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A comparison of 'active' and 'physiological' management of the third stage of labour

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A randomised, controlled trial of 1429 women was carried out to compare 'active' management of the third stage of labour, using i.v. Ergometrine 0.5 mg, with a method of 'physiological' management, in women at 'low risk' to haemorrhage. In the "active" management group a higher incidence of the following complications was found:– manual removal of placenta ($p < 0.0005$), problems such as nausea ($p < 0.0005$), vomiting ($p < 0.0005$), and severe after-birth pains ($p < 0.02$), hypertension ($p < 0.0001$) and secondary postpartum haemorrhage ($p < 0.02$).

The incidence of postpartum haemorrhage (blood loss greater than 500 ml) and postnatal haemoglobins less than 10 gm/100 were higher in the 'physiological' group ($p < 0.0005$, $p < 0.002$). No difference was found in the need for blood transfusion in either group.

The routine use of i.v. Ergometrine 0.5 mg during the third stage of labour in women at 'low risk' to haemorrhage does not appear to be necessary and has many adverse effects. Further studies comparing different methods of 'physiological' management are recommended in order to reduce to a minimum the incidence of postpartum haemorrhage and anaemia.

INTRODUCTION

The discovery of Ergometrine and its subsequent use in the treatment of postpartum haemorrhage was a landmark in the history of obstetric care. In the 1920s, postpartum haemorrhage (PPH) was a common cause of maternal death in Ireland and the UK, accounting for 22% and 14%, respectively, of those countries' maternal mortality rates (Tierney, 1932). This problem extended world-wide and in the years 1931–1943 (which spanned the introduction of Ergometrine), 8% of total maternal deaths in one area of the USA were still caused by PPH (Beecham, 1947).

Chassar Moir (1932) carried out the initial studies on crude ergot and found, with Dudley (1935), that Ergometrine was the substance responsible for the oxytocic effect of ergot. The introduction of this drug as a therapeutic agent to control haemorrhage was hailed as a major break-through in the obstetric field. Deaths from haemorrhage fell in Ireland from 23 in 1936 (Department of Local Government and Public Health, 1936), to none in 1983 (Central Statistics Office, 1983).

During the period there were, of course, other factors such as increased availability of blood transfusions, improved antenatal care and the improved state of nutrition and general health of the women which may have contributed to the reduction in the mortality rate due to PPH. For example, the incidence of anaemia in the study

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hospital was 75% in 1950 (Feeney, 1950), had fallen to 14.5% in the period 1955–1957 following the introduction of oral iron supplements to all pregnant women (Stuart, 1958), and has remained at a level of between 4% and 7% over the past decade 1978–1987 (Drumm, 1987).

Few obstetric practitioners would dispute that oxytocic drugs have played the greatest part in treating haemorrhage and reducing the mortality rate. However, once Ergometrine was established as a useful drug in the treatment of PPH, it was gradually introduced as a method of prevention also and many studies were carried out in the 1940s and early 1950s to ascertain the effects of prophylactic administration of the drug (Diddle, 1942; Davis & Boynton, 1942; Lister, 1950; Daley, 1951; Snaith, 1951).

In 1963 Embrey et al compared the use of i.m. Ergometrine with i.m. Syntometrine (Ergometrine combined with Syntocinon), both given on delivery of the baby's anterior shoulder. They reported a decrease in the PPH rate using Syntometrine, with no increase in the rate of retained placenta. This rapidly became the drug of choice in the UK and to some extent in Ireland also. The majority of midwifery and obstetric textbooks recommend the routine use of an oxytocic drug, given with the anterior shoulder or during the third stage of labour, and Syntometrine is specifically mentioned in some of these (Reid et al, 1972; Beischer & Mackay, 1978; Anderson, 1981; Myles, 1981; Myerscough, 1982; Clayton et al, 1985; Llewellyn-Jones, 1986).

A recent overview (Elbourne et al, 1988) of controlled trials comparing combinations of Ergometrine and oxytocin concluded that the unwanted side-effects of Ergometrine were such that it was no longer justifiable to use Ergometrine routinely in the management of the third stage. They further suggest that the prophylactic use of Syntometrine is as effective as Ergometrine, with reduced side-effects, and more effective than oxytocin in reducing PPH. They emphasise the need for further controlled studies in this area.

