Home self-administration of misoprostol for medical abortion up to 56 days' gestation

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Abstract

Objective Studies from the USA have suggested the feasibility and acceptability of home medical abortion, however the issue has not been addressed in the UK. This study aimed to assess the feasibility, efficacy and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation.

Methods Mifepristone 200 mg was given orally in hospital under nursing supervision. Women were provided with misoprostol tablets 600 μg and advised to take them sublingually 36–48 hours later. The main outcome measures were (1) feasibility, assessed through successful completion of abortion at home without the need for hospital admission, (2) efficacy, assessed through complete uterine evacuation without the need for further medical or surgical intervention and (3) women's acceptability of the procedure as assessed by questionnaire.

Results A total of 49 women participated in this study. Of these, 48 women aborted at home while one opted to be admitted to hospital after receiving misoprostol at home. One woman underwent surgical evacuation 5 weeks following abortion for excessive bleeding and retained products of conception. A total of 43/44 (98%) women were satisfied with having the abortion at home. Side effects experienced by women included nausea [32/40 (80%], vomiting [17/41 (42%)], diarrhoea [17/41 (42%)], shivering [26/40 (65%)], tiredness [32/40 (80%)], headache [12/39 (31%)], hot flushes [14/40 (35%)], dizziness [24/39 (62%)] and unpleasant mouth taste [19/38 (50%)].

Conclusions This study suggests the feasibility and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation. These findings need to be assessed in the context of a randomised trial.

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Key message points

- **This study suggests the feasibility and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation.**
- **These findings and the potential cost implications for health service provision, need to be assessed in the context of a randomised trial.**

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Introduction

In 1991, the anti-progesterone mifepristone, in combination with a prostaglandin analogue, was licensed for termination of pregnancy up to 63 days' gestation. During 2002, 175 569 abortions were carried out in England and Wales.[1] Of these, 99 350 (57%) were under 9 weeks' gestation and 18% were undertaken medically. During 2002, 11 594 abortions were carried out in Scotland and 56% of those under 9 weeks' gestation were carried out medically.[2]

Studies from the USA have suggested the safety, feasibility and acceptability of home self-administration of misoprostol for medical abortion.[3–7] To date there has been no reported work on this topic in the UK.

The aim of this study was to assess the feasibility, efficacy and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation.

Methods

The study was conducted at the Aberdeen Royal Infirmary during the period July 2002–December 2003. Ethical approval was obtained from the Grampian Research and Ethics Committee. Women requesting abortion under the 1967 Abortion Act criteria were counselled about medical and surgical methods. Women wishing to undergo medical treatment and meeting the study criteria were asked to participate. Women were eligible to participate if they met the following criteria: up to 56 days' gestation at the time of abortion, confirmed by ultrasound scan; requesting medical abortion; with a singleton, viable, intrauterine pregnancy; had a contact telephone number and companion (partner, relative, friend) available throughout the day of misoprostol administration; and living within a 5-mile radius of the hospital (this was increased, with ethical committee approval, to a 12-mile radius halfway through the study). Both parous and nulliparous women were included in the study. Exclusion criteria were: gestations over 56 days at the time of abortion; aged under 20 years; suspected ectopic pregnancy; chronic adrenal failure; long-term corticosteroid treatment; haemorrhagic disorders and treatment with anticoagulants; known allergy to mifepristone or misoprostol; contraindication to prostaglandin administration; psychiatric history; and breastfeeding.

Those interested were given a study information sheet and written consent was obtained. Assessment of the gestational age was based on transvaginal ultrasound measurement in all cases, as per hospital protocol.[8] Ultrasonographic identification of a yolk sac or embryonic pole was used to confirm an intrauterine pregnancy. In cases where a gestational sac was seen with no yolk sac or embryonic pole, a repeat ultrasound scan was arranged 1 week later. Samples for full blood count, blood group and rubella antibody titres were assessed at the initial clinic consultation and all women were screened for *Chlamydia trachomatis*. The objectives of the study were to assess the feasibility, efficacy and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation. Feasibility was assessed through successful completion of the procedure at home without the need for hospital admission. Efficacy was assessed by confirming complete uterine evacuation without the need for further

medical or surgical intervention. Women's acceptability of the procedure was assessed by questionnaire. A total of 340 abortions were carried out at the Aberdeen Royal Infirmary at gestations up to 56 days during the study period. Of these, 248 (72.9%) underwent medical abortion and 92 (27.1%) had surgical abortion. Of the women who underwent medical abortion, a total of 49 (19.8%) opted to take part in the study. We do not have data on the number of women who were eligible to take part in the study but declined.

