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Effectiveness and acceptability of "at home" versus "at hospital" early medical abortion – A lesson from the COVID-19 pandemic: A retrospective cohort study

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ABSTRACT

Background: Since the lockdown caused by the COVID-19 pandemic, restrictions on hospitals' activity forced healthcare practitioners to innovate in order to provide continuity of care to patients. The aim of this study was to evaluate the efficiency of a newly established protocol for medical abortion and to measure the level of satisfaction of the patients who experienced abortion at home.

Methods: This retrospective study compared all the patients who had an early medical abortion at up to 9 weeks of gestation during the two drastically different periods between December 2018 and March 2021 ("hospital" and "home" groups). We evaluated the expulsion of the gestational sac as a primary outcome. The rates of infection, hemorrhage, retained trophoblastic material and need for surgical management were also assessed. A survey was also used to measure the satisfaction and acceptability of the method.

Results: The rate of expulsion of pregnancy was not significantly different between the two groups: 92.9% in hospital versus 99% at home. Early retained trophoblastic material and surgical interventions were higher in the hospital group. No significant difference was observed for the remaining outcomes. Moreover, the level of acceptability was similar in both groups, though patients felt safer in the "hospital" group.

Conclusion: Switching an early medical abortion protocol from expulsion of pregnancy in hospital to expulsion of pregnancy at home is effective and acceptable to women, and may be associated with decreased rate of retained trophoblastic material. Further larger studies are needed to test the long-term result of this protocol.

Introduction

Prior to the pandemic, 24 out of 27 countries of the European Union (EU) had legalized or decriminalized abortion in order to preserve women's physical and mental health and to decrease the mortality caused by illegal and uncontrolled procedures. Nevertheless, it seems that this right has to be always defended at a social, economic, and political level or during a health crisis [1].

Since March 2020, the lockdown caused by the new coronavirus disease 19 (COVID-19) pandemic has led to multiple restrictions on hospitals' activity and has forced healthcare practitioners to find efficient alternatives to guarantee adequate health services for their patients [2,3]. Essential healthcare services had to be defined and telemedicine was prioritized [4].

There was lack of consensus for abortion within the EU during the pandemic, which further enhanced inequalities in its access. In some countries, it was considered as non-essential due to a ban on non-life-threatening care in state hospitals, hence risking a rise in illegal abortions [1,5]. In contrast, other countries categorized abortion as an essential healthcare service. They introduced innovations such as using telemedicine to facilitate and ensure continuity and equity in abortion care. During this health crisis, no country so far has raised the gestational age for abortion in response to it.

In Belgium, the conditions to access abortion were not modified during the pandemic [1,4,5], but there was no official recommendation of good practice: each institution took its own initiative. In our hospital, we encouraged early medical abortion at home and modified our protocol with expulsion of pregnancy "at home"

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instead of "in hospital" as it was before the outbreak of COVID-19 [6].

The aim of this study was to evaluate the effectiveness and acceptability of the newly established protocol in comparison to the previous one.

Methods

Study design

This was a single-center retrospective study conducted between December 2018 and March 2021. We included all patients who asked for a voluntary medical abortion at less than 9 weeks of gestation. We excluded patients with surgical abortion, spontaneous abortion, and those with incomplete data. Patients with medical abortion performed between December 17th 2018 and March 17th 2020 were planned to have expulsion of pregnancy in hospital and were called the "hospital group". Patients with medical abortion during the COVID-19 lockdown between March 18th 2020 and March 30th 2021 were planned to have expulsion of pregnancy at home and were called the "home group". The study was approved by the institutional ethical committee (CE2020/146).

Protocol of management of medical abortion

Before COVID-19 lockdown, the management of medical abortion consisted of five onsite appointments. In the first one, the gynecologist calculates the gestational age by ultrasound, performs classical investigations (such as blood group, gonorrhea, and chlamydia tests...), and discusses future contraception. In the second one, the social worker validates the decision of the patient and assures her psychological support. Seven days later, the patient takes mifepristone 600 mg during her third appointment. Two days later, she is admitted to the day hospital in order to take oral misoprostol (400 mcg at 08:00 am. followed by an additional 400 mcg at 12:00 pm. if no material is expelled). A post-abortion appointment is given 1 or 2 weeks after a complete expulsion or 2 to 3 days after a failed expulsion. During this appointment, the patient is either scheduled for dilation and aspiration in the case of persistent intrauterine sac or is given an additional misoprostol in the case of retained trophoblastic material (800 mcg twice maximum). If medical treatment fails, operative hysteroscopy is planned 7 days later.

