Management of premature rupture of the membranes after 34 weeks' gestation — early versus delayed induction of labour

J. van Heerden, D. W. Steyn

Objective. To determine the optimal way to manage patients with premature rupture of the membranes after 34 weeks' gestation.

Design. A prospective, randomised controlled trial comparing immediate induction and delayed induction after 24 - 48 hours.

Setting. Tygerberg Hospital, Cape Town.

Participants. Seventy consecutive patients with premature rupture of the membranes who presented at Tygerberg Hospital between July and October 1991.

Main outcome measures. The two groups were compared with regard to infectious morbidity and antibiotic requirements in the mothers and babies, days spent in hospital, caesarean section rates, duration of labour and analgesic requirements.

Results. There was no difference between the two groups in terms of infectious morbidity in either the mothers or the babies, the duration of labour or the caesarean section rates. Nine patients (26%) in the delayed induction group required analgesic treatment during labour versus 18 patients (52%) in the group that was induced immediately ($P = 0.049$; odds ratio = 0.327; 95% confidence limits = 0.014 - 0.0998). In the delayed induction group, 74% of the patients went into spontaneous labour during the conservative management period. Patients in the active group (immediate induction) had a statistically significant better chance of being discharged within 48 hours of admission ($P = 0.028$; odds ratio = 3.34; 95% confidence limits = 1.12 - 10.73).

Conclusions. The management of patients with premature rupture of the membranes after 34 weeks should be decided upon according to the level of antepartum and neonatal care which is available at the particular unit. Where there is adequate neonatal support and pressure on bed occupancy, immediate induction of labour should be considered, while peripheral units should consider conservative management before referral of patients.

S Afr Med J 1996; **86:** 262-266.

MRC Perinatal Mortality Research Unit and Department of Obstetrics and Gynaecology, Tygerberg Hospital and University of Stellenbosch, Tygerberg, W. Cape

J. van Heerden, M.B. CH.B.

D. W. Steyn, M.MED. (O.&G.), F.C.O.G. (S.A.)

Conflicting views on the management of patients with premature rupture of the membranes (PROM) have been reported.[1-8] Advocates of early induction of labour have cited the risk of maternal and fetal infection as the reason for their preference. A recent meta-analysis has indicated that early administration of intravenous oxytocin for induction of contractions after PROM at term is associated with an increase in the likelihood of caesarean section (CS) without convincing evidence that the mother and fetus will be more effectively protected against the risks of infectious morbidity than when treated by a more conservative policy.[9] However, methodological limitations of some of the studies included in the meta-analysis could invalidate these conclusions. The risk of chorio-amnionitis might be influenced by the prevalence of vaginal and pelvic infections in the particular population, necessitating community-based studies.[10,11] Fayez *et al.*[12] reported that early induction of labour in a population at high risk for infection leads to a minimal incidence of fetal and maternal morbidity and mortality without a significant increase in CS rate. In the only South African study published, it was concluded that the CS rate was increased in the group managed actively with oxytocin and that maternal and serious neonatal infectious morbidity rates were similarly low in both groups.[13]

Serving a population with a high incidence of vaginal and pelvic infections, we undertook a study to evaluate the influence on maternal and fetal infectious morbidity, CS rate, the need for analgesia and duration of hospitalisation of both mothers and babies of early compared with late induction of labour in patients with PROM after 34 weeks' gestation.

Materials and methods

A randomised controlled trial was undertaken prospectively at Tygerberg Hospital between July and October 1991. PROM was defined as rupture of the membranes in the absence of uterine contractions. Rupture of membranes was confirmed by sterile speculum examination's demonstration of a pool of amniotic fluid in the posterior vaginal fornix, validated by a positive nitrazine test and a positive fern test on microscopy.

Seventy consecutive patients presenting to the labour ward with PROM at a gestational age of more than 34 weeks were entered into the study. For the duration of the study, patients presenting to the maternal obstetric units were also transferred to the hospital if they were not in labour (3 contractions of at least 40 seconds each per 10 minutes) 6 hours after PROM. In the case of unbooked patients (and therefore an uncertain gestational age), those with a sonar fetal weight estimation of $> 2\,000$ g were entered. Exclusion criteria were as follows: fetal distress as diagnosed on cardiotocograph, fetal death, fetal congenital abnormalities, PROM of more than 24 hours' duration before admission, digital vaginal examinations after rupture of membranes, antepartum haemorrhage, two or more previous CSs and fetal presentations other than cephalic ones. Patients with chorio-amnionitis diagnosed clinically in the presence of maternal and fetal tachycardia, fever, uterine tenderness and offensive vaginal discharge were also

excluded. Patients with only one previous CS were included in the study and managed according to the standard protocol.

