



# Summary

## Background

Medical termination of pregnancy has through the last decade become an alternative to the traditional surgical method in an exceeding number of countries. In 1999 the medical board of Copenhagen Hospital Corporation (H:S) took initiative to perform a Health Technology Assessment (HTA) in order to investigate the pros and cons for the introduction of medical abortion. While this HTA analysis was running from 2000-2004, medical abortion was introduced as an alternative to surgical abortion in H:S as well as in most other counties in Denmark.

This HTA report includes both an extensive and systematic literature review and primary clinical studies to investigate essential clinical, economical, organisational and patient related matters that has not been analysed.

#### Aim

The aim of this report was to evaluate whether the introduction of medical abortion was the right decision or whether this decision should be revised.

# The technology

#### **Primary efficacy**

The efficacy of medical as well as surgical abortion is high. After both procedures however, women experience incomplete emptying of the uterus, necessitating a following surgical intervention. There is strong evidence to support that the primary success rate (complete abortions with no need for a following surgical intervention) is higher after surgical (98%) than after medical abortion (95%). Moderate evidence supports that the surgical interventions are performed later after an unsuccessful medical procedure (3 weeks) than after an unsuccessful surgical procedure (within 1 week). Based on many studies of weak evidence, the success rate after medical abortion decreases with increasing gestational age.

#### **Complications**

The risk of a life-threatening adverse event is minimal after both the medical and the surgical abortion procedure. The few serious adverse events in relation to surgical abortion are associated with instrumentation of the uterus and general anaesthesia. There is moderate evidence to support a higher rate of antibiotic prescriptions based on verified or suspected infections after surgical (8-12%) compared to medical abortion (1-5%).

#### **Side effects**

The side effects related to medical and surgical termination of pregnancy are abdominal pain, nausea, diarrhoea and dizziness. Based on moderate evidence, these side effects are more intense and last longer after medical compared to surgical abortion.

#### The optimal medical regimen

A medical abortion is initiated with an antiprogesteron (mifepristone) that interrupts normal development of the pregnancy, followed by a prostaglandin analogue to initiate contractions of the uterus. The optimal medical abortion regimen is defined as the regimen with the highest safety and highest primary efficacy combined with the fewest side effects. The present analysis concludes that the optimal medical regimen is mifepristone 200 mg followed by vaginally administered misoprostol. The optimal dose of misoprostol is unknown.

#### Recommendations based on the technology

The technology based conclusion aims at the highest safety-efficacy profile for the patient. Since both abortion methods are safe and turn out successfully in the long run, focus is on complications. The higher risk of infection/suspected infection in relation to a surgical procedure assumes to be associated with reduced fertility in the future, but this association has not been directly investigated yet. If this assumption is proven, the medical procedure is recommended as the optimal abortion procedure, since most of the women undergoing termination of pregnancy wish to become pregnant later in life.

### Impact on the patient

The women's preference for medical or surgical termination of pregnancy varies depending on education, tradition, culture and recommendations from friends and doctors.

Patient satisfaction and acceptability is high after both medical and surgical abortions. Moderate evidence supports that more women are satisfied with the surgical procedure (90-95%) than the medical procedure (75-80%). More women would also choose the same method of termination again after a surgical than after a medical procedure (85-94% vs. 55-95%). Moderate evidence indicates that the incidence of psychological and psychiatric diseases is similar after medical and surgical terminations.

Based on moderate evidence, more women are satisfied after choosing the medical method of termination themselves (82%) than if the method is determined by randomisation (68%). More women would also choose the same abortion method again after having chosen method than after randomisation. Consequently, having a choice between the two methods is decisive for patient satisfaction.

Medical abortion is a new procedure compared with surgical abortion. In the future, the medical regimen will most likely be further optimised. The lower satisfaction with the medical procedure is related to pain and increasing gestational age. An optimisation of the pain medication and improved patient information might increase patient satisfaction in the future.

# The organisation

The introduction of medical abortion requires organisational changes to achieve a reduced delay from verification of pregnancy to initiation of the abortion. This includes a quick referral procedure without significant delays. The written and oral information to the women must be of high quality to enable a qualified decision between the medical and the surgical procedure.

At Hvidovre Hospital the introduction of medical abortion resulted in a decreased need for operation theatre facilities, theatre nurses, anaesthesiologists, anaesthetic nurses and porters that could be transferred to other tasks. The medical abortion procedure could be managed and performed largely by specially educated nurses.

#### Economic evaluation

The direct costs related to personnel and materials in connection with medical as well as surgical abortion depend on the regimens and the way the procedures are organised locally.

The medical regimen (mifepristone 200 mg+misoprostol 0.8 mg) with follow-up including a blood sample at the hospital and a clinical check-up at the general practitioner, is more cost-effective than surgical abortion in general anaesthesia. From the hospital's viewpoint medical abortion at home is more cost-effective than medical abortion in the hospital, but less cost-effective from a societal viewpoint. An organisation that offers both the medical and the surgical abortion procedure is probably less efficient compared to an organisation that offers only one procedure.