions and the incidence of unwanted complications were the same for the use of both at home and in the medical establishment (Mannisto et al., 2017). A non-randomized comparative study involving 731 rural and urban women from India up to 63 days pregnant (9 g.w.) (Mannisto et al., 2017) and 10 weeks of pregnancy found no difference in abortion success or adverse complications. In the United Kingdom during the COVID-19 pandemic 52,142 women up to 70 days (10 g.w.) pregnancy used at home as the rates of complete abortions are over 98.0% and the incidence of serious complications is less than 1.0% (Mannisto et al. 2017).

Data from studies conducted in outpatient settings, women brought therapy for medical abortion at home. The survey was conducted in outpatient clinics and medical practices, due to the availability of opportunities for laboratory and highly specialized examinations of the uterus and condition of the uterine mucosa. The evacuation of uterine contents is followed in outpatient clinics, after conducting a medicated abortion at home.

Abortion results from 64-84 days' amenorrhea (9-12 g.w.) were published in a study from 2011 in terminations of pregnancy up to 70 days' amenorrhea with 200 Mifepristone followed by 24-36 hours later Misoprostol at home at a dose of 800 µg -97.7% efficacy was found. The effectiveness of a similar abortion scheme has been investigated in other studies (Dikke, 2018). In a study in 2012. 729 pregnancy interruptions were analyzed over a period of 64-70 days' amenorrhea compared to a period of 57-63 days (the same dosage was used with Mifepristone 200 and Misoprostol 800 µg p.os). The effectiveness was the same in both groups: in the group 57-63 days (8-9 g.w.) - 93.5% (95% CI 90-96); in the group 64-70 days (9-10 g.w.) - 92.8% (95% CI - 89-95). The number of ongoing pregnancies also does not differ significantly (57-63 days - 3.1%; 95% extravehicular - 1.6-5.8; 64-70 days - 3.0%; 95% extravehicular - 1.5-5.7). High technology acceptability and patient satisfaction were high in both groups, as follows - 87.4% and 88.3%. The authors conclude that medical abortion with Mifepristone and Misoprostolin outpatient practice is an effective and acceptable method of Terminating Pregnancy up to 64 - 70 days of amenorrhea (9-10 g.w.).

The safety and effectiveness of Misoprostol, admitted at home and in hospital was also established in a meta-analysis involving 9 prospective cohort studies and covering n= 4522 abortions (Dikke, 2017). Serious complications were not reported when taken at home, and the conclusion was that there was no difference in effectiveness, according to the place of taking the drug – home or hospital.

Data and monitoring are carried out in medical outpatient clinics and centers because there is no way to document results at home due to lack of equipment and laboratory services.

In 10-12 g.w. In 12g.w. or more with a medical abortion is usually performed in a medical facility. However, there is no evidence showing that medical abortion outside the medical establishment is unsafe (Strehle, 2006).

Medical abortion in outpatient conditions and telemedicine:

This model of Home Care has been proven safe, effective and acceptable to clients and improves access to abortion (Royal College OG, 2022). From a systematic review involving four randomized control studies comparing telemedicine with MA services and in-person clinics, it was found that there was no difference between the two groups in rates of successful abortions or continued pregnancies. Satisfaction with telemedicine services is high and comparable to normal clinical abortion services (WHO, 2022).

A study in the United States in 2011. comparing women who received Medical abortion through telemedicine or face-to-face at doctor visits concluded that providing the service through telemedicine is an effective method and has high levels of patient acceptability. Data were obtained for 223 telemedicine patients and 226 face-to - face patients-99.0% of telemedicine patients and 97.0% of face-to-face patients had a successful abortion; 91.0% of all patients were very satisfied with their abortion, but telemedicine patients were more likely to recommend the service to a friend; 25.0% of telemedicine patients would prefer face-to-face communication. *Monitoring of medical abortions is carried out in medical practices and medical centers.*