Random numbers generated by computer were used to allocate patients to either an active management group (AMG) or a delayed induction group (DIG). Sealed opaque envelopes were used; these were only opened once it was ascertained that the patient qualified for the study. Labour was immediately induced in the AMG with a standardised regimen of intravenous oxytocin for up to 12 hours. If labour had not been established at this stage, intravenous prostaglandin F_2-alpha was administered for a further 6 hours. If labour had still not occurred after 18 hours, induction was regarded as failed and a CS was performed. Patients allocated to the DIG were admitted to an antenatal ward where 4-hourly maternal and fetal observations were done. Labour was induced as above in those patients who had not gone into labour spontaneously at 08h00 the morning after completion of 24 hours after rupture of membranes. This resulted in 24 - 48 hours of conservative management being achieved. Labour was immediately induced if there were signs of fetal distress or chorio-amnionitis. Digital vaginal examinations were restricted to patients in active labour.

Maternal and neonatal outcome in the two groups were analysed. Febrile morbidity was defined as oral temperatures of at least 38°C taken at least 6 hours apart any time after vaginal delivery. Febrile morbidity was not diagnosed in the first 24 hours postoperatively after CS. Neonates were not routinely subjected to a septic screen in accordance with local policy.[12] Further clinical management of patients was decided upon by the managing clinician.

Results were analysed using Student's *t*-test to compare means of normally distributed data and the signed rank test for data not normally distributed. Ratios were compared using the χ^2 test and Fisher's exact test if expected values were less than 5. *P*-values of less than 0.05 were considered significant.

Results

Thirty-five patients were entered into each of the management groups. The groups were comparable as far as maternal age, gravidity, parity and gestational age were concerned (Table I). This also applied to birth weight and Apgar scores (Table II). Two major neonatal problems, both occurring in the AMG, were unrelated to the management. A baby with hydrocephalus died 7 days after birth, while another baby recovered well after surgery for a diaphragmatic hernia.

Table I. Maternal characteristics of the two management groups

	Actively managed group		Delayed induction group	
	Mean (range)	Median	Mean (range)	Median
Age (yrs)	25.14 (18 - 34)	25	26.2 (16 - 36)	25.5
Gravidity	2.09 (1 - 5)	2	2.23 (1 - 6)	2
Parity	1 (0 - 4)	0.5	1.17 (0 - 5)	1
Gestation (wks)	38 (35 - 41)	38	38 (34 - 42)	38
Previous CS	4		5	

Table II. Neonatal characteristics in the two management groups

	Actively managed group		Delayed induction group	
	Mean (range)	Median	Mean (range)	Median
Birth weight (g)	2 944 (2 010 - 3 790)	2 900	2976 (1 850 - 4 060)	2 910
Apgar score (1 min)	8.54 (2 - 10)	9	8.11 (1 - 10)	9
Apgar score (5 min)	9.5 (6 - 10)	10	9.4 (6 - 10)	10
Apgar score (5 min) < 7	2			1
Neonatal death	1		0	

Antibiotic treatment (other than prophylaxis at CS) was deemed necessary in 5 mothers in the AMG and 4 in the DIG (Table III). Of these patients, only 3 received intravenous antibiotic treatment. The only case of chorio-amnionitis occurred in a patient with a McDonald suture who was managed conservatively. The suture was not removed on admission. A CS was eventually performed for fetal distress. After an initial period of 72 hours of intravenous antibiotics, she was discharged on oral antibiotics 7 days postoperatively. Her baby, who had a positive blood culture for *Staphylococcus aureus,* was the only neonate to receive antibiotics. The baby recovered after a course of intravenous antibiotics and was discharged with its mother without further complications. No other babies had any signs of infection. All but the 2 with serious congenital defects were discharged with their mothers.