Side-effects

The unpleasant and occasionally dangerous side-effects of Ergometrine have been documented in many studies. Nausea has been noted in 20% of women who had 0.2 mg of Ergonovine (Friedman, 1957) and 13% and 32% respectively have had retching or vomiting following Ergometrine 0.5 mg i.v. (Moir & Amoa, 1979; Garrioch et al, 1981). Nausea and vomiting are especially severe when women have had epidural analgesia (Milne & Murray Lawson, 1973; Moodie & Moir, 1976).

Hypertension has frequently been noted following the administration of Ergometrine i.v. (Forman & Sullivan, 1952; Friedman, 1957). i.m. Syntometrine causes less severe changes (Hacker & Biggs, 1979), due perhaps to a combination of the slower uptake of the intramuscular drug and the hypotensive effect of oxytocin (Woodbury et al, 1944; Hendricks & Brenner, 1970; Nakono, 1973; Weiss et al, 1975).

Johnstone (1972) studied the cardio-vascular effects of oxytocic drugs and found that Ergometrine constricted the alpha and beta blood vessels. He suggested that this widespread vasoconstriction might precipitate postpartum hypertension or pulmonary oedema in obstetric patients 'at risk' (i.e. those with 'toxaemia', chronic anaemia, cardiovascular or renal disease). This view was shared by Browning (1974) and Dommisse (1980), and also by McFadyen (1960) and Abouleish (1976) who separately presented evidence that the use of Ergometrine may contribute to postpartum eclampsia. Intracerebral haemorrhage resulting in death has also been reported (Ringrose, 1962).

Ergot alkaloids can cause coronary artery spasm in susceptible people (Heupler et al, 1978) and pulmonary oedema has been seen in cardiac patients (Dumoulin, 1981). Cases of cardiac arrest following i.v. injection of Ergometrine have been described (Browning, 1974; Valentine et al, 1977; Taylor & Cohen, 1985), possibly due to the depression of the sinoatrial node which has been demonstrated following i.v. injection of 0.5 mg of Ergometrine (Baillie, 1969).

Vaughan Williams et al (1974) have shown that Ergometrine given i.v. and Syntometrine given i.m. both cause a significant rise in central venous pressure. Venous vasoconstriction has also been demonstrated in other ways, an i.v. injection of Ergometrine 0.25 mg causing a 41%

reduction in venous compliance in the forearm (Brooke & Robinson, 1970). A variety of other side-effects have been noted such as uterine cramping, occurring in 80% of patients given IV Ergonovine 0.2 mg on the 2nd and 3rd postpartum days, dizziness, headaches, perspiration and tinnitus affecting 32%, and backache and leg pain affecting 16% (Forman & Sullivan, 1952). Retinal detachment has also been seen (Gombes et al, 1969), and gangrene of the extremities following therapeutic doses (1 mg, three times a day) of oral ergotamine tartrate (Cameron & French, 1960).

Prendiville et al (1988) have analysed the results of 9 published reports of controlled trials in which an oxytocic drug was compared with either a placebo or no routine oxytocic. Their finding is that oxytocic drugs used routinely appear to reduce the risk of PPH by about 40%. These studies, which spanned the period from 1951 to the present day, included all women without considering age, parity, type of delivery, or other variables. A number of the women included were presumably at 'high risk' to PPH.

The majority of women in the 1980s are better nourished, less anaemic, and of lower age and parity than the women of earlier decades. As previously stated, the incidence of anaemia in the study hospital fell from 75% in 1950 (Feeney, 1950), to a level of between 4% and 7% over the past decade 1978–1987 (Drumm, 1987). In 1955, 31% of deliveries were to women who had four or more previous children, compared with 14% in 1984 (Central Statistics Office 1955, 1984). Twenty-nine per cent of deliveries in 1955 were to women aged 35 or over, compared with 16% in 1984 (Central Statistics Office 1955; 1984). Women today may thus be less likely to have a PPH, and should be better equipped to withstand normal blood loss at delivery without ill effects.

This study was designed to determine whether the routine use of i.v. Ergometrine during the third stage of labour is justified when caring for women at 'low-risk' to haemorrhage.

Hypotheses

That the 'active' management of the third stage of labour:

1. reduces the incidence of manual removal of the placenta.
2. reduces the incidence of postpartum haemorrhage (<500 ml) and the mean blood loss measured clinically.
3. reduces the mean length of the third stage of labour.
4. reduces the incidence of maternal haemoglobin (Hgb) values of <10 gm/100 measured between 48–72 hours postpartum.
5. reduces the mean difference between the maternal haemoglobin (Hgb) value at approximately the 32nd week of pregnancy and 48–72 hours postpartum.
6. reduces the incidence of postpartum blood transfusion.
7. reduces the incidence of haemorrhage, nausea, vomiting, raised blood-pressure, afterbirth pains and headache in the first 1–2 hours post delivery.
8. reduces the incidence of complications in the first 6 postpartum weeks.