Two prospective cohort studies reporting on the effectiveness of telemedicine for the delivery of Ma during the COVID-19 pandemic used reported LMP of women alone to determine gestational age and eligibility for medical abortion (Mannisto et al., 2017). One study from England compared a cohort of 22,158 women who received a traditional MA before a pandemic, which included a personal assessment and routine ultrasound, to a group of women who received a MA with telemedicine (if they had a low risk of ectopic pregnancy and their self-reported medication for abortion was consistent with a gestational age of less than 10 weeks (n =18435) or a traditional Ma if they did not meet these criteria (n =11549) (Mannisto et al., 2017).

Treatment success, serious adverse reactions, and ectopic pregnancy rates did not differ between the two cohorts. 11 women (0.04%) of the telemedicine cohort were found to have gestational age greater than the expected 10 weeks. All were able to complete their abortions at home without incident.

Another, smaller Scottish cohort study followed a similar telemedicine protocol, but included women who were up to 12 g.w. by self-assessment of the LMP (Mannisto et al., 2017). Of the 663 women included in the cohort, at 79.0%, gestational age was determined only with the LMP. Due to uncertain gestational age, ultrasound was made at 14.0%, and to confirm intrauterine pregnancy at 5.0%. Complete abortion occurred in 98.0% of cases, with continued pregnancy occurring in less than 1.0% of women. In 2.4% of women, additional medical services were sought, but no serious adverse complications were reported. Although they can usually remember their aposematic when asked to determine their gestational age or eligibility for MA based on the aposematic, a small fraction of women's estimates differ from those of their abortion providers.

Three studies compared the determination of gestational age made with the help of the LMP with those determined by a provider assessment (Mannisto et al., 2017). All three studies also assessed the ability of women to determine for themselves whether they were eligible for MA based on their LMP. In the earliest of these studies, 10.0% of the 173 women in India who used a worksheet and their LMP to determine their gestational age determined that they were eligible for MA, while providers determined that their pregnancy was above the 56 - day limit (8 g.w.).

In Nepal, 13.0% of the 3,091 women who used their LMP and modified gestational dating wheel to determine their eligibility for MA using a 63-day limit (9 g.w.), were incorrect compared to supplier estimates. Finally, in Ghana, 770 women used a modified gestation wheel to determine whether their pregnancy was before or after 13 g.w. Compared to the provider's assessment, 3.6% of women incorrectly determined that their pregnancy was less than 13 g.w. Of these women, one pregnancy was 13 g.w. (0.1% of 770), 15 were 14 g.w. (1.9%), seven were 16 g.w. (0.9%), 2 were 18 and 22 g.w. (0.3% each), and 1 was 28 g.w. (0.1%).

DISCUSSION

Telemedicine accelerates access to early abortion. It enables more clinics to provide abortion services, facilitates the use of MA among women living in remote areas, reduces clinic waiting times (NIACT, 2021). In a UK study of over 50,000 cases, telemedicine found that the time to receive the service was shorter by approximately 4.2 days (NIACT, 2021). Also, telemedicine may reduce abortion-related costs such as absence from

work and travel costs. Lower education, younger age, and pregnancy after 20 g.w. were significantly associated with a preference for face-to-face and steady-state communication (NIACT, 2021).

Detailed studies have been conducted in the United States and UK where it is possible to conduct a telemedicine examination and digitally monitor the patient's condition. Follow-up monitoring requires a visit to a doctor to monitor the effect of the procedure.

Requirements for conducting MA in outpatient conditions

- Women can take the medicines at the medical facility or at home.

Two prospective, non-randomized multicenter cohort studies conducted in the United States, which together included 701 women, showed that between one-third and a half of the women who were offered the use of Mifepristone at home or in a clinic chose a Home Application (Mannisto et al., 2017). In similar studies conducted in Azerbaijan (Mannisto et al., 2017) the majority of women also chose home use-72.0% and 64.0%, respectively.