Table III. Details of maternal antibiotic treatment considered necessary by attending physicians

Patient	Particulars
Actively managed group	
1	CS for failed induction. Bronchitis clinically diagnosed on day 3. Oral AB.
2	CS for abruptio placentae. Bronchitis clinically diagnosed on day 5. Oral AB.
3	NVD. Septic episiotomy. Oral AB. No febrile morbidity.
4	NVD. Offensive lochia day 3. Oral AB. No febrile morbidity.
5	CS for secondary arrest of labour. Wound sepsis day 3. Intravenous AB for 3 days. Oral AB thereafter.
Delayed induction group	
1	NVD. Offensive lochia. Oral AB. No febrile morbidity.
2	NVD. Septic vaginal tear. Oral AB. No febrile morbidity.
3	CS for poor progress. Maternal diabetes mellitus on insulin. Clinically diagnosed pyelonephritis on day 3. Intravenous AB. Wound sepsis on day 5. Follow-up oral AB. Discharged on day 24.
4	CS for fetal distress. Mother with McDonald suture developed chorio-amnionitis before induction. Intravenous AB. Follow-up oral AB. Discharged on day 7. Baby had AB but was discharged with its mother.

AB = antibiotics; NVD = normal vaginal delivery.

More CSs were performed in the DIG (7 compared with 4; $P = 0.51$). Of the 7 CSs in the DIG, 3 were for fetal heart rate (FHR) abnormalities and 4 for some degree of dystocia (Table IV). Of the 4 CSs in the AMG, only 1 was for failed induction. This was one of only 2 cases where oxytocin alone was insufficient for induction of labour. Another patient

should also have had a CS for failed induction according to protocol, but refused this option and was successfully delivered the following day after the oxytocin regimen commenced once again. In the DIG, 26 patients (74%) went into spontaneous labour before induction began and only 4 of these patients needed oxytocin augmentation. In the remaining 9 patients in this group, the average time from induction to onset of contractions (2.31 hours) was the same as for the AMG (2.36 hours). Average time spent in the labour ward, necessitating more intensive nursing care, was on average 1 hour longer in the AMG (6.64 hours compared with 5.74 hours), but this difference was not statistically significant.

Table IV. Distribution of CS according to management groups

Patient	Group	Indication	Apgar 1 min/ 5 min/10 min	Birth weight (g)
1	AMG	Failed induction	9/10/10	3 275
2	AMG	Abruptio placentae†	10/10/10	2 920
3	AMG	Failed vacuum extraction	2/6/97	3 030
4	AMG	Secondary arrest of labour	9/10/10	3 450
1	DIG*	Cephalopelvic disproportion	5/7/10	4 030
2	DIG	FHR decelerations	3/10/10	2 910
3	DIG*	Poor progress†	8/9/9	3 680
4	DIG*	Secondary arrest of labour†	1/7/9	3 650
5	DIG*	Poor progress	6/9/10	3 480
6	DIG*	FHR decelerations	5/6/9	2 620
7	DIG*	FHR decelerations	7/10/10	2 780

* Spontaneous onset of labour.
† Previous CS.

Six of the 9 patients (66.7%) entered into the study who had previously had a CS delivered vaginally (Table V). Three of the 5 patients who had had their previous CSs for either poor progress in labour or cephalopelvic disproportion, had successful vaginal deliveries. No serious morbidity occurred in any of these patients.

Table V. Outcome of patients with previous CS according to management groups

Group	Indication for previous CS	Outcome of index pregnancy
DIG	Poor progress in labour	CS for poor progress
DIG	Eclampsia	CS for poor progress
DIG	Antepartum haemorrhage	Normal vertex delivery
DIG	Failed induction	Normal vertex delivery
DIG	Cephalosporin disproportion	Normal vertex delivery
AMG	Cephalosporin disproportion	CS for abruptio placentae
AMG	Poor progress in labour	Vacuum extraction delayed second stage
AMG	Poor progress in labour	Normal vertex delivery
AMG	Uncertain	Normal vertex delivery

In the DIG, analgesic treatment other than nitrous oxygen was administered during labour to 9 (26%) patients, compared with 18 (52%) patients in the AMG ($P = 0.049$; odds ratio = 0.327; 95% confidence limits = 0.104 - 0.998). The mean duration of labour, from the onset of contractions till delivery, was 3.38 hours in the AMG compared with 4.33 hours in the DIG ($P = 0.25$) (Table VI). This relatively short duration of labour contributed to several patients' not needing analgesia.