Women were given mifepristone 200 mg orally in hospital under nursing supervision. They were provided with misoprostol tablets 600 mg and advised to take them sublingually 36–48 hours later and were supplied with oral analgesia [codeine phosphate and paracetamol in combination tablet (Tylex®)] to use, as required. A study questionnaire was given to each woman to assess satisfaction with the procedure and side effects experienced, and each was asked to return it at follow-up. Women were contacted at 4-hourly intervals by the pregnancy advisory nurses and a bed was reserved in hospital should emergency admission be needed or the patient wished to be admitted to hospital. The data on analgesia use were obtained at follow-up by the pregnancy advisory team for all 49 patients. Women were counselled about side effects and the availability of stronger analgesia preparations and anti-emetics and were advised to attend hospital if either of these was required. A follow-up appointment was arranged 1 week following abortion either at hospital or at the family planning clinic with a pelvic ultrasound performed to confirm abortion.

The Aberdeen Royal Infirmary is the only referral hospital within a 50-mile radius for both gynaecological and maternity cases. All significant complications requiring hospital admission would have, therefore, been referred and documented through re-admission.

Data were entered on a PC-held database and analysed using the Statistical Package for Social Sciences (SPSS v.11.5; SPSS Inc., Chicago, IL, USA). Distribution of the data was assessed by the Kolmogorov–Smirnov *Z*-test. Normally distributed data were presented as means and SDs. The denominators used to report the questionnaire items varied according to the number of women responding to the individual questionnaire items.

Results

A total of 49 women were recruited to the study. The mean (SD) age of the women was 29 (6.2) years and the mean (SD) gestation at abortion was 45 (7.0) days. A total of 17 (35%) women were in their first pregnancy, 19 (39%) women had a previous abortion while 26 (53%) women had a previous live birth. A total of six (12%) women reported the use of emergency contraception while *C. trachomatis* was detected in two (4%) women.

A total of 48 women aborted at home while one woman opted to be admitted to hospital to complete treatment following administration of misoprostol at home. Oral analgesia (codeine phosphate and paracetamol) was used by 45 (92%) women, three (6%) did not use any analgesia and there was no documentation as to whether analgesia was used in one (2%) case. None of the women used or received anti-emetics. The time of passing the products of conception was available for 43 (88%) women, while there was no documentation of the exact time the products of conception were passed for six (12%) women. The mean (SD) induction to abortion interval (calculated for the 43 patients for whom data were available) was 3.2 (1.3) hours. A total of 47 (96%) women attended for follow-up; of these, 43 (88%) attended follow-up in hospital and four (8%) attended the family planning clinic. Abortion was confirmed by ultrasound scan in 47 women (96%). Two (4%) women failed to attend for follow-up, but both had telephone follow-up and had regular menstrual cycles in the months following abortion. One woman underwent surgical evacuation 5 weeks following abortion for excessive bleeding and retained products of conception.

A total of 45 (92%) women returned the study questionnaires. Side effects experienced by the women included nausea [32/40 (80%)], vomiting [17/41 (42%)], diarrhoea [17/41 (42%)], shivering [26/40 (65%)], tiredness [32/40 (80%)], headache [12/39 (31%)], hot flushes [14/40 (35%)], dizziness [24/39 (62%)] and unpleasant mouth taste [19/38 (50%)]. A total of 37/44 (84%) women were very satisfied with having the abortion at home, 6/44 (14%) were satisfied, 1/44 (2%) answered 'no strong feelings' and none expressed dissatisfaction. A total of 15/45 (33%) women were very satisfied with the use of the sublingual route of misoprostol administration, 23/45 (51%) were satisfied, 6/45 (13%) answered 'no strong feelings' and one (2%) woman was dissatisfied with sublingual administration. A total of 42/45 (93%) women said they would ask to undergo abortion at home should they undergo an abortion in the future and 39/44 (89%) women said they would recommend home abortion to a friend.

Discussion

To our knowledge this is the first study to evaluate home self-administration of misoprostol for medical abortion in the UK. All the women apart from one (who opted to be admitted after administering the misoprostol tablets at home) aborted at home, while one woman required surgical evacuation 5 weeks following abortion. There was high acceptability of the procedure and the majority of women indicated they would undergo the procedure at home again in the hypothetical situation of needing to have another abortion. Providing medical abortion at home allows the procedure to be carried out in the privacy of a familiar environment and avoids the inconvenience of an additional visit to the hospital. This may also have potential cost implications for health service provision, although the cost-effectiveness of home medical abortion is yet to be evaluated.

