Randomised clinical trial of medical evacuation and surgical curettage for incomplete miscarriage

E T M de Jonge, J D Makin, E Manefeldt, G H De Wet, R C Pattinson

Department of Obstetrics and Gynaecology, Kalafong Hospital, University of Pretoria, Private Bag X 396, Pretoria 0001, Republic of South Africa
E T M de Jonge, *senior consultant*
J D Makin, *clinical epidemiologist*
E Manefeldt, *registrar*
G H De Wet, *senior consultant*
R C Pattinson, *professor*

Correspondence to:
Dr de Jonge.

BMJ 1995;311:662

In South Africa surgical curettage under general anaesthesia is considered to be the standard management for incomplete miscarriage. It constitutes a substantial proportion of the gynaecological services rendered and therefore places an ever increasing burden on the medical resources available. Research into the safety and efficacy of outpatient surgical curettage has resulted in a cost effective procedure with minimal illness.[1,2] Henshaw *et al*, however, have shown that medical management of an uncomplicated incomplete first trimester miscarriage with misoprostol, a synthetic prostaglandin analogue, had a 96% success rate and may be a suitable cost saving alternative.[3] We compared medical with surgical management in terms of efficacy and morbidity.

Patients, methods, and results

We conducted a randomised clinical trial of 50 consecutive patients fulfilling the following eligibility criteria: history of amenorrhoea followed by abdominal cramping and vaginal bleeding; uterine size ≤ 14 weeks of gestation, evaluated clinically before randomisation; dilated cervical os and palpable products of conception; no foul smelling products; temperature $<37{\cdot}5°C$; no excessive vaginal bleeding requiring immediate surgical evacuation; haemoglobin concentration >90 g/l after resuscitation; and no contraindication to prostaglandin treatment.

Medical management consisted of a single dose of misoprostol 400 μg orally and was considered to be successful if bleeding had reverted to a blood stained discharge, pain had subsided, the uterus was smaller, and the cervical opening had closed on repeat pelvic examination 12 hours after misoprostol administration. Pelvic ultrasonography was performed when uncertainty existed about the completeness of the abortion. Surgical curettages were performed twice a day. A hundred opaque sealed envelopes were randomised by means of computer generated random numbers. Even numbers were assigned to misoprostol and odd numbers to surgical evacuation. The study was approved by the hospital ethics committee. Informed consent was obtained in all cases. No case was excluded because of excessive bleeding. The protocol included an interim analysis of 50 cases, and after analysis the study was stopped. This resulted in differences in size of the two groups. The χ^2, Mann-Whitney U, and Wilcoxon matched pairs tests were used for statistical analysis where appropriate.

Comparison of medical evacuation and surgical curettage for uncomplicated incomplete miscarriage. Values are medians (ranges) unless stated otherwise

	Misoprostol 400 μg (n=23)	Surgical curettage (n=27)
Age (years)	27 (17-41)	31 (18-42)
Parity	2 (0-5)	2 (0-5)
Estimated gestation (days)	80 (35-140)	93 (44-161)
Uterine size (gestational weeks)	13 (10-14)	13 (10-14)
Haemoglobin (g/l):		
Before treatment	107 (75-135)	99 (40-150)
After treatment*	97 (64-124)*	100 (85-120)
No of patients requiring >1 unit of blood	7	7
No (%) of patients with successful outcome	3 (13)	26 (96)†

*Comparison of haemoglobin concentration before and after treatment: P=0·04 in misoprostol group and P=0·76 in surgical group.
†Comparison between misoprostol and surgical group: P>0·001.

The table summarises demographic data and findings. The two groups were comparable in terms of the entry criteria. Only 3 (13%) of the women receiving misoprostol had a successful evacuation compared with 26 (97%) of the women in the surgical group ($P<0{\cdot}00001$). In the misoprostol group there was a significant fall in haemoglobin concentration after treatment ($P=0{\cdot}04$), whereas no difference was found in the surgical group ($P=0{\cdot}76$).

Comment

Although expectant management of the first trimester miscarriage is increasingly advocated in countries with good access to medical services,[4,5] cost effective high turnover management strategies are more realistic for developing countries.[2] The concept of medical management in fact addresses these needs. Our results, however, could not confirm the efficacy of a single dose of misoprostol 400 μg in completing the expulsion of the retained products of conception. The mean duration of amenorrhoea in this study was 80 days compared with the 66 days in the study of Henshaw *et al*.[3] Although the decision to proceed with a surgical curettage was made 12 hours after misoprostol administration, all 20 patients in whom misoprostol failed were observed for an extended period (median 17 hours, range 13-23) while awaiting curettage; none had a successful outcome during this time. Most of the patients in the misoprostol group continued to bleed, and this was reflected in a significant fall in haemoglobin concentration ($P=0{\cdot}04$; table).

As no drug related complications were encountered in the misoprostol group, further randomised trials using higher dosages of misoprostol or in combination with mifepristone when available are necessary to determine the place of medical management of incomplete miscarriage.

Funding: Reproductive Health Research Fund.
Conflict of interest: None.

1 Greenslade FG, Leonard AH, Benson J, Winkler J, Henderson VL. *Manual vacuum aspiration: a summary of clinical and programmatic experience worldwide.* Carrboro, North Carolina: IPAS, 1993.
2 de Jonge ETM, Pattinson RC, Makin JD, Venter CP. Is ward evacuation for uncomplicated incomplete abortion under systemic analgesia safe and effective? *S Afr Med J* 1994;84:481-3.
3 Henshaw RC, Cooper K, El-Refaey H, Smith NC, Templeton AA. Medical management of miscarriage: non-surgical uterine evacuation of incomplete and inevitable spontaneous abortion. *BMJ* 1993;306:894-5.
4 Smith LFP. Should we intervene in uncomplicated miscarriage? *BMJ* 1993; 306:1540-1.
5 Dickey RP. Management of uncomplicated miscarriage. *BMJ* 1993;307:259.

(Accepted 29 June 1995)