Table VI. Duration of various periods

Duration of period (h)	Actively managed group		Conservatively managed group		
	Mean (range)	Median	Mean (range)	Median	*P*
Rupture to admission	7.3 (0 - 22.7)	6.6	7.7 (1.2 - 23.8)	5	NS
Admission to labour	7 (1.5 - 21)	3.4	14.3 (0.5 - 46.3)	13	< 0.05
Labour to delivery	5.1 (0.8 - 26.9)	3.4	5.4 (0.8 - 13.5)	4.3	NS
Delivery to discharge*	44.6 (6.9 - 182)	32.5	67.1 (7.5 - 566)	38.1	NS
Delivery to discharge†	33.1 (6.9 - 99)	30.7	37.3 (8 - 112)	27.5	NS
Admission to discharge	56.7 (24 - 216)	48	86.74 (24 - 576)	60	NS

* Including patients with CS.
† Excluding patients with CS.

Patients in the AMG had a statistically significant better chance of being discharged within 48 hours of admission ($P = 0.028$; odds ratio = 3.43; 95% confidence limits = 1.12 - 10.73) (Fig. 1). This difference persisted even when patients undergoing CS were excluded from the analysis ($P = 0.048$; odds ratio = 3.9; 95% confidence limits = 1.01 - 15.82) (Fig. 2). The interval between admission and the onset of contractions was significantly longer in the DIG as a whole. However, there was no difference in the interval between PROM and admission to hospital or that between labour and delivery (Figs 3 and 4). The delivery till discharge period is influenced by the fact that patients are generally discharged from our wards only once daily, resulting in postponement of hospital stay by 24 hours if a patient is not ready for discharge at 08h00. This resulted in the 9 patients in the DIG who required induction of labour having the shortest average delivery till discharge period because of the policy of commencing induction at 08h00. It is uncertain whether the occurrence of abruptio placentae in the 1 patient managed actively should be linked to the method *per se*, but this endorses the need for continuous fetal monitoring during the induction process. No other serious complications occurred, apart from those related to infection already mentioned.

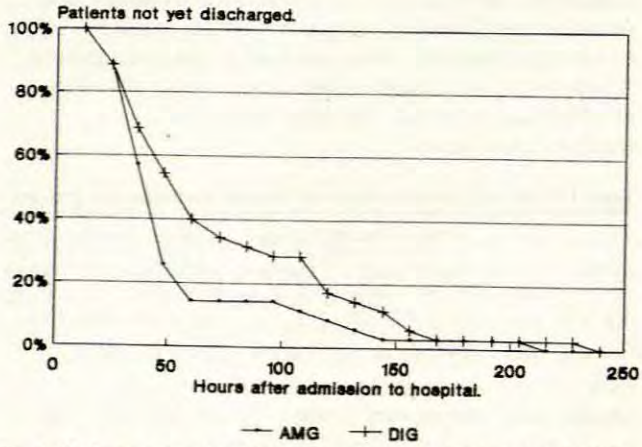

Fig. 1. Patients not yet discharged, including patients with CSs (%).

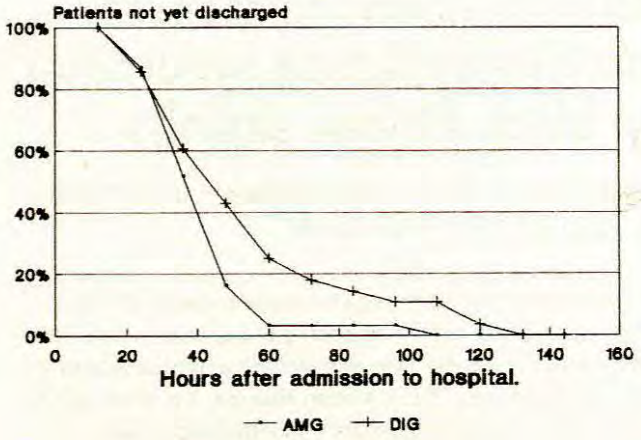

Fig. 2. Patients not yet discharged, excluding patients with CSs (%).

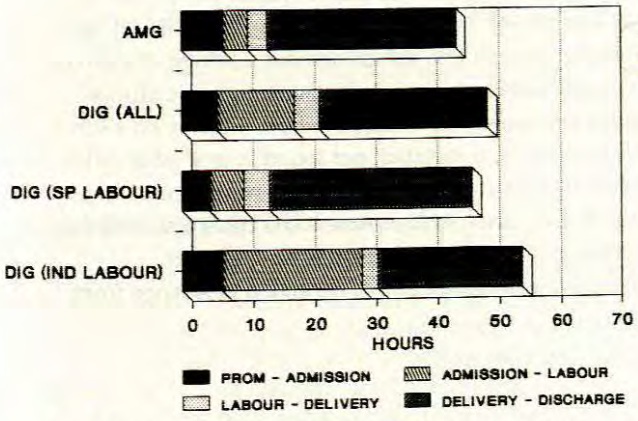

Fig. 3. Median duration of various periods after rupture of membranes (including patients with CSs). SP = spontaneous; IND = induction.