During and after the COVID-19 lockdown, the first appointment was kept onsite. The second appointment with the social worker was done by video. During the third appointment, mifepristone was given directly by the gynecologist who provided sufficient information to the patient about taking misoprostol at home (800 mcg on day 2 and 3 after mifepristone), explained the potential complications, prescribed adequate painkillers and future contraception. The expulsion took place at home, and the post-abortion appointment was kept onsite 15 days later (Table A1).

Primary and secondary outcomes

The primary outcome was the expulsion of the gestational sac within 30 days of mifepristone intake without any surgical intervention. Total success of the medical method was defined as the expulsion of the gestational sac without any further treatment. Partial success was defined as the expulsion of the sac after administration of additional misoprostol doses. Nevertheless, failure of the medical method was defined as the evacuation of the gestational sac by surgical interventions.

The secondary outcomes included the complications of medical abortion within 30 days of mifepristone intake, such as infection (need for antibiotics), hemorrhage (need for blood transfusion or urgent surgical intervention), retained trophoblastic material (thickness $\geq$ 15 mm +/- vascularization seen on ultrasound between day 3 and day 17 after mifepristone intake [early retention] or between day 18 and day 30 [late retention]), and need for hysteroscopy or aspiration.

Acceptability

The satisfaction and acceptability of the abortion method were assessed through a survey. Patients were contacted by phone and the study was thoroughly explained. The following four questions were asked after obtaining the informed consent: 1: How would you qualify your overall experience?; 2: Would you recommend this method to a friend?; 3: Would you choose this method of abortion again?; 4: Did you feel safe during abortion? A score of 0, 1, or 2 was assigned for each question if the answer was bad, neutral, or good, respectively. The minimum score of the survey was 0 and the maximum score 8. Patients who had more than one abortion during the period of the study were excluded for the analysis of acceptability.

Statistical analysis

Data were analyzed using the SPSS 26 statistical software (IBM SPSS statistics). Continuous variables were expressed as mean ± 1 standard deviation (SD) and categorical variables were expressed as number (frequency). We used the Kolmogorov-Smirnov test to examine the normal distribution of continuous variables. We then used Student's test to compare the means of these variables. Fisher's exact test was used to compare categorical variables. Statistical significance was assumed when the p value was $\leq$ 0.05.

Results

Baseline characteristics

During the study period, 208 patients asked for medical abortion. Among them, 27 were excluded and 181 included in the final analysis. The home group included 96 patients, whereas the hospital group included 85. For the acceptability survey, 6 further patients were excluded (because of 2 abortion events during the study period). Of 175 patients, 101 answered the survey (57.7%): 50 in the hospital group and 51 in the home group (Fig. 1). Age, gravidity, parity and history of abortion of patients were similar in both groups. The gestational age at intake of mifepristone was also similar in both groups: 48 ± 7.6 days in the hospital group and 46.5 ± 5.9 days in the home group (Table 1).

Effectiveness: Primary outcome

The primary outcome was achieved in 174 patients: 92.9% in the hospital group versus 99% in the home group (p-value = 0.052). Partial success was observed in 2 patients in the hospital group. Moreover, five failures were recorded: 4 in the hospital group, 1 in the home group (Table 2).

Effectiveness: Secondary outcomes

The rate of infection, visits to the emergency department and hemorrhage were similar in both groups. There was a statistically significant difference between the two groups regarding early retained trophoblastic material and the need for surgical interventions (28.2% in the hospital group versus 10.4% in the home group,

