Vaginal misoprostol was superior to oral misoprostol after pretreatment with mifepristone in induced abortion


Objective
To compare the safety and efficacy of vaginal and oral misoprostol after pretreatment with mifepristone for induction of abortion.

Design
Randomised controlled trial.

Setting
Fertility-control clinic in Scotland.

Patients
270 women (mean age 26 y, range 14 to 46 y, first pregnancy for 53%) who requested termination of an ultrasound-confirmed early pregnancy (within 63 d of amenorrhoea). Exclusion criteria were suspected ectopic pregnancy or contraindications to mifepristone or prostaglandin.

Intervention
All women received oral mifepristone, 600 mg, and were admitted to a gynaecology unit 36 to 48 hours later. 130 women were allocated to oral misoprostol, 800 μg; 133 women were allocated to vaginal misoprostol, 800 μg (4 tablets deep in the vagina). Follow-up at 2 weeks was > 80%. Vacuum curettage was done for continued pregnancies and missed abortions.

Main Outcome Measures
Primary end points were expulsion of conceptus with no need for surgical intervention and abortion < 4 hours after receiving misoprostol. Secondary end points were rate of continued pregnancy and adverse effects.

Main Results
Women assigned to vaginal misoprostol, compared with women assigned to oral misoprostol, had a higher rate of expulsion of conceptus without the need for surgical intervention (94.7% vs 86.9%; relative risk reduction 9.0%); 95% CI for the 7.8% absolute risk improvement [ARI] 9.0% to 5.3%, P = 0.03; number needed to treat [NNT] 13, CI 7 to 111*); a higher rate of abortion within 4 hours of misoprostol (93.2% vs 78.5%; ARI 18.7%); CI for the 14.7% ARI 6.6% to 23.4%, P < 0.001; NNT 7, CI 4 to 15*); a lower rate of continued pregnancy (0.8% vs 6.9%; relative risk reduction 89.0%); CI for the 6.1% absolute risk reduction 1.9% to 12.0%, P = 0.01; NNT 16, CI 8 to 52*); and a lower rate of vomiting (31.1% vs 44.0%, P = 0.04) or diarrhoea (18.2% vs 36.2%, P = 0.002). The groups did not differ for other adverse effects (nausea, tiredness, headache, hot flushes, and dizziness), duration of bleeding, or mean haemoglobin concentration at 2 weeks.

Conclusion
The vaginal route of adding misoprostol to mifepristone for induced abortion was more effective and better tolerated than the oral route.

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*Numbers calculated from data in article.

Commentary
It is estimated that 30 million abortions are surgically induced each year. Many of these are done for adolescents and young adults. Access to surgical interruption of pregnancy often is limited, especially for the latter groups, predominantly because of sociocultural barriers. Countries with an open attitude toward teenage sexuality and easy availability of oral contraceptives have low abortion rates. The combination of an antigestagen (RU 486; mifepristone) and a prostaglandin analog is effective in terminating early pregnancy, but the prostaglandin component of the regimen is cumbersome to give and may have side effects.

Two Scottish groups (1, 2) have pioneered the investigation of alternative routes of giving the prostaglandin. The study by El-Refaey and colleagues extends earlier investigations by the same group, reporting high effectiveness, low incidence of side effects, and high acceptance by patients of vaginal misoprostol in addition to oral mifepristone for early induction of abortion (amenorrhoea ≤ 63 days). Changing attitudes toward teenage sexuality, an open mind about sex education for young people, and easy availability of contraceptives should prevent a considerable proportion of unwanted pregnancies in many parts of the world. Low threshold accessibility of facilities to obtain the proposed antigestagen and prostaglandin combination may, for the time being, come as close to the ideal back-up guard as we may get.

This study convincingly shows a definite advantage to the vaginal route, compared with the oral route, of prostaglandin addition to antigestagen treatment. This is good news for women with early unwanted pregnancies. A safe, effective abortifacient with minimal side effects has now become available for use in the reassuring setting of, for example, the family physician's surgery.

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References
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