Women were contacted at 4-hourly intervals and it could be argued that such frequent contact might affect women's acceptability. Further studies are needed to evaluate whether providing contact details and allowing these women to care for themselves and seek advice when needed might prove more acceptable to women.

Studies from the USA have reported high efficacy and acceptability of medical abortion in home settings[3–7] and indeed home care is becoming the standard of care in the USA. However, home medical abortion is yet to be evaluated in the context of a randomised trial. Despite the reported work from the USA, it would be insufficient to extrapolate these findings to UK settings, and to date there have been no studies evaluating the feasibility or acceptability of home medical abortion in the UK. A multicentre questionnaire survey sponsored by the **fpa** (Family Planning Association) assessed women's views on home administration of misoprostol for medical abortion.[9] The survey was carried out on women who underwent medical abortion in UK hospital settings to assess their perceived acceptability and perceived ability to cope with the process at home. A total of 71% of women said there was nothing that happened during the abortion procedure in hospital that they would have been unable to cope with at

home. Some 36% said they would have opted for home abortion, had that choice been available, while 64% indicated that they would prefer to have undergone hospital abortion, suggesting that medical abortion at home is acceptable to most women who currently undergo hospital-based medical abortion in UK settings; and that home abortion would be preferred by some. These findings need to be further evaluated in different settings.

The medical regimen for induced abortion in hospital settings is now well established at all gestations and the risk of serious medical complications and psychological sequelae following abortion remains low.[10–16] Caution, nonetheless, is essential in advising women about undergoing medical abortion at home. Ensuring that women live within a reasonable distance of the hospital remains important at this stage until more safety data become available. There is also a need to assess women's willingness to undergo medical abortion at home and their capability of handling abortion at home.

Ashok *et al*.[12] reported the outcomes of 4132 women undergoing medical abortion up to 63 days' gestation and reported a complete abortion rate of 97.7%. However, 0.3% of women had a continuing pregnancy. Counselling women on the teratogenic effect of misoprostol and stressing the need for follow up to exclude this risk remains crucial.

It has been shown that the majority of women undergoing early medical abortion used oral analgesia or no analgesia, with only a small percentage of women requiring intramuscular opiates.[12,17] These findings may be useful in counselling women undergoing medical abortion in home settings. However, analgesia requirements will need to be evaluated in different settings and preferably in the context of a randomised trial.

Studies have shown that women value having a choice of method of abortion[18], and introducing home medical abortion will increase the options available to women undergoing early medical abortion. Elul *et al*.[19] conducted in-depth interviews with women undergoing home medical abortion in the USA. The overwhelming majority of respondents found the home regimen acceptable and described it as the principal appeal of medical abortion. They also reported that the side effects were more tolerable in the comfort of their homes with someone familiar nearby for support. Furthermore, women said they felt prepared for the experience and competent in assessing any problems that arose. In a further study from the USA, Fielding *et al*.[20] reported a qualitative analysis of women's experience with home medical abortion. Personal control was the overarching theme expressed regarding the procedure. Women stressed the importance of being able to select the type of abortion procedure and maintain control. Some women expressed concern about the long-term health effects of the procedure, but generally felt that having a home abortion was a comfortable experience.

Studies have reported the vaginal route of misoprostol administration to be more effective than the oral route of administration and to be associated with fewer side effects.[21] However, it has been reported that women preferred oral administration and valued having additional choice.[22] Sublingual administration avoids the first-pass effect through the liver associated with oral administration and the inconvenience and intrusion of vaginal administration. Recently, several studies have reported the feasibility, high efficacy and good acceptability of the sublingual route of misoprostol administration for medical abortion.[23–25] Sublingual administration was used in the present trial as it was felt that it may be more convenient for women to self-administer and to avoid possible difficulties with self-administration into the posterior vaginal fornix. Studies from the USA have reported the successful use of vaginal self-administration of misoprostol in the context of home medical abortion. Furthermore, a study from Cardiff reported that vaginal self-administration of misoprostol was acceptable to the majority of women undergoing medical abortion in a hospital setting.[26] Further research is needed to assess the feasibility and acceptability of vaginal self-administration of misoprostol in comparison to sublingual administration in the context of medical abortion.

Future research assessing home medical abortion will also be needed to address the legal issues related to self-administering misoprostol outside licensed premises. The use of misoprostol for abortion procedures represents an unlicensed use of the product. The Medicines Act and Regulations, however, provide exemptions which enable doctors to prescribe unlicensed medicines or to use or advise the use of licensed medicines for indications, or in doses, or by routes of administration, outside the terms of the product licence and the Royal College of Obstetricians and Gynaecologists has stated that the use of misoprostol in the context of abortion is both effective and acceptable.[27]

Information on the disposal of the products of conception should be made available to women and abortion services should make provision for women to return the products of conception to the provider for disposal if they wish to do so.[27]

Conclusions

This study suggests the feasibility and acceptability of home self-administration of misoprostol for medical abortion up to 56 days' gestation. The safety, acceptability and cost-effectiveness of home medical abortion need to be assessed in the context of a randomised trial.