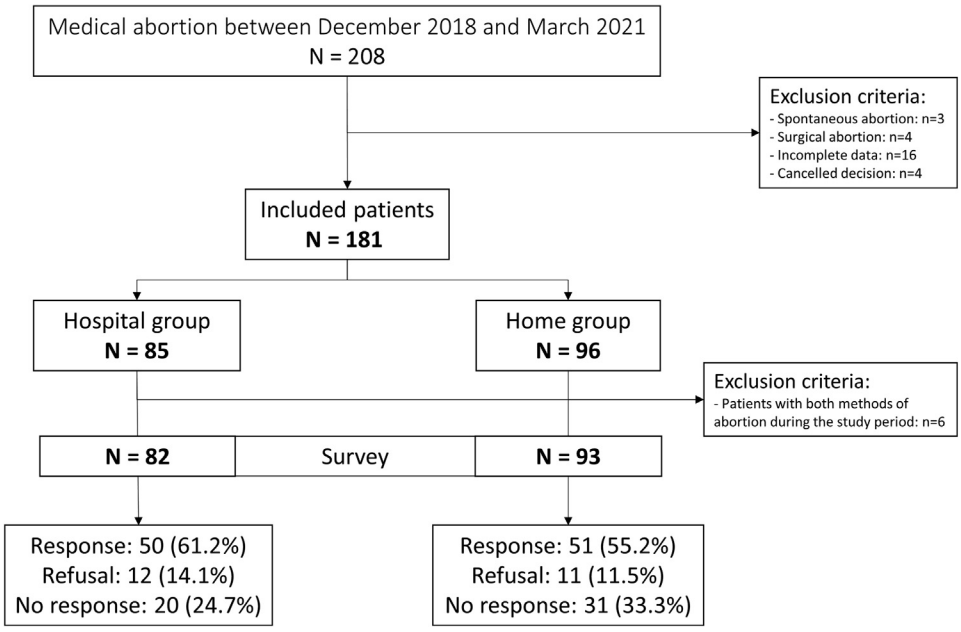

Fig. 1. Flow chart of the study population.

Table 1
Baseline characteristics of the study population.

	Hospital group N = 85	Home group N = 96	p-value
Age, years	31.4 ± 6	29.6 ± 6.9	0.059
Gravidity	3.4 ± 1.9	3.1 ± 2	0.116
Parity	1.8 ± 1.4	1.5 ± 1.3	0.274
Gestational age on ultrasound at the moment of mifepristone intake, days	48 ± 7.6	46.5 ± 5.9	0.106
Abortion history	18 (21.2%)	15 (15.6%)	0.343

Table 2
Comparison of primary and secondary outcomes in the two groups of the study.

	Hospital group N = 85	Home group N = 96	p-value
Primary outcome	79 (92.9%)	95 (99%)	0.052
- Total success	79 (92.9%)	95 (99%)	0.099
- Partial success	2 (2.4%)	–	
- Failure	4 (4.7%)	1 (1%)	
Secondary outcomes			
Early retained trophoblastic material	24 (28.2%)	10 (10.4%)	0.004
Late retained trophoblastic material	8 (9.4%)	4 (4.2%)	0.231
Hysteroscopy/Aspiration	14 (16.5%)	6 (6.3%)	0.034
Admission to the emergency department	2 (2.4%)	7 (7.3%)	0.127
Hemorrhage	5 (5.9%)	2 (2.1%)	0.186
Infection	2 (2.4%)	1 (1%)	0.490

p-value = 0.004, and 16.5% versus 6.3%, p-value = 0.034, respectively) (Table 2).

The time interval between the intake of mifepristone and the diagnosis of early retained trophoblastic material was shorter in the hospital group in comparison to the home group (p-value = 0.011). Nevertheless, the time interval between the intake of mifepristone and the hysteroscopy or aspiration was similar in both groups (Table A2).

Table 3
Assessment of the patient satisfaction and acceptability.

	Hospital group N = 50	Home group N = 51	p-value
How would you qualify your global experience?	1.6 ± 0.7	1.4 ± 0.8	0.295
Would you recommend this method to a friend?	1.5 ± 0.8	1.3 ± 0.8	0.247
Would you choose this method of abortion again?	1.4 ± 0.9	1.3 ± 0.9	0.936
Did you feel safe during the abortion?	1.8 ± 0.6	1.4 ± 0.8	0.004
Total score	6.2 ± 2.2	5.4 ± 2.8	0.151

Acceptability

The results of the global satisfaction score showed no significant difference between groups. However, analysis of the different items separately showed a significant statistical difference regarding the feeling of safety: patients felt safer in the hospital rather than at home (p value = 0.004) (Table 3).

