Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS)

Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS)

SC Robson,[1*] T Kelly,[1] D Howel,[1,3]
M Deverill,[2] J Hewison,[4] MLS Lie,[2]
E Stamp,[2] N Armstrong[2] and CR May[2]

[1]Institute of Cellular Medicine, Newcastle University, Newcastle upon Tyne, UK
[2]Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK
[3]School of Mathematics and Statistics, Newcastle University, Newcastle upon Tyne, UK
[4]Leeds Institute of Health Sciences, University of Leeds, Leeds, UK

*Corresponding author

Executive summary

Health Technology Assessment 2009; Vol. 13: No. 53
DOI: 10.3310/hta13530

Health Technology Assessment
NIHR HTA programme
www.hta.ac.uk

Executive summary

Objectives

To determine the acceptability, efficacy and costs of medical termination of pregnancy (MTOP) compared with surgical termination of pregnancy (STOP) at less than 14 weeks' gestation, and to understand women's decision-making processes and experiences when accessing the termination service and taking part in the trial.

Design

A partially randomised preference trial and economic evaluation with follow-up at 2 weeks and 3 months.

Setting

The Royal Victoria Infirmary, Newcastle upon Tyne, UK, a large tertiary unit providing both MTOP and STOP up to 20 weeks' gestation to women throughout the north-east of England. The termination service is nurse practitioner-led and undertakes around 1800 terminations per year.

Participants

Participants were women accepted for termination of pregnancy (TOP) under clause C of the Human Fertilisation and Embryology Act (1990) amendment of the Abortion Act (1967) with pregnancies less than 14 weeks' gestation (based on ultrasound) on the day of abortion. A further group of women attending contraception and sexual health clinics in Newcastle upon Tyne participated in a discrete choice experiment.

Interventions

Surgical termination of pregnancy

All women ≥ 6 weeks' and < 14 weeks' gestation were primed with misoprostol 400 µg 2 hours prior to the procedure. All STOP procedures were performed under general anaesthesia using vacuum aspiration (VA) by two consultants each on a dedicated operating list.

Medical termination of pregnancy

All women < 14 weeks' gestation were given mifepristone 200 mg orally. They returned 36–48 hours later to the gynaecological day-case ward for prostaglandins (detailed below).

1. Women ≤ 9 weeks' gestation were given misoprostol 800 µg vaginally, followed 4 hours later by misoprostol 400 µg if no abortion had occurred. Subsequently if abortion did not occur by 1630–1700 and there was no excessive bleeding, women were discharged home with 2-week follow-up scan review.
2. Women ≥ 9^{+1} weeks' gestation were given misoprostol 800 µg vaginally followed by misoprostol 400 µg every 3 hours up to a maximum of four doses. If by midnight no abortion had occurred, mifepristone 200 mg orally was administered followed by gemeprost 1 mg vaginally 3-hourly from 0800 up to a maximum of five doses. If abortion had not occurred by 0800 the following morning, STOP was arranged.

Main outcome measures

The main outcome measure was acceptability determined by responses to the question: 'If you ever have another termination of pregnancy, would you opt for the same method?'

Secondary outcome measures included strength of preference by willingness to pay (WTP) using the payment card method; distress using the Impact of Event Scale (IES); anxiety and depression using the Hospital Anxiety and Depression Scale (HADS); satisfaction with care using a 5-point Likert scale; experience of care using a semantic differential rating scale; frequency and extent of symptoms including self-assessment of pain using a visual analogue scale; clinical effectiveness using unplanned/emergency admission requiring an overnight stay and complications.

A discrete choice experiment was used to identify key factors (attributes) that shape women's preferences for abortion services.

Results

The trial recruited 1877 women: 349 in the randomised arms and 1528 in the preference arms. Of those in the preference arms, 54% chose MTOP. When questioned 2 weeks after the procedure more women having STOP would choose the same method again in the future {adjusted difference 24.9% [95% confidence interval (CI) 15.8 to 34.9%] in the randomised arm and 15.9% [95% CI 12.2 to 19.6%] in the preference arm}. Acceptability of MTOP declined with increasing gestational age. The difference in acceptability between STOP and MTOP persisted at 3 months.

There was no difference in the maximum amount women were willing to pay for their preferred method prior to the procedure. At 2 weeks after TOP, women in the preference arms were prepared to pay more to have their preferred option, but there was no difference in the mean maximum WTP values between MTOP and STOP in the randomised or preference arms.