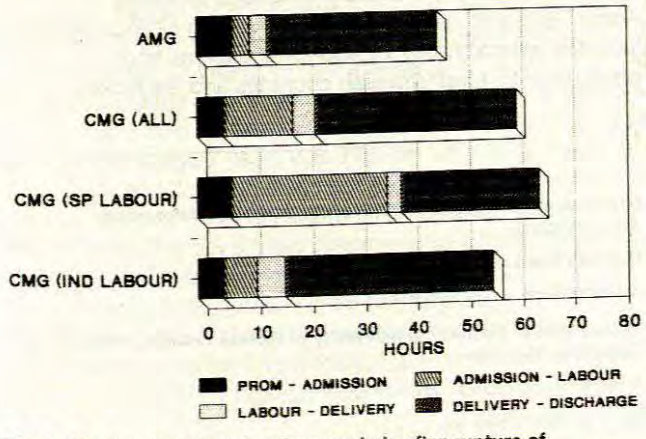

Fig. 4. Median duration of various periods after rupture of membranes (excluding patients with CSs). SP = spontaneous; IND = induction.

Discussion

The main concerns associated with PROM when it occurs at term are maternal and fetal infection in patients managed conservatively and an increased incidence of CS when labour is induced. From this study, neither of these seem to be a significant problem locally. However, it should be borne in mind that labour was never induced later than 48 hours after PROM in our study. Because of logistic problems, observers of maternal and neonatal outcome were not blinded with regard to the maternal management group in this study. This could be a possible source of bias regarding infectious morbidity. However, it has been established in our paediatric unit that routine screening for infection in neonates delivered after PROM does not improve diagnosis of subclinical infection.[14] The distribution of mothers receiving antibiotics was similar in the two management groups. Of the 9 patients who received antibiotics, only 3 were given intravenous therapy. In 1 of these patients, alternative management might have altered the eventual course favourably, as the McDonald suture was only removed at the time of diagnosis of chorio-amnionitis. This was the only patient in the study who had diabetes mellitus. Patients with diabetes mellitus and PROM, in addition to having a higher risk for infection, have a higher chance of neonatal respiratory distress if preterm delivery takes place. This complicates management decisions, which should be individualised in these particular patients.

CS was undertaken more often in the DIG, a finding which deviates from previous reports.[1-3,5] This difference is not statistically significant and is probably due to small numbers. However, the overall incidence of CS in the two groups (16%) is not different from the general incidence at Tygerberg Hospital. Of the 7 conservatively managed patients who required CS, 6 developed contractions spontaneously. Three CSs were performed for cardiotocographic abnormalities and 4 for some degree of dystocia. In the latter group, the birth weight was 4 030 g in 1 patient who developed cephalopelvic disproportion, 2 CSs were performed in patients who had had previous CS and poor progress in the index pregnancy and the last CS was in an insulin-dependent diabetic with poor progress in labour. In the AMG, the definition of failed induction was probably too rigid. It seems safe to discontinue the induction process after 18 hours if no contractions occur at that stage and to start again the next morning if no contraindications are present. Successful induction is possible then, as was confirmed in the case of the patient who declined CS after failed induction. Six of the 9 patients in our series with previous CS were successfully delivered vaginally, which confirms the recommendations of others that induction of labour is a viable option under these circumstances.[15]

While no apparent advantage related to the major concerns of either management group materialised, a significant finding was that patients managed actively as in this study had a statistically better chance of spending less than 48 hours in hospital than patients initially managed conservatively (9 as opposed to 19 patients not yet discharged) (Fig. 3). This tendency persisted even when patients undergoing CS are excluded (5 as opposed to 12 patients not yet discharged) (Fig. 4). With a restricted health budget, unnecessarily long hospitalisation should be

avoided, especially in tertiary units. Beds could be better utilised by other antenatal patients.

However, in smaller referral units where beds are more readily available, patients could be managed conservatively for up to 48 hours without increased morbidity. It has been reported that after 48 hours of PROM the incidence of chorio-amnionitis increases from 10% to 26.6%.[12] In our study, 76% of patients managed conservatively went into spontaneous labour and could possibly have delivered in peripheral units, thus further reducing the workload of the referral hospitals. Close observation for signs of chorio-amnionitis is essential and vaginal examination should be limited to patients in active labour.

