Abstract

The European Society of Contraception Expert Group on Abortion identified as one of its priorities the need to disseminate up-to-date evidence-based information on the use of urine pregnancy tests by women for the self assessment of the success of early medical abortion. A concise communication was produced which summarises the latest research in an easy-to-read format suitable for busy clinicians. Information about individual urinary pregnancy tests is presented in boxes for ease of reference.

Keywords

Medical abortion, low sensitivity urine pregnancy test, multilevel urine pregnancy test, human chorionic gonadotrophin.

wordcount 963

Background

Simplifying early medical abortion (EMA) (< 10 weeks) is an important step in facilitating access to safe abortion. This includes simplifying follow-up after medical abortion. Traditionally, a follow-up visit with the abortion provider was scheduled to confirm the success of the procedure- and this usually necessitated a routine ultrasound examination of the uterus to confirm that the pregnancy had been successfully terminated. Whilst ultrasound can reliably exclude a continuing pregnancy, ultrasonically visible but clinically unimportant blood and tissue commonly seen on ultrasound can lead to unnecessary intervention (1,2). The reliance on ultrasound also limits the range of providers and settings where this follow-up can take place. The reliance on ultrasound is also a disadvantage for women who live at a distance from an ultrasound facility. In addition, the need for multiple visits has been cited as a reason that women give for not choosing a medical method of abortion (3). Multiple visits may create difficulties to get time off work or to get help with childcare. Women with mental health problems, those living in rural areas, those under coercive control and those from marginalised groups may be particular groups who find multiple visits problematic (4,5). Furthermore, studies report that approximately 50% of women do not attend a scheduled routine followup visit and so get no confirmation that the pregnancy has been successfully terminated (6,7).

Women value the opportunity to take more control over their treatment (8) and there is good evidence from both randomised controlled trials and observational studies that women can reliably determine the success of EMA based on a self-assessment of bleeding, presence / disappearance of pregnancy symptoms and the results of a self-performed urine pregnancy test (9,10,11). In addition, there is evidence that given the choice women preferentially opt for this-self-assessment option over a clinic follow-up (12,13).

In many parts of Europe it is now possible for women who wish to have an EMA to make only a single visit to an abortion provider for assessment of gestation, receipt or provision of mifepristone and/or misoprostol (to self-administer at home), receipt and provision of effective ongoing contraception and instructions on how to self-

assess the success of the abortion using a self-performed urinary pregnancy test (13,14).

Types of urine pregnancy tests

Low sensitivity urine pregnancy test (LSUPT)

A LSUPT (detection limit 1000 IU) is already widely used throughout Europe and marketed for home use to confirm the success of EMA up to 9 weeks (63 days) gestational age. At two to three weeks post EMA, the urine level of human Chorionic Ggonadotrophin (hCG) will be less than 1000 IU in most women (90%) who have a successful expulsion (7,12,15) (table 1). Approximately 10% of women will have a positive LSUPT at two weeks; but of this group only 10% (i.e. 1% of all women) are subsequently shown to have an ongoing pregnancy (7,12,15). This means that use of the LSUPT can reduce the proportion of women requiring a follow-up clinical assessment / ultrasound to exclude or confirm an ongoing pregnancy from all women, to just one in ten women.

Studies in a number of countries (including Europe, India and South Africa) have shown that women are able to use and interpret a LSUPT, <u>includingeven</u> those women with low literacy levels (9,10,11,13). The LSUPT (1000 IU) has not yet been evaluated for use with EMA beyond 9 weeks.

High sensitivity urine pregnancy test (HSUPT)

In contrast to the LSUPT, a 'regular' pregnancy test used to make the diagnosis of pregnancy (typical detection limit 10-25IU hCG) is highly sensitive and hence is known as also known as a high sensitivity urine pregnancy test (HSUPT). A HSUPT is of limited value for the purposes of self-assessment of the success of EMA as the HSUPT may remain positive for several weeks as it may take this time for hCG to fall beneath the low threshold level for a positive result (16). A HSUPT has been tested in studies to determine the usefulness to confirm the success of EMA, but approximately one quarter of HSUPT are still positive at one month- after treatment (17,18).

Multilevel urine pregnancy test (MLUPT)

A MLUPT that has a range of five thresholds of hCG (25, 100, 500, 2 000, 10 000 IU) has also been developed and can be used to determine the success of EMA (18). If conducted on the day of EMA and then-if repeated (as early as three days later) and if the threshold of hCG that was formerly positive no longer tests positive, a significant decrease in hCG is assumed and ongoing pregnancy excluded. Studies from a number of countries have shown that a MLUPT with five windows is reported to be easy to use and interpret by women undergoing EMA (19). This MLUPT is not yet available in Europe.

What to advise women

Women should be advised that if they experience little or no bleeding after EMA or if they still have continuing pregnancy symptoms then they should contact their abortion provider as they may have an ongoing pregnancy. Studies have reported

that approximately one half of all ongoing pregnancies can be detected in this way at an early stage i.e. within two weeks of an EMA and before a LSUPT is scheduled (13).

Counselling for self-assessment of success of EMA using a LSUPT

Abortion providers who are considering introducing self-assessment of success of EMA with a LSUPT, may find it helpful to use a structured counselling proforma such as that shown in figure 1.

Conclusion

Women are able to determine the success of early medical abortion (EMA) themselves using a combination of signs, symptoms and a urine pregnancy test. This simplifies EMA, expands the range of professionals able to provide EMA and most importantly gives women greater control over their bodies and treatment.

