Medical Abortion

Description

Medical abortion (MA) is a nonsurgical procedure in which drugs are used to induce abortion. The most effective and safest medical abortion regimen requires the use of two medications: mifepristone and misoprostol. Mifepristone blocks the action of progesterone to enhance the contractility of the uterus and prompt the detachment of the implanted embryo. Misoprostol stimulates strong contractions of the uterus, expelling the products of conception. This process is very similar to that of a spontaneous abortion or miscarriage. Repeated administration of misoprostol alone can also be used to induce abortion. Both drugs also soften and dilate the cervix.

Quality abortion care should include counseling, confirmation of intra-uterine pregnancy, and estimation of length of gestation by the patient's history, bimanual exam, or with ultrasound—although the latter is not required. Family planning and contraception counseling should be provided at the time of the abortion or afterwards. Medical abortion options have made abortion more available to women in a variety of health care settings, and home administration of medical abortion is also highly acceptable.2

Efficacy

The International Federation of Obstetrics and Gynaecology (FIGO) published revised guidelines for the use of mifepristone and misoprostol for MA up to nine weeks, 9-12 weeks, and after 12 weeks gestation in December 2011. All the regimens use 200 mg of mifepristone followed by 800 μg of misoprostol administered vaginally, buccally, or sublingually. The misoprostol is taken 24–48 hours after mifepristone up to 9 weeks gestational age or 36–48 hours from 9–12 weeks and after 12 weeks gestational age. Additional doses of 400 μg misoprostol may be required depending on gestational age. These combinations result in complete abortion in more than 95 percent of cases; the rate of continuing pregnancy is less than 1 percent in gestations up to 63 days’ amenorrhea.

Even though the combined regimen of mifepristone followed by misoprostol is significantly more effective than use of misoprostol-alone for early medical abortion, misoprostol is generally more widely available than mifepristone and has been used alone safely and successfully for medical abortion around the world. Complete abortion rates with misoprostol-only regimens range from 76 to 96 percent, according to existing research.3,6,7

The use of mifepristone and misoprostol is very safe; medical abortion has not been associated with long-term health impacts and is statistically less risky than continuation of pregnancy.4 Medical abortion may be preferable to surgical abortion for some women and their providers, as medical abortion is less invasive and can be perceived to be a more private procedure by some women.

Current program/sector use

There are a number of political, logistical, cultural, religious, financial, and other barriers that limit universal access to medical abortion. Elective abortion is legally restricted in many countries, but almost all countries have provisions under which abortion is legal, including to save the woman's life, preserve physical or mental health, when the pregnancy is a result of rape or incest, or on socioeconomic grounds. Where abortion is legal, challenges may arise in terms of health-system restrictions on where the services can be provided, procurement of the drugs, and provider training to properly inform and counsel patients about their options. However, medical abortion is being made available to women in numerous countries, including some sub-Saharan African countries. The level of use in developed countries such as the United States and those in Europe suggests that women appreciate having an alternative to surgical abortion; women in Europe have
been using mifepristone and misoprostol for more than 20 years.

Manufacturer/supplier

Mifepristone and misoprostol are available from generic manufacturers, as individually-packaged medicines and in combination packs made specifically for MA. There are numerous manufacturers of all three products (mifepristone, misoprostol, and combination packs).

Mifepristone

Two branded generics of mifepristone, Mifeprex (Danco Laboratories) and Mifegyne (Laboratoire Exelgyne), and a non-branded generic (Linepharma), are available in mostly high-income countries. Many more branded and non-branded generic versions of mifepristone are made by numerous pharmaceutical companies in low- and middle-income countries such as India and China, but their export capacity is limited.

Misoprostol

More than 50 branded and non-branded generic versions of misoprostol are manufactured by pharmaceutical companies in high-, middle-, and low-income countries including India, Bangladesh, Brazil, Egypt, China, Peru, South Korea, Chile, Argentina, Mexico, the United States, France, and Russia. Some of these manufacturers are making products for export to low- and middle-income countries, but, as with mifepristone, many only make products for their local markets. Cytotec® (Pfizer), registered in more than 80 countries, is the most widely available misoprostol product. Gymiso® (HRA Pharma) is another brand-name misoprostol product, though it is currently only available in France.

Mifepristone-misoprostol combination packs

Combination packs containing one tablet of mifepristone (200mg) and four tablets of misoprostol (200 μg each) are currently only made by manufacturers in low-and middle-income countries. Most of these products are made in India and China and are for use in the local market only. However, Medabon®, a combination pack manufactured by Sun Pharmaceuticals, is available for export. Other manufacturers are also planning to export combination packs as interest grows globally.

In May 2010, misoprostol and mifepristone became eligible for the WHO’s Prequalification of Medicines Programme, and efforts are underway to support applications from generic manufacturers of misoprostol.

Registration status

Registration of the drugs used for MA is often difficult in many countries, due to political sensitivities and a lack of awareness among policy makers. For example, misoprostol products are registered in most countries around the world, but in a large number of those countries the most commonly available product (Cytotec®) is only registered for the treatment and prevention of gastric ulcers. This is despite a breadth of existing evidence supporting misoprostol’s effectiveness for a number of obstetric indications, including MA. In 2005, the combination of mifepristone and misoprostol for MA was included on the World Health Organization (WHO) Model List of Essential Medicines for termination of pregnancy where legal and acceptable, up to 9 weeks of gestation. A number of international organizations are working with policy makers and health care officials to ensure both drugs are registered for the breadth of uses for which they are effective, including MA. The information below highlights the global registration status for each drug and the combination pack.

Mifepristone

Mifepristone has been registered and approved for use in medical abortion in 50 countries worldwide; the low-income countries where mifepristone is currently registered are Cambodia, Ghana, India, Mozambique, Nepal, Vietnam, and Zambia.

Misoprostol

As noted above, registration of misoprostol for MA is far from universal. Misoprostol products have only been approved for MA in a few countries, including Ethiopia and Ghana. Misoprostol has been registered specifically for use with mifepristone for pregnancy termination in France (registered by HRA Pharma as Gymiso®) and Russia (registered by Pentcroft Pharma as Misoprostol).

Mifepristone-misoprostol combination packs

Medabon® is the only product currently registered for medical abortion in Bangladesh, Cambodia, Ghana, India, Nepal, and Zambia. Efforts are underway to register combination packs from other manufacturers in several other countries in sub-Saharan Africa. In India, many brands of Indian-made combination packs are registered for MA, but they are not available for export.

Public-sector price agreements

The Concept Foundation has negotiated a preferential price for public-sector procurement of Medabon® in developing countries. Overall, the number of

---

* For more information, see Concept Foundation website at www.conceptfoundation.org and www.medabon.info.
‡ For more information on misoprostol use for obstetric indications in addition to medical abortion, please see the Caucus’ brief New and Underused RH Technologies brief on Misoprostol.
manufacturers for these drugs is large, and the market is continuing to evolve. Pricing varies by manufacturer, is country-specific, and is often dependent upon product demand.

References