The greater need for analgesics in the AMG was not unexpected, although the overall requirement per patient was low. Pethidine and hydroxyzine are generally available in obstetric units and personnel are familiar with their administration. It was reassuring to find that the active stage was not prolonged in these patients and that the incidence of instrumental deliveries was not increased.

The decision to induce delivery at 34 weeks' gestation was based on the excellent prognosis of these babies in our hospital.[16] This does not necessarily reflect the situation at other units, especially those accommodating patients from higher socio-economic environments than our own, in whom induction of labour should probably be postponed till 38 weeks. We recommend that management of patients with PROM after 34 weeks should be decided upon according to the level of antepartum and neonatal care available at the particular unit. Where there is pressure on bed occupancy and adequate neonatal support, immediate induction of labour should be considered, while peripheral and other units should consider conservative management before referral of patients. We have successfully implemented such a policy at our obstetric units since the completion of this study.

REFERENCES

1. Duff P, Sanders R, Gibbs RS. The course of labour in term patients with chorio-amnionitis. *Am J Obstet Gynecol* 1983; **147:** 391-395.
2. Morales WJ, Lazar AJ. Expectant management of spontaneous rupture of the membranes at term. *South Med J* 1986; **79:** 955-958.
3. Tamsen L, Lyrenas S, Chattinguis S. Premature rupture of the membranes. Intervention or not? *Gynecol Obstet Invest* 1990; **29:** 128-131.
4. Conway DI, Prendiville WJ, Morris A, *et al.* Management of spontaneous rupture of the membranes in the absence of labour in primigravid women at term. *Am J Obstet Gynecol* 1984; **150:** 947-951.
5. Kappy KA, Cetrulo CL, Knuppel RA, *et al.* Premature rupture of the membranes: a conservative approach. *Am J Obstet Gynecol* 1979; **134:** 655-660.
6. Garite TJ. Premature rupture of the membranes: The enigma of the obstetrician. *Am J Obstet Gynecol* 1985; **151:** 1001-1005.
7. Rovinsky JJ, Shapiro WJ. Management of premature rupture of the membranes; 1: Near term. *Obstet Gynecol* 1968; **32:** 855-866.
8. Kappy KA, Cetrulo CL, Knuppel RA, *et al.* Premature rupture of the membranes at term. A comparison of induced and spontaneous labors. *J Reprod Med* 1982; **27:** 29-33.
9. Grant J, Keirse MJNC. Premature rupture of the membranes at term. In: Chalmers I, Enkin MW, Keirse MJNC, eds. *A Guide to Effective Care in Pregnancy and Childbirth.* Oxford: Oxford University Press, 1989: 1112-1117.
10. Munson LA, Graham A, Koos BJ, *et al.* Is there a need for digital examination in patients with premature rupture of the membranes? *Am J Obstet Gynecol* 1985; **153:** 562-563.
11. Schutte MF, Treffers PE, Kloosterman GJ, *et al.* Management of premature rupture of the membranes: The risk of vaginal examinations to the infant. *Am J Obstet Gynecol* 1983; **146:** 395-400.
12. Fayez JA, Hasan AA, Jonas HS, *et al.* Management of premature rupture of the membranes. *Obstet Gynecol* 1978; **52:** 17-21.
13. Van der Walt D, Venter PF. Management of term pregnancy with premature rupture of the membranes and unfavourable cervix. *S Afr Med J* 1989; **75:** 54-56.
14. Hesseling PB, Henning PA, Kirsten GF, *et al.* Verlengde ruptuur van vliese (VRVV): Antibiotikabeleid en uitkoms in 161 neonate by Tygerberg Hospitaal. *Geneeskunde* 1990; **32:** 8-13.
15. Enkin MW, Keirse MJNC, Chalmers I. Labour and delivery after previous caesarean section. In: Enkin MW, Keirse MJNC, Chalmers I, eds. *A Guide to Effective Care in Pregnancy and Childbirth.* Oxford: Oxford University Press, 1989: 253.
16. Vansteenkiste MAL, Pattinson RC, Kirsten GF. The role of obstetric factors in determining fetal viability. *S Afr Med J* 1992; **81:** 508-511.

Accepted 16 Jan 1995.