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Book Reviews

Female Reproductive Health. N Manassiev and MI Whitehead. New York, NY: Parthenon Publishing Group, 2003. ISBN: 1 85070 491 0. Price: £55.00. Pages: 195 (hardback)

This is a concise and very readable textbook on a range of female reproductive health topics divided into nine chapters. The authors are mainly from the UK, making the book relevant to a UK audience.

Chapter 1 describes the anatomy and physiology of the female reproductive system. Chapters 2 and 3 (hormones in reproduction and the female reproductive cycle), although interesting to read, could perhaps have been shortened or combined to allow more time for exploring the clinical aspects of female reproductive health.

In this slim book the chapter on contraception is surprisingly comprehensive. Unfortunately there are some discrepancies between statements in this text and guidelines developed by the Clinical Effectiveness Unit of the Faculty of Family Planning and Reproductive Health Care. There is no reference to the evidence-based recommendations of the WHO *Medical Eligibility Criteria for Contraceptive Use*.

Chapter 5 provides a very good overview on infertility and its management. However, sperm survival in the female genital tract is usually quoted as up to 7 days, rather than the 28–48 hours stated in this book.

Chapter 6 is a good summary of the menopause and its management with relevant study results on risks and benefits of hormone replacement therapy (HRT). It is, however, virtually impossible to provide a truly up-to-date picture in this area. The section on pharmacological and 'alternative' treatment options could perhaps have been expanded to include topical oestrogens, progestogen-only therapies and could have also discussed the role of the Mirena® intrauterine system as the progestogen component of HRT. Furthermore, it would have been helpful to include practical referral guidelines for bone densitometry.

Chapter 7 provides a concise overview of genitourinary medicine and the up-to-date management of common sexually and non-sexually transmitted infections. Chapter 8 is dedicated to breast disorders and screening, making some very informative reading. The final chapter deals with normal and disturbed sexual function and gives a good introduction to sexual medicine.

On balance I think this is a well presented and useful reference text aimed at trainees and health professionals working in reproductive health settings, gynaecology and general practice.

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Yen and Jaffe's Reproductive Endocrinology: Physiology, Pathophysiology, and Clinical Management (5th edn). JF Strauss III and RL Barbieri (eds). Philadelphia, PA: Elsevier Saunders, 2004. ISBN: 0 7216 9546 9. Price: £117.00. Pages 1042 (hardback)

Yen and Jaffe's Reproductive Endocrinology is a textbook that comprehensively covers both basic science and clinical management of reproductive medicine.

The book is divided into three sections. The first of these describes normal reproductive physiology. Although very detailed, this section is written in a manner which is easy to follow, while a generous number of diagrams and illustrations make the text easy to understand. At the end of each chapter the clinical relevance of the subject dealt with is discussed, with an overview of common abnormalities and their management. Throughout the book references are up to date and comprehensive.

The second section focuses on the pathophysiology and management of reproductive problems. The chapter on male fertility covers all the important aspects of pathophysiology, diagnosis and treatment, and while being detailed is easy to follow. As this textbook is published in the USA, several aspects of clinical management differ from normal UK practice. In particular the recommended investigations for male factor subfertility include tests that are no longer commonly used in UK practice. A comment on the limited clinical relevance of some of the research-orientated tests described might give the reader a more realistic idea of current clinical practice. Other chapters in this section are also well written and up to date; for example, discussing the use of metformin in polycystic ovarian syndrome and the evidence for increased breast cancer risk with hormone replacement therapy.

The third section of the book deals with reproductive technology, including *in vitro* fertilisation (IVF) and cytogenetics. Once more the chapter dealing with IVF treatment is well written, but reflects North American rather than UK clinical practice. Investigations that are not used in this country are described in detail, and the description of embryo transfer involves higher numbers of replaced embryos than currently permitted by the Human Fertilisation and Embryology Authority. This might be confusing for readers with limited clinical experience of IVF practice in the UK. The chapter briefly touches on the ethical, emotional and social aspects of IVF treatment, areas that are overlooked by many authors.

In summary, this book is a comprehensive, up-to-date and detailed work that is aimed at those with a special interest in reproductive medicine. It is a little too detailed for the generalist except for reference use. In some cases the clinical management suggested differs from national UK guidelines.

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