Time to relax the rules about administration of mifepristone

Salmon Omokanye, FMCOG, MRCOG, MFFP, Senior Clinical Medical Officer

Correspondence. Dr S Omokanye, SCMO, Family Planning and Reproductive Health Care, Nottingham Community Health NHS Trust, Victoria Health Centre, Glass House Street, Nottingham, NG1 3LW, UK.

(Accepted January 20th, 2001)

Summary
Pre-clinical and clinical data indicate that mifepristone is a safe and effective drug for the termination of pregnancy. The author suggests that it could be given by nursing staff rather than by a doctor, and that the 2-hour post-administration observation period is unnecessary in the majority of cases.

Key words
abortion, mifepristone

Mifepristone is effective and safe for early pregnancy termination.1-3

The manufacturer’s data sheet and control procedures in hospitals include the following rules, which often create practical problems:
1. administration of oral mifepristone in the presence of the doctor
2. the patient should be observed for at least 2 hours following administration.

There is some variation in the extent to which service providers respect these rules. Some centres have no problem making a doctor available to observe the ingestion of the tablets. In small units, strict adherence to the rules means that some patients have to wait for the doctor.

In our experience at Bassetlaw Hospital, Worksop, with medical termination of pregnancy for 40 to 50 patients per year (1993 - 1998), there were only four patients on our record who reported transient nausea, and only one patient actually vomited. We observed no other adverse effect. All the patients felt well and ready to go home as soon as possible, but we kept them under observation for 2 hours in compliance with our protocol.

The most remarkable pharmacodynamic of mifepristone is the antiglucocorticoid effect for a minimum of 24 hours after a single oral administration. However, no clinical or biological signs of adrenal insufficiency have ever been observed.4

Faintness and vomiting were reported in clinical trials in 5.1% and 2.3% of patients, respectively, but it was difficult to differentiate these symptoms from the effect of the pregnancy and also from the process of abortion.5

Toxicological studies in rodents estimated the LD50 to be greater than 1 g/kg.6 By deduction, the therapeutic ratio for human would be about 1:100 for a 600 mg dose, and 1:200 for the 300 mg dose, which implies that it is safer than paracetamol.

It would therefore be safe and more practical if the prescribing doctor might delegate the supervision of oral administration of mifepristone to nursing staff who also have extended role to administer prostaglandins for termination of pregnancy. Furthermore, patients who have no relative contraindications, and those who experienced no side effects, may be free to take their leave at once.

Statements on funding and competing interests
Funding. None declared.
Competing interests. None.

References
1 Cameron IT, Mchir A, Baird DT. Therapeutic abortion in early pregnancy with antiprogestogen RU486 alone or in combination with prostaglandin analogue (gemeprost). Contraception 1986; 34: 459–468.
7 Department of Health and UK. Central Council. Termination of pregnancy by medical methods: The role of the registered nurse or midwife and others who are not medical practitioners. PLCMO (94) 8; PLNCO (94) 10.
Time to relax the rules about administration of mifepristone

Salmon Omokanye

J Fam Plann Reprod Health Care 2001 27: 102
doi: 10.1783/147118901101195164

Updated information and services can be found at:
http://jfprhc.bmj.com/content/27/2/102

These include:

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/