4-weekly used by our local hospitals and clinics be changed to 1,2 MU 3-weekly as recommended by the WHO. This latter regimen has been shown to protect against recurrences in clinical trials. Further studies should be performed to clarify which are the best antibiotic regimens for secondary prophylaxis of rheumatic fever. The findings of this study suggest that benzathine penicillin 1,8 MU 4-weekly may protect against recurrences even though patients may not have therapeutic serum penicillin concentrations. Such studies should include measurement of both clinical and pharmacological parameters in the same cohort of patients followed up for at least 5 years to document recurrence rates.

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Is ward evacuation for uncomplicated incomplete abortion under systemic analgesia safe and effective?

A randomised clinical trial

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Objective. To compare evacuation under systemic analgesia (fentanyl and midazolam) in a treatment room (ward group) with evacuation under general anaesthesia in theatre.

Design. A prospective randomised clinical trial.

Setting. A tertiary medical centre serving a black urban population.

Subjects. One hundred and forty-two patients with uncomplicated incomplete abortions.

Intervention. Randomisation into two groups, those for evacuation under systemic analgesia and those for evacuation under general anaesthesia.

Main outcome measures. Both groups were compared in terms of safety, efficacy, acceptability, blood consumption and time delay between admission and evacuation.

Results. Significantly less blood was used in the ward group (37 units for 13 patients) than in the theatre group (65 units for 24 patients) ($P < 0,03$). Significantly less time was taken between admission and evacuation in the ward group (median 7 hours 15 minutes) than in the theatre group (median 12 hours 38 minutes) ($P < 0,0003$). Evacuation under fentanyl and midazolam was safe, effective and acceptable for the majority of patients compared with evacuation under general anaesthesia.

Conclusion. Patients with uncomplicated incomplete abortions (uterine size equivalent to a pregnancy of 14 weeks' duration or less) can undergo evacuation safely and effectively under fentanyl and midazolam and have a significantly smaller chance of requiring a blood transfusion.

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Evacuation of the uterine cavity after an incomplete abortion is done according to techniques described in standard gynaecological textbooks and is usually performed under general anaesthesia.[1] Over-occupancy of gynaecological beds (129%), a high turnover of gynaecology patients (3 339 gynaecological emergency admissions for 1991), overbooking of the emergency theatre and a shortage of theatre nursing staff forced us to investigate evacuation of uterine contents in a treatment room under systemic analgesia. A combination of pethidine hydrochloride and diazepam was initially used. During the initial period very few patients needed to be re-evacuated and there were no serious complications.

On the basis of our undocumented experience with evacuation under systemic analgesia, we decided to perform a randomised clinical trial to test the following hypotheses: *(i)* evacuation under systemic analgesia for uncomplicated incomplete abortion is safe, effective and acceptable for the patient; *(ii)* the delay between admission and the evacuation procedure is shorter for ward evacuations than for evacuations done in theatre; and *(iii)* blood loss for the ward group is less than for the theatre group.

Patients and methods

Permission for the study was given by the Kalafong Hospital Ethics Committee and written consent was obtained from each patient before entry to the study. Only patients fulfilling the following criteria were included in the study: uterine size equivalent to a pregnancy duration of 14 weeks or less, a dilated cervical canal, a haemoglobin concentration more than 8 g/dl after resuscitation and no signs of sepsis (temperature > 37,5°C, foul-smelling vaginal discharge). No patient refused to participate. Randomisation was done using numbered sealed opaque envelopes drawn by the clinician on a consecutive basis.

Sedation was provided by an opioid analgesic, fentanyl, and a benzodiazepine, midazolam. For the ward evacuation the analgesic technique was as follows: pre-oxygenation for at least 3 minutes with 6 - 7 litres oxygen delivered through a close-fitting mask; fentanyl 1,5 µg/kg given slowly intravenously up to a maximum of 100 µg, followed by midazolam administered slowly intravenously and titrated against the consciousness level of the patient to a maximum of 15 mg. Oxygenation was monitored by pulse-oximetry for the entire procedure. The anaesthetic technique for the evacuation in theatre was: pre-oxygenation; thiopentone 3,0 - 5,0 mg/kg intravenously, succinyldicholine 1,0 mg/kg intravenously; routine intubation because none of the patients was starved; inhalation of oxygen and nitrous oxide (50/50) 70 ml/kg and halothane 0,5 - 1,0% with spontaneous respiration. All the evacuations, both in the ward and in theatre, were performed with a sharp curette by a trained house officer or registrar.

Both groups were evaluated in terms of delay between admission and evacuation; complications (anaesthetic- and procedure-related); acceptability, measured retrospectively by the level of fear and/or pain experienced by the patient (grading: 1 - none; 2 - mild; 3 - moderate; 4 - severe; 5 - very severe); requirement for blood transfusion; and the need for re-evacuation. Acceptability was evaluated by an observer not directly involved in the surgical procedure.

From a pilot study we estimated that to show a difference of 50% between the two groups in terms of blood requirements, we would need 91 patients in each group (power = 80%, $\beta = 0,2$; error risk of 0,05, $\alpha = 0,05$). The number of patients requiring blood transfusions was used as the end-point because it was objective, easily documented and clinically important. The data were analysed using standard statistical techniques. Categorical data were compared using the χ^2-test. Where data were not normally distributed, the Mann-Whitney *U*-test was used. A *P*-value of less than 0,05 was regarded as indicating a significant difference.

Results

A total of 142 patients was included in the study between February and May 1992, of whom 73 were randomised to the ward group and 68 to the theatre group. The sample size of 182 could not be achieved because of hospital strikes and unrest.