Discussion

Main findings

In this retrospective study, we observed that the new protocol of early medical abortion, with at home expulsion of pregnancy, implemented during the COVID-19 pandemic, has the same effectiveness as the pre-pandemic protocol with expulsion of pregnancy at hospital. The success rates of medical abortion at home and at hospital were comparable to the literature values [1,7,8]. Both protocols were adapted following the World Health Organization (WHO) management of abortion recommendations [9]. Gambir et al. showed that the effectiveness of medically assisted abortion was superior to 90% without any statistically significant difference between abortion at the hospital or at home [7]. The baseline characteristics of both groups were similar in contrast to what is found in the literature. This could be explained by the fact that patients in

this study could not choose between hospital and home medical abortion [1,7-25].

Interpretation

Abortion at home was associated with a reduced diagnosis of early retained trophoblastic material and a reduced rate of hysteroscopy or uterine aspiration. The rate of infection in both groups was similar to that in the literature (1–2%) [10]. The rate of hemorrhage varies widely amongst studies (from 0.05% to 13%) because of the use of multiple definitions, such as decrease of two units of hemoglobin, need for blood transfusion, or need for surgical intervention [11,13,23]. The rate of hemorrhage in our study was similar in both groups and to the range in the literature. No significant between-group difference was observed regarding the rate of visits to the emergency department. This criterion though, is difficult to assess as it is not regularly mentioned in the literature, and the fact that access to healthcare was compromised during lockdown should not be overlooked. The uncertainty and the anxiety linked to the pandemic could play a role.

Another interesting finding of this study is the higher rate of diagnosis of retained trophoblastic material and need for surgical intervention in the group of medical abortion done at hospital. Two hypotheses may explain this finding. First, the dose of misoprostol in this group was lower (400 to 800 mcg in the hospital group versus 1600 mcg in the home group). However, a dose of more than 800 mcg was not proven to be mandatory prior to 9 weeks of gestation [9]. Second, during the pandemic the post-abortion visit was fixed on day 14. Free access and earlier post-abortion visit (as in the hospital group) may lead to the over-diagnosis of retained trophoblastic material. The time interval between the intake of mifepristone and the diagnosis of early retained trophoblastic material and the time interval between the intake of mifepristone and the day of hysteroscopy/aspiration were significantly shorter in this group.

Recommendations about the post-abortion follow-up range from no follow-up [15], to only if there are symptoms [9]. Thus, if a post-abortion appointment seems necessary, it would be wise to plan it on day 15 following the intake of mifepristone [16]. In addition, adding a quantitative assay of plasma beta human chorionic gonadotrophin (b-HCG) in association with ultrasound on day 15 may also decrease premature diagnosis of retained trophoblastic material and its related management [15,20,21].

In our study, the acceptability evaluation showed that both groups were globally satisfied with their management and only the feeling of insecurity was significantly higher in patients who underwent medical abortion at home. Many studies show that patients prefer to undergo medical abortion at home where they feel confident, comfortable and supported, rather than in hospital [7,8,14]. One should not overlook that this group was selected during the COVID-19 pandemic which could increase the level of stress, anxiety, uncertainty and fear. Unlike other studies, patients did not choose to be in the home group of medical abortion. This enabled us to highlight the importance of the insecure feeling in such a protocol, especially when the patients' preferences are not taken into consideration [24].

The implementation of an automated user-friendly message system could be a new advance in the management of medical abortion at home: the patient is warned about taking her pills and analgesics, reassured about potential side effects such as bleeding or cramping, and warned about seeking medical advice in more serious situations [19]. Lester et al. showed that mobile phones might be an effective tool to improve patient outcome in resource-limited settings while they were studying patients' drug adherence to antiretroviral treatments [18].

During these last years, researchers and practitioners have dramatically remodeled the management of medical abortion, especially during the pandemic. This study could help clinicians to shift to medical abortion at home even after the pandemic, because the success rate is similar to that of medical abortion at hospital, without any increase in serious complications [25]. It is important to underline that many countries have already implemented "at home" protocols for the management of abortion. The pandemic has enhanced the growth of telemedicine [15,16,18,22]. Abortion can also be done exclusively via telemedicine and mifepristone and misoprostol may be sent to the patient's home, as suggested by the WHO, though ectopic pregnancy or more advanced pregnancies may be overlooked if this practice is implemented [15-17].