METHODS

A randomised controlled study comparing 'active' management of the third stage of labour, using i.v. Ergometrine 0.5 mg with a method of 'physiological' management using no routine oxytocic drug was designed. The study was to be carried out on women deemed to be at 'low risk' to postpartum haemorrhage.

Ergometrine was chosen for comparison with physiological management because it was, at the time, the drug used routinely in the study hospital, and no change in management was envisaged in the near future. Thus the 'active' group had the third stage managed exactly as it had been for the preceding decade and a half (using i.v. Ergometrine 0.5 mg and controlled cord traction (Myles, 1981) although this management was now documented for the midwives' guidance (Fig. 1). The 'physiological' management was more difficult to define. It was necessary to combine the ideal management—upright attitude, delivery by maternal effort (Inch, 1985) and delayed clamping of the cord (Walsh, 1968; Inch, 1985), with a management policy which

1. Give Ergometrine 0.5 mg i.v. immediately following delivery (once a second twin has been excluded).
2. Place a sterile receiver against the perineum to catch the blood lost. Try not to include liquor if possible.
3. Try to clamp the cord within 30 seconds of delivery of the baby.
4. When the uterus has contracted, attempt delivery of the placenta by controlled cord traction. Deliver the placenta into a separate bowl, not the receiver.
5. Try not to give any special instructions about posture. If delivery has taken place in the birthing chair, tilt the chair to a semi-recumbent position as soon as the baby is born.
6. Measure blood loss. Please DO NOT add an estimate for any blood spilt—try to collect as much as possible and measure it.

Retained placenta—1 hour after delivery
- ensure bladder is empty
- attempt delivery again using controlled cord traction
- manual removal of placenta under general anaesthetic
- try to collect and measure all blood lost during this procedure.

Fig. 1 Instructions to midwives on: Active management of the third stage of labour

would be acceptable to, and therefore more likely to be followed by, the midwives in charge of the deliveries (Fig. 2).

The hypotheses were phrased in the form of 'reducing' the various incidences of complications rather than the more conventional form of 'having no effect on', in line with the prevailing opinions of obstetric practitioners at the time. However, it was felt that two-sided statistical tests should be used in order to detect possible changes in either direction (i.e. a reduction or an increase in incidences).

The Manual Removal of Placenta rate in the study hospital is approximately 3%. To detect a reduction in this rate to a level of 0.2% at a 5% level of statistical significance (2-tailed test) with a 90% chance of detecting the effect required 690 in each group (1380 in all).

Two sub-studies were also conducted to ascertain the possible effect of Ergometrine on serum prolactin levels and duration of breast-feeding. A third sub-study looked at women's perceptions of the third stage of labour and a fourth was conducted on the women excluded from the main study due to epidural analgesia, and compared 'active' management using Syntocinon 5 units i.v. with 'physiological' management. The findings of these sub-studies will be reported in the future.

1. No oxytocic drug to be given routinely.
2. Place a sterile receiver against the perineum to catch the blood lost. Try not to include liquor if possible.
3. Try to leave the cord attached to the baby until pulsation has ceased. When the cord is cut 'milk' any placental blood into a bowl and discard it.
4. Encourage the mother to breastfeed now, if she intends to use this method of feeding.
5. Watch for signs of placental separation and ask the woman to tell you if she feels a contraction or the urge to push. Please DO NOT touch the abdomen or manipulate the uterus at this stage.
6. When the woman feels a contraction or there are signs of separation, help her to sit, kneel or squat on the couch, (or raise the chair to an upright position) and encourage her to push. The placenta may be delivered by maternal effort or gentle controlled cord traction.
7. Deliver the placenta into a separate bowl, not the receiver.
8. If the mother does not experience a contraction within 8 minutes of delivery, place your hand gently on the fundus to detect intra-uterine bleeding, and await separation.
9. Measure blood loss. Please DO NOT add an estimate for any blood spilt—try to collect as much as possible and measure it.

Special circumstances in the physiological management. The baby's cord is clamped and cut before pulsation ceases (due to cord around neck, asphyxia etc.): do not give ergometrine. 'Milk' any placental blood into a bowl and discard it. Watch for signs of separation and deliver the placenta by controlled cord traction when they occur.