- After 11 g.w. It should only be taken in a medical facility.

While the safety and effectiveness of the ambulatory use of ambiguities as part of the repeatable and repeatable mode is well established up Misoprostol to 70 days of pregnancy, the upper gestational limit at which Repeatable can be safely used at home is not well established. However, ambiguities, ambiguities are recommended for outpatient use of ambiguities up to 70 days of pregnancy (10 g.w.) the search for optimal doses for abortion in the period 10-13 g.w. on tines. There is currently no comparative data for home use of misoprostol after 11 g.w. It is accepted that abortion regimens that involve taking additional doses of Misoprostol are not suitable for abortion in outpatient conditions. The WHO suggests that when women have access to a source of accurate information and a healthcare provider, they can manage the abortion process themselves by the age of 12gw.

- Expert clinical advice available 24 h / 7 days a week. A study (Strehle et al., 2006) found that 13% (n=224/1726) of women made contact with a clinician for help after taking the drugs for abortion at home for an abortion before 9 weeks' gestation. Most of those who called did not have indications to visit the Emergency Medical Assistance (84.0%, n=188), while a minority (1.0%, n=36) were advised to visit the CSMP for review. Overall, only 2.0% (36/ out of 1,726) of women showed up for an emergency check-up. This study highlights the need for expert clinical advice available 24 h/ 7 days a week for women with early Medical abortion at home.

Risks associated with Medical abortion in outpatient conditions (WHO, 2016)

- The greatest risk is if Ma is performed in the presence of an unrecognized ectopic pregnancy.
- The second major risk is associated with an underestimated gestational age determined at the diagnosis and stage of pregnancy.
- The third most important risk is the lack of routine in women to properly assess the severity of clinical symptoms and their combination with symptoms of concomitant systemic diseases.

Like any new activity related to medical services, telemedicine has its advantages and disadvantages. The *first*-the greatest risk when performing Medical abortion in outpatient conditions is the presence of unrecognized ectopic pregnancy. The *second* logistical problem is the incorrectly determined gestational age-most often underestimated. From 5.0% to 15.0% of women self-identify their gestational age incorrectly! When the true gestational age is in the range of II-nd trimester, and is treated with an abortion methodology used in I-st trimester due to undervalued gestational age - there is a high risk that the abortion will remain incomplete, with retention of abortion parts in the uterus and all related complications threatening the health and life of the woman.

The *third* significant risk associated with the use of Medical abortion (WHO, 2018) in outpatient settings is the occurrence of very rare severe complications of abortion such as uterine rupture, profuse bleeding, ascending infection and allergic reaction or intra-vascular coagulation (DIC). Any delay in recognizing and diagnosing these complications is associated with a risk to the woman's life. On the other hand, Medical abortion in outpatient conditions and the use of telemedicine for its management is an excellent alternative in conditions of pandemic, living in an area with geographical remoteness or lack of health personnel to ensure the performance of legal abortion.

In Bulgaria at this stage there is no established and legally regulated practice for the use of Medical abortion in outpatient conditions, but with the development of telemedicine standards - such is forthcoming. Telemedicine reduces the time frame for abortion and reduces the costs associated with it. That is why currently there is a legislative, administrative and health-medical regulation of the use of telemedicine, so that it becomes an effective and safe part of the procedure of Medical abortion and in Bulgaria. The study was conducted among 56 women who had a medical abortion on medical advice. They were observed in outpatient settings to monitor the effectiveness of therapy and all were carried out ultrasound diagnostics. The greatest effectiveness is the three-fold administration of a drug regimen between 6 and 12 hours ($\chi^2=74,000$, $p=0,000$)

and the gestation period of 12-20 g.w. ($\chi^2=38,858$, $p=0,025$), and single Drug Administration during pregnancy 8-13 g.w. ($\chi^2=30,537$, $p=0.006$) and effect up to the 6th hour ($\chi^2=8,133$, $p=0,004$). Within 2 weeks after closing the abortion are followed outpatient, laboratory tests and ultrasound examination are conducted. They all had antibiotic prophylaxis.