Funding

None

Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

References

- 1. Fiala C, Safar P, Bygdeman M, Gemzell Danielsson K Verifying the effectiveness of medical abortion: Ultrasound versus HCG testing. Eur J Obstet Gynecol Reprod Biol. 2003 Aug 15;109(2):190-5.
- 2. Saav I, Stephansson O, Gemzell-Danielsson K (2012) Early versus Delayed Insertion of Intrauterine Contraception after Medical Abortion. A Randomized Controlled Trial. PLoS ONE 7(11): e48948. doi:10.1371/journal.pone.0048948
- 3. Reeves MF, Fox MC, Lohr PA, Creinin MD. Endometrial thickness following medical abortion is not predictive of subsequent surgical intervention. Ultrasound Obstet Gynecol. 2009;34(1):104-9.

Formatted: Title, title

- 4. Aiken ARA, Guthrie KA, Schellekens M, Trussell J, Gomperts R. Barriers to accessing abortion services and perspectives on using mifepristone and misoprostol at home in Great Britain. Contraception. 2018;97(2):177-183.
- 5. Caird L, Cameron ST, Hough T, Mackay L, Glasier A. Initiatives to close the gap in inequalities in abortion provision in a remote and rural UK setting. J Fam Plann Reprod Health Care. 2016;42(1):68-70
- 6. Saav I, Stephansson O, Gemzell-Danielsson K (2012) Early versus Delayed Insertion of Intrauterine Contraception after Medical Abortion. A Randomized Controlled Trial.

PLoS ONE 7(11): e48948. doi:10.1371/journal.pone.0048948

- 7. Michie L, Cameron ST. Simplified follow up after early medical abortion: 12 months experience of a telephone call and self-performed low sensitivity urine pregnancy test. Contraception. 2014:89(5):440-5
- 8. Purcell C, Cameron S, Lawton J, Glasier A, Harden J. Self-management of first trimester medical termination of pregnancy: a qualitative study of women's experiences. BJOG. 2017;124(13):1983-1992.
- 9. Oppegaard KS, Qvigstad E, Fiala C, et al. Clinical follow up compared with self-assessment of outcome after medical abortion: a multicentre, non-inferiority, randomised, controlled trial. Lancet 2015;385:698–704.
- 10.lyengar K, Paul M, lyengar SD, et al. Self-assessment of the outcome of early medical abortion versus clinic follow-up in India: a randomised, controlled, non-inferiority trial. Lancet Glob Health 2015;3:e537–45.
- 11.Constant D, Harries J, Daskilewicz K, et al. Is self-assessment of medical abortion using a low-sensitivity pregnancy test combined with a checklist and phone text messages feasible in South African primary healthcare settings? A randomized trial.PLoS One 2017;12:e0179600.
- 12. Cameron ST, Glasier A, Johnstone A, et al. Can women determine the success of early medical termination of pregnancy themselves? Contraception 2015;91:6–11.
- 13.Millar S, Cameron ST. Comparison of two low sensitivity urine pregnancy tests used for the self-assessment of the success of early medical abortion. BMJ Sexual and reproductive healthcare 2018;44(1):54-57
- 14. Hognert H, Kopp Kallner H, Cameron S et al. Insertion of an etonogestrel releasing implant at medical abortion does not affect the efficacy of treatment but reduce subsequent unintended pregnancy a randomised controlled equivalence trial. Human Reproduction 2016;31(11):2484-2490
- 15. Cameron ST, Glasier A, Dewart H, Johnstone A, Burnside A. Telephone follow-up and self-performed urine pregnancy testing after early medical abortion: a service evaluation. Contraception 2012;86(1):67-73

Formatted: Font: 12 pt

Formatted: Font: 12 pt

- 16. Honkanen H, Ranta S, Ylikorkala O, Heikinheimo O. The kinetics of serum hCG and progesterone in response to oral and vaginal administration of misoprostol during **medical** termination of early pregnancy. Hum Reprod. 2002;17(9):2315-9.
- 17. Perriera LK, Reeves MF, Chen BA, Hohmann HL, Hayes J, Creinin MD. Feasibility of telephone follow-up after medical abortion. Contraception. 2010;81(2):143-9.

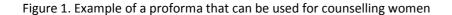
18. Blum J, Sheldon WR, Ngoc NT, Winikoff B, Nga NT, Martin R, Van Thanh L, Blumenthal PD. Randomized trial assessing home use of two pregnancy tests for determining early medical abortion outcomes at 3, 7 and 14 days after mifepristone. Contraception. 2016;94(2):115-21

Formatted: Font: 12 pt

19. Raymond EG, Shochet T, Blum J, et al. Serial multilevel urine pregnancy testing to assess medical abortion outcome: a metaanalysis. Contraception 2017;95:442–8.

Table 1. Urine pregnancy tests for self assessment to exclude ongoing pregnancy after $\ensuremath{\mathsf{EMA}}$

Urine pregnancy test	Key Features
Low sensitivity urine pregnancy test (1000iu)	 Conduct at two weeks Approx. 10% test positive Available from abortion provider
High sensitivity urine pregnancy test (25-50iu)	 Conduct at one month Approx. 25 % test positive Cheap, readily available in shops/pharmacies
Multi level urine pregnancy test (range of levels)	 Conduct before and after EMA Can be used as early as three days Multiple windows to read and interpret Not currently available in EU



□ I am accepting responsibility to perform a 'self assessment' to exclude the possibility of an ongoing pregnancy
 □ Signs that treatment may not have worked and that I may be pregnant are:

 ○ No bleed within 24 hours of receiving misoprostol
 ○ <4 days of bleeding
 ○ still 'feel' pregnant at the end of one week or symptoms of pregnancy e.g. sore breasts, sickness, tummy growing etc.

 □ In such circumstances I should contact the clinic immediately, as I may require more treatment to end the pregnancy
 □ If the test is positive, or invalid, or I am unsure, I should contact the clinic as

soon as possible to arrange for an appointment, as I might still be pregnant