Retained placenta—one hour following delivery
- ensure bladder is empty
- attempt delivery again using controlled cord traction
- give Ergometrine 0.5 mg i.v. and reattempt delivery
- manual removal under general anaesthetic
- try to collect and measure all blood lost during this procedure.

Fig. 2 Instructions to midwives on: Physiological management of the third stage of labour

Inclusion criteria

Women attending a consultant privately were not included in the study because there were twelve consultants involved in their care and not all would agree to comply with the study requirements. 'Public' clients attend the public clinic, receive ante-natal care from a number of obstetricians and are attended at delivery by a midwife and a student with no doctor present. 'Semi-private' clients receive ante-natal care from one obstetrician of senior registrar level, and are attended at delivery by a midwife and a student with no doctor present. All the midwives were willing to co-operate with the protocol.

The charts of all women attending the ante-natal clinic of the Coombe Hospital were checked

weekly by the researcher, and an initial selection made under these criteria:

public or semi-private clients
singleton pregnancy
cephalic presentation
gestation now at 35–36 weeks
no medical complications which would contra-indicate the use of Ergometrine or increase the risk of bleeding (cardiac disease, use of Heparin, hypertension)

In addition, these women were classed as 'low-risk' to haemorrhage by the following criteria:

Thirty-five years old or under at time of booking; Mathie and Snodgrass (1967) found that the mean blood loss decreased up to 34 years old and from 35 years it rose slightly above the level for the younger age-groups.

Parity 5 or less; most studies agree that primigravidae or primiparous women have the highest PPH rate (Daley, 1951; Clarke & Douglas, 1962; Mathie & Snodgrass, 1967; Brinsden & Clarke, 1978; Hall et al, 1985), although others (Embrey et al, 1963; Nieminen and Jarvinen, 1964) disagree. Many factors are involved in this, not least the higher incidence of long labours, episiotomies, operative deliveries and greater use of analgesia among primiparous women in labour. Episiotomy has been shown to account for 130.5 to 253 ml of blood lost (Odell & Seski, 1947; Wallace, 1967). As women with operative deliveries, epidural anaesthesia, and first stage labours lasting longer than 15 hours were to be excluded from this study, it was felt that this might decrease many of the possible factors leading to increased haemorrhage in lower parity women. The present (declining) episiotomy rate of 34% among primiparous deliveries in the Coombe Hospital (Begley, 1987) appeared also to be appreciably lower than rates in other hospitals, countries, or in previous years (Friedman, 1957; Moir & Amoa, 1979; Buchan & Nicholls, 1980; Harrison et al, 1984).

No previous history of primary postpartum haemorrhage; Hall et al (1985) have shown that the risk of a recurrence of PPH is 3 times greater for women who have had one previously, than for those who have not.

Haemoglobin level of 11 gm or more (i.v. sample) or 10.6 or more (capillary sample); this test was taken within 8 weeks of the expected date of delivery. As the mean blood loss of women not receiving an oxytocic drug has been shown to be 305–344 ml (Daley, 1951; Clarke & Douglas, 1962; Vaughan Williams et al, 1974) it was essential that only women with a haemoglobin adequate to withstand this increased, but physiological, blood loss should be included.

All women fulfilling these criteria were deemed suitable for recruitment and an information leaflet was attached to the front of their charts. The study was discussed with each woman as she waited her turn in the clinic and when verbal consent to participate was given, the name was checked off and a numbered, sealed envelope containing the randomly allocated group was stapled to the woman's chart in readiness for admission.

Randomisation was carried out in batches of 100 to avoid any possible bias due to time of year, holiday rostering of staff, etc. The envelope remained sealed until the woman was in the second stage of labour and the midwife was certain a normal delivery would ensue. The envelope was then opened and the allocated treatment either 'active' management or 'physiological' management carried out.

Blood loss was measured as accurately as possible, with full realisation of the well-documented problems of clinical measuring and estimation (Brant, 1967; Wallace, 1967; Moir & Amoa, 1979).

Exclusion criteria

During the second stage of labour evidence of any of the following points allowed the midwives to exclude the subject from the trial:

Hypertension; defined as a blood pressure of 140/95 or greater, exclusion was necessary as this woman would not normally be given Ergometrine.

Epidural anaesthesia; again—this woman would not normally be given Ergometrine, hospital policy is to administer Syntocinon 5 units i.v.