Strengths and limitations

The limitations of this study are similar to those of all studies with a retrospective design. Selection bias was limited by having a balanced population with similar baseline characteristics between both groups. In addition, the two protocols were not identical. Patient follow-up, dose of misoprostol and historical context were different.

Conclusion

The effectiveness of the protocol of early medical abortion at home is similar to that of medical abortion at hospital. It is, however, associated with reduced rates of early retained trophoblastic material, hence, reduced rates of hysteroscopy and aspiration. By offering expulsion of pregnancy at home, we would correct the problem of high rates of retained trophoblastic material and avoid over-medicalization. Nevertheless, patients feel less safe when the abortion occurs at home. Efforts should be focused on implementing this protocol and reducing its drawbacks.

Implication

Medical abortion at home is safe, effective, and acceptable to the patients, however, patients feel less safe in comparison to medical abortion at hospital.

Ethics statement:

The study was approved by the ethical committee of University Hospital Brugmann (number CE2020/146) on December 8th, 2020.

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Contribution to authorship

Conception: I.M., C.V.P. Planning: C.V.P., J.C.J. Data collection: I. M., D.A.B. Formal analysis: I.M., C.V.P., J.C.J., D.A.B. Writing of the manuscript: I.M., D.A.B. Revision of the manuscript: C.V.P., J.C.J.

Declaration of Competing Interest

The 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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejogrb.2021.10.035.

References

[1] Bayefsky MJ, Bartz D, Watson KL. Abortion during the Covid-19 Pandemic - Ensuring Access to an Essential Health Service. N Engl J Med. 2020 May 7;382 (19):e47. doi: 10.1056/NEJMp2008006.

[2] Badr DA, Mattern J, Carlin A, Cordier A-G, Maillart E, El Hachem L, et al. Are clinical outcomes worse for pregnant women at ≥20 weeks' gestation infected with coronavirus disease 2019? A multicenter case-control study with propensity score matching. Am J Obstet Gynecol 2020;223(5):764–8. https://doi.org/10.1016/j.ajog.2020.07.045.

[3] Badr DA, Picone O, Bevilacqua E, Carlin A, Meli F, Sibiude J, et al. Severe Acute Respiratory Syndrome Coronavirus 2 and Pregnancy Outcomes According to Gestational Age at Time of Infection. Emerg Infect Dis. 2021 Aug 5;27(10). doi: 10.3201/eid2710.211394

[4] Belgian Health Care Knowledge Center. Assessing the management of hospital surge capacity in the first wave of the covid-19 pandemic in Belgium. KCE, 2020. Available: https://kce.fgov.be/sites/default/files/atoms/files/KCE_335B_Capacite_hospitaliere_durant_pandemie_COVID-19_Synthese_0.pdf. [Accessed August 14th, 2021].

[5] Moreau C, Shankar M, Glasier A, Cameron S, Gemzell-Danielsson K. Abortion regulation in Europe in the era of COVID-19: a spectrum of policy responses. BMJ Sex Reprod Health. 2020 Oct 22:bmjsrh-2020-200724. doi: 10.1136/bmjsrh-2020-200724

[6] Gambir K, Garnsey C, Necastro KA, Ngo TD. Effectiveness, safety and acceptability of medical abortion at home versus in the clinic: a systematic review and meta-analysis in response to COVID-19. BMJ Glob Health. 2020;5 (12):e003934. https://doi.org/10.1136/bmjgh-2020-003934.

[7] Schmidt-Hansen M, Pandey A, Lohr PA, Nevill M, Taylor P, Hasler E, et al. Expulsion at home for early medical abortion: A systematic review with meta-analyses. Acta Obstet Gynecol Scand. 2021;100(4):727–35. https://doi.org/10.1111/aogs.v100.410.1111/aogs.14025.