There were no differences in anxiety or depression between women having MTOP and STOP as measured by HADS. However, women randomised to MTOP had higher scores on the intrusion subscale of the IES at 2 weeks and both the intrusion and avoidance subscales at 3 months. There was no difference in IES scores between the MTOP and STOP groups in the preference arms.

Women were more likely to be satisfied overall and with the technical and interpersonal aspects of care if they had STOP rather than MTOP whether in the preference arms or randomised arms.

Experience of care as determined by median semantic differential scores were lower after MTOP in both randomised and preference groups. MTOP was felt to be more unpleasant, more disagreeable, harder and more painful while STOP was felt to be milder, more agreeable, faster and safer.

During admission women undergoing MTOP had more symptoms and reported higher mean pain scores. Compared with women having STOP, more women having MTOP reported nausea and diarrhoea after discharge. There were no differences in time taken to return to work between groups; around 90% of women had returned to work and normal activity by 2 weeks.

Rates of unplanned or emergency admissions were higher after MTOP than STOP (4.2% versus 0.7% respectively). Overall complication rates were also higher after MTOP (5.0% versus 2.6% respectively), although this difference only achieved statistical significance in the preference arm.

The overall cost of STOP was greater than MTOP (£498 versus £287 respectively) due to higher inpatient standard costs. Even though complication rates were higher with MTOP, the medical procedure was more cost-effective based on the measure of effectiveness used (successful completion of TOP on the day of admission).

A discrete choice experiment identified three service attributes that had an almost equal impact on women's preferences: the provision of counselling, the number of days delay to the procedure and the possibility of the need for an overnight stay. Women would be prepared to wait approximately one extra day to ensure access to post-termination counselling and to avoid an overnight stay following a termination.

Qualitative substudy

Women wanted quick access to abortion, but were concerned about what professionals thought of them. Women also found accessing the service via family planning clinics easier than via general practitioner surgeries. Once in the hospital service, quick assessment and treatment was important to them.

Women participated in the trial because by helping others they were able to feel compensated in some way for the unpleasant experience of undergoing termination. Some felt a general ethical obligation to help while others gained different levels of personal benefit; some women found talking about their experiences cathartic.

Some women found the concept of letting the computer 'choose' difficult to understand. For those with a strong pre-existing preference the trial design meant that women could still benefit by both choosing which method they preferred and participate in the trial to help others.

Conclusions

MTOP was associated with more negative experiences of care and lower acceptability. Acceptability of MTOP declined with increasing gestational age. MTOP was less costly, but also less effective than STOP. Women value the option to choose their preferred abortion method. However, the majority of women choosing MTOP were

satisfied with their care and found the procedure acceptable, suggesting that a patient-centred abortion service should offer the choice of medical or surgical abortion up to 14 weeks of pregnancy.

Recommendations for further research

An audit of provision of MTOP and STOP in England and Wales is urgently required. Further studies exploring the barriers to offering women the choice of method of TOP are needed, together with research on the acceptability and effectiveness of (1) MTOP and manual VA in pregnancies below 9 weeks' gestation and (2) MTOP and dilatation and evacuation after 14 weeks' gestation.

Trial registration

This trial is registered as ISRCTN07823656.

Publication

Robson SC, Kelly T, Howel D, Deverill M, Hewison J, Lie MLS, *et al*. Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS). *Health Technol Assess* 2009;**13**(53).

How to obtain copies of this and other HTA programme reports
An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with **credit card** or **official purchase order**)
– post (with **credit card** or **official purchase order** or **cheque**)
– phone during office hours (**credit card** only).

Additionally the HTA website allows you **either** to pay securely by credit card **or** to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch
Magellan
Concept House, Bell Road
Basingstoke, Hants RG24 8FB, UK

Email: orders@hta.ac.uk
Tel: 02392 492 000
Fax: 02392 478 555
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can be purchased only for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *Direct Mail Works Ltd* and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of *HTA on CD*?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. *HTA on CD* is currently free of charge worldwide.

The website also provides information about the HTA programme and lists the membership of the various committees.

NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

Second, the HTA programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

Criteria for inclusion in the HTA journal series

Reports are published in the HTA journal series if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 03/11/02. The contractual start date was in May 2005. The draft report began editorial review in January 2009 and was accepted for publication in June 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

ISSN 1366-5278

Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NETSCC, HTA.

Printed on acid-free paper in the UK by Henry Ling Ltd, The Dorset Press, Dorchester.