Results for the ward and the theatre group are summarised and compared in Table I. Procedure-related complications, namely uterine or viscous perforation or any complication leading to hysterectomy, did not occur in either group. Blood loss greater than 500 ml occurred in 2 of the theatre cases. In 1 patient who underwent evacuation under systemic analgesia the oxygen saturation dropped to 79% during the operation; this was corrected by repositioning the patient's head, with immediate normalisation of the condition. None of the patients in either group had to be re-evacuated and in all cases the postoperative course was uncomplicated. The acceptability of the procedure is presented in Table II.

Table I. Comparative results between evacuations done in a treatment room (ward) and in theatre

	Ward	Theatre	*P*-value
Mean age (yrs)	24	25	NS
Hb (g/dl) (mean ± SD)			
On admission	10,8 ± 2,46	10,4 ± 2,73	NS
After evacuation	10,8 ± 2,86	10,7 ± 1,34	NS
Time delay from admission to evacuation			
Median	7 h 15 min	12 h 38 min	< 0,0003
Range	15 min - 63 h	1 h 5 min - 70 h 15 min	
Blood transfusions			
No. of patients	13	24	< 0,03
No. of units	37	65	< 0,03

Hb = haemoglobin concentration; SD = standard deviation; NS = not significant.

Table II. Comparison of acceptability between the ward and the theatre group*

	Ward (N = 73)	Theatre (N = 68)
Fear†		
Level 1	36	36
Level 2	18	11
Level 3	14	12
Level 4	2	6
Level 5	3	3
Pain†		
Level 1	54	65
Level 2	12	3
Level 3	5	0
Level 4	1	0
Level 5	1	0

* For interpretation see 'Discussion'.
† For definition see 'Patients and methods'.

Discussion

This randomised clinical trial demonstrated that evacuation of uterine contents in patients with an incomplete abortion and uterine size equivalent to less than 14 weeks' gestation could be performed safely and effectively in a well-equipped treatment room under systemic analgesia, with fewer patients requiring blood transfusion. Systemic analgesia appeared to be acceptable to the majority in terms of experience of pain.

Studies on evacuation of incomplete abortion under systemic analgesia[2-4] have concluded that this procedure is safe, effective, easy to perform and acceptable to the majority of patients. Different analgesic techniques were used. In the studies by Filshie *et al.*[2] and Verkuyl and Crowther[4] a combination of pethidine and diazepam was used, and in the study by O'Dowd and Sil[3] ketamine was used as a sole agent. We used fentanyl for its potent analgesic properties and midazolam because it has a short half-life and the patients were likely to benefit from its properties of retrograde amnesia. However, the danger of respiratory depression still exists, and the evacuation room must therefore be equipped with a resuscitation unit and a pulse-oximeter for continuous oxygen saturation monitoring. Evacuation in such a treatment room was shown to be as safe as evacuation in theatre under general anaesthesia.

There was less need for blood transfusion in the ward group than in the theatre group (Table I), but the reason for this is uncertain. There are two probable explanations: *(i)* ward patients were evacuated much earlier after admission than those waiting for an evacuation in theatre, as was clearly demonstrated; and *(ii)* anaesthetic agents such as halothane and/or nitrous oxide are known to cause uterine relaxation, and might have been responsible for the higher blood requirements in the theatre group. Since the pre- and postoperative haemoglobin concentrations were similar in both groups, bias is a very unlikely third possibility.

Assessment of pain is notoriously difficult and by its nature is subjective. In 2 patients (2,7%) (Table II) the procedure was clearly unacceptable; however, in the remainder acceptability depends on what is defined by the individual doctor (and patient) as acceptable. Stated more precisely, is moderate experience of pain by the patient acceptable? If a moderate level of pain is acceptable for this procedure, acceptable pain levels 1 - 3 would be compared with unacceptable levels 4 and 5. In this case there is no significant difference between the ward and the theatre groups (P = 0,17). On the other hand, if moderate experience of pain during the evacuation procedure is not considered acceptable, and pain levels 1 and 2 are therefore compared with levels 3 - 5, there is a significant difference between the ward and the theatre group (P < 0,04), with the ward group having more substantial pain. Keeping in mind that pain tolerance varies according to the individual we are satisfied with the analgesic potential of the combination of fentanyl and midazolam. It also compares favourably with the study of Filshie *et al.*,[2] in which 4 of 121 patients (3,3%) said they had experienced pain during the procedure performed under pethidine and diazepam. It is interesting to note from this study that 97 of the 99 patients who were available for their 6-weeks follow-up visit were pleased that they had not had general anaesthesia; only 2 would have preferred it. We realise that this outcome may be biased.

In terms of costs, ward evacuation is much more economical than theatre evacuation. From our data we calculated the hospital costs (Transvaal Provincial Administration tariffs) to be R433,72 per patient for an evacuation in the ward (hospitalisation at R266,50 per day = R333,00; blood at R150,00 per unit = R84,00; fentanyl and midazolam 1 ampoule each R16,72) and R860,69 for an evacuation in theatre (hospitalisation R422,00; blood R134,69; theatre fee R281,00; thiopentone and succinydicholine R23,00), a difference of R426,97 per patient. In 1991, 868 ward evacuations were performed at Kalafong, saving R370 609,96 (R426,97 x 868) on the hospital budget.

In conclusion, uncomplicated incomplete abortions with a uterine size equivalent to a pregnancy of up to 14 weeks' duration can be evacuated safely and effectively in a ward treatment room under fentanyl and midazolam, provided the patient is well resuscitated pre-operatively and respiratory depression can be diagnosed early by monitoring the oxygen saturation. Patient care can be improved by searching for the most safe and effective combination of drugs for systemic analgesia.

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