[8] Provansal M, Mimari R, Grégoire B, Agostini A, Thirion X, Gamerre M. Interruption volontaire de grossesse médicamenteuse à domicile et à l'hôpital : étude d'efficacité et d'acceptabilité [Medical abortion at home and at hospital: a trial of efficacy and acceptability]. Gynecol Obstet Fertil. 2009 Nov-Dec;37(11-12):850-6. French. doi: 10.1016/j.gyobfe.2009.07.016.

[9] World Health Organisation. Medical management of abortion recommendations. WHO, 2018. Available: https://www.who.int/health-topics/abortion#tab=tab_1 . [Accessed August 14th, 2021].

[10] Shannon C, Brothers LP, Philip NM, Winikoff B. Infection after medical abortion: a review of the literature. Contraception 2004 Sep;70(3):183–90. https://doi.org/10.1016/j.contraception.2004.04.009.

[11] Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. Obstet Gynecol 2013 Jan;121 (1):166–71. https://doi.org/10.1097/aog.0b013e3182755763.

[12] Ganer Herman H, Kogan Z, Dabas A, Kerner R, Feit H, Ginath S, et al. Clinical and Sonographic Findings in Suspected Retained Trophoblast: Correlation with Histological Findings. Isr Med Assoc J 2018 Dec;20(12):761–4.

[13] Carlsson I, Breding K, Larsson PG. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. BMC Womens Health 2018 Sep 25;18(1):158. https://doi.org/10.1186/s12905-018-0645-6.

[14] Song L-P, Tang S-Y, Li C-L, Zhou L-J-G-Y-K, Mo X-T. Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol. J Obstet Gynaecol Res 2018;44(9):1705–11. https://doi.org/10.1111/jog.2018.44.issue-910.1111/jog.13716.

[15] British pregnancy advisory service. Available: https://www.bpas.org/abortion-care/abortion-aftercare/ [Accessed August 14th, 2021].

[16] Fédération des centres de plannings familial des FPS : l'avortement : un dossier d'informations complètes, fiables et pratiques. Available: https://www.planningsfps.be/nos-dossiers-thematiques/dossier-interruption-de-grossesse-ivg/ [Accessed August 14th, 2021].

[17] World health organization : Maintenir les services de santé essentiels : orientations de mise en œuvre dans le cadre de la COVID-19 : orientations provisoires. WHO, 2020.

[18] Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, et al. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial. Lancet 2010;376(9755):1838–45. https://doi.org/10.1016/S0140-6736(10)61997-6.

[19] Free C, Phillips G, Watson L, Galli L, Felix L, Edwards P, et al. The effectiveness of mobile-health technologies to improve health care service delivery processes: a systematic review and meta-analysis. PLoS Med. 2013;10(1): e1001363. doi: 10.1371/journal.pmed.1001363.

[20] Michie L, Cameron ST. Simplified follow-up after early medical abortion: 12-month experience of a telephone call and self-performed low-sensitivity urine pregnancy test. Contraception. 2014 May;89(5):440–5. https://doi.org/10.1016/j.contraception.2014.01.010.

[21] Le Lous M, Gallinand AC, Laviolle B, Peltier L, Nyangoh Timoh K, Lavoué V. Serum hCG threshold to assess medical abortion success. Eur J Contracept Reprod Health Care. 2018 Dec;23(6):458–63. https://doi.org/10.1080/13625187.2018.1539162.

[22] Reynolds-Wright JJ, Johnstone A, McCabe K, Evans E, Cameron S. Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic. BMJ Sex. Reprod Health. 2021;47(4):246–51. https://doi.org/10.1136/bmjsrh-2020-200976.

[23] Meaidi A, Friedrich S, Gerds TA, Lidegaard O. Risk factors for surgical intervention of early medical abortion. Am J Obstet Gynecol. 2019 May;220 (5):478.e1–478.e15. https://doi.org/10.1016/j.ajog.2019.02.014.

[24] Harden J, Ancian J, Cameron S, Boydell N. Women's experiences of self-administration of misoprostol at home as part of early medical abortion: a qualitative evaluation. BMJ Sex Reprod Health. 2021 Apr;47(2):144–9. https://doi.org/10.1136/bmjsrh-2020-200661.

[25] Baiju N, Acharya G, D'Antonio F, Berg RC. Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis. BJOG 2019;126(13):1536–44. https://doi.org/10.1111/bjo.v126.1310.1111/1471-0528.15922.