If women who have had a medical abortion are not followed in outpatient settings, there will be no documentary records of the procedure. This requires monitoring by ultrasound and laboratory tests the effectiveness of the medications taken. therefore, the database includes the results of documentation of cases of medicated abortion, traced in the pre-hospital practices of the relevant.

CONCLUSIONS

We can draw the following important conclusions:

First: Medical abortion (Mifepristone and Misoprostol), in outpatient and inpatient conditions are modern highly effective, safe and acceptable methods of induced abortion during the 1-st trimester of pregnancy. Medical abortion in outpatient conditions is associated with a risk to the life and health of the woman in unrecognized ectopic pregnancy, underestimated gestational age and delayed recognition and diagnosis of severe complications of induced abortion - such as uterine rupture, profuse bleeding, ascending infection and allergic reaction or intra-vascular coagulation (DIC).

Second: this model of Home Care has been proven safe, effective and acceptable to clients and improves access to early abortion. Satisfaction with telemedicine services is high and comparable to normal clinical abortion services. Telemedicine counseling allows women to do Medical abortion (depending on the stage of pregnancy) in their own home with remote support from the abortion provider. They do not need personal contact with the provider. Telemedicine speeds up access to early abortion, shortening the time by an average of 4 days. It enables more clinics to provide abortion services, facilitates the use of Medical abortion among women living in remote areas, reduces waiting times in the clinic. Telemedicine may also reduce abortion-related costs such as absence from work and travel expenses.

Third: lower education, younger age and pregnancy after 12gw. are significantly associated with a preference for face-to-face communication and Medical abortion in stationary conditions.

Fourth: safely performed induced Medical abortion is not a risk factor for late complications and subsequent pregnancy.

REFERENCES

- Dikke GB (2017). Indications and modern schemes of medical termination of pregnancy PRACTICAL MEDICINE, ,pp. 108.
- Dikke GB (2018). Medical abortion in outpatient practice, Moscow: GEOTAR-Media, - 384 p.: ill. - ISBN 978-5-9704-4430-6.
- Gemzell-Danielsson K, Lalitkumar S (2008). Second trimester medical abortion with mifepristone-misoprostol and misoprostolone: a review of methods and management. *Reprod Health Matters*, (31 Suppl):16;pp.162–172.
- Georgiev K, Stavrev D. et al. (2018). Telemedicine in the context of low-budget healthcare, proceedings of University of Ruse. Volume 57, book 8.1, .
- Ipas (2021). *Clinical Updates in Reproductive Health*. N. Kapp (Ed.). Chapel Hill, NC: Ipas.
- Mannisto J et al. (2017). The effects of termination of pregnancy on future reproduction, Academic dissertation to be presented with the assent of the Doctoral Training Committee of Health and Biosciences of the University of Oulu for public defence in Auditorium 4 of Oulu University Hospital.
- Royal College of Obstetricians and Gynaecologists, Best practice in abortion care (2022).
- Strehle EM, Shabde N (2006). One hundred years of telemedicine: does this new technology have a place in paediatrics? *Arch Dis Child*;91:pp.956–959. DOI: 10.1136/adc.2006.099622. www.archdischild.com
- The Northern Ireland Abortion and Contraception Task group (NIACT) (2021). Report on Sexual and Reproductive Health in Northern Ireland
- World Health Organization (2016). Global diffusion of Health: making universal health coverage achievable. Report of the third global survey on Health. Geneva: <http://apps.who.int/iris/bitstream/handle/10665/252529/9789241511780eng.pdf>
- World Health Organization (2018). Institute of Obstetricians and Gynaecologists. Interim Clinical Guidance, Termination of pregnancy under 12 weeks. Version 1.0
- World Health Organization (2022). Abortion care guideline, ISBN 978-92-4-003948-3.