Antepartum haemorrhage; antepartum haemorrhage, whether due to placenta previa (Pernoll, 1987) or abruptio placental (Sher, 1977), can lead to severe PPH.

Table 1
Reasons for exclusion from main study

Reason	N	%
Epidural analgesia	399	33
Forceps or vacuum delivery	354	29
Caesarean delivery	132	11
Rapid delivery	95	8
Hypertension	77	6
'Missed' (staff forgot)	53	4
Low haemoglobin	40	3
Woman's request	28	2
Misc. (resuscitation, twins, APH etc.)	23	2
Breech	20	2

First stage of labour in excess of 15 hours; Gilbert et al (1987) have shown that prolonged labour increases the risk of PPH.
Operative delivery; (forceps, vacuum, breech delivery, caesarean section) these women are also at increased risk of haemorrhage (Gilbert et al, 1987).

When a woman was excluded from the study, her envelope was returned, unopened, to the researcher. All returned envelopes were reallocated in numerical order prior to starting the next batch of 100 envelopes.

The study proposal was reviewed by the ethical committee of the study hospital and permission was granted for it to commence. A pilot study was conducted for a 3-week period in July 1987. Ninety-four women were included, 47 in the 'active' group and 47 in the 'physiological'. No changes were required following this.

The study commenced on 1 October 1987 and ended on 31 October 1988. Within this time 2901 women were deemed suitable for initial inclusion in the study, and 2650 agreed to take part, a response rate of 91%. One thousand two hundred and twenty-one of these women were excluded during labour (Table 1).

Data analysis

Throughout the study, proportions from independent samples which are normally distributed have been compared using a 'z' test (Bourke et al, 1985). A chi-square test was used when comparing more than two proportions (Bourke et al, 1985). A chi-square test with Yate's correction was used in one instance where the sample sizes were relatively small and Fisher's exact test (Bourke et al, 1985) was also used on one occasion with small sample sizes, to obtain a more precise estimation of probability.

The data on blood loss and length of the third stage were considerably skewed, as demonstrated by rankit plots and the Wilk-Shapiro statistic. Logarithmic transformation (Bourke et al, 1985) was carried out and the means compared by 't' test. Mean postnatal haemoglobin was normally distributed and a two-tailed two sample 't' test was used for comparison (Bourke et al, 1985).

Ninety-five per cent confidence intervals have been calculated for the outcomes of the study. These indicate the range within which we can be 95% certain that any future difference between the two treatments will lie.

FINDINGS

The study population numbered 1429 women, 705 in the 'active' management group and 724 in the 'physiological'. The two groups were comparable for age, parity, gestation, antenatal haemoglobin, baby's sex and birth weight, syntocinon infusion in labour, lengths of first and second stages of labour, use of birthing chair, episiotomy/tears requiring sutures, previous retained placentae and/or secondary PPH (Table 2). There was a difference found in the groups between the numbers who had pethidine in labour ($p<0.05$). The similarity of the two groups was assessed by using a 'z' test for comparison of proportions and a 't' test (Bourke et al, 1985) for comparison of means.

The 'active' management group were all given Ergometrine 0.5 mg i.v. following the birth of the baby and the placenta was delivered by controlled cord traction (93%) or, in a few instances (5%) by maternal effort. The posture chosen for the third stage was upright for 46 women (7%) and recumbent for 659 (93%). The umbilical cord was clamped and cut in the majority (89%) of cases (Table 3).

Those in the 'physiological' group were not to be given Ergometrine routinely but the midwife could administer the drug as a treatment. Ninety-nine women (14%) did receive Ergometrine, 6 of them (1%) before the placenta was delivered. The reasons given for administering

Table 2
Subject characteristics and possible effect modifiers

	Active N=705		Physiological N=724	
	Mean	(Range)	Mean	(Range)
Age (years)	26.95	(15–36)	27.03	(15–36)
			N.S. (t=0.37, p=0.7)	
Parity	1.48	(0–5)	1.41	(0–5)
			N.S. (t=1.01, p=0.3)	
Ante-natal hgb (gm)	11.70	(10.6–15)	11.63	(10.6–14.6)
			N.S. (t=1.78, p=0.07)	
Gestation (days)	283.80	(252–300)	283.50	(252–303)
			N.S. (t=0.58, p=0.6)	
Birthweight (gm)	3489.00	(2126–4990)	3476.00	(2155–5160)
			N.S. (t=0.50, p=0.6)	
Length 1st stage (mins)	211.40	(0–875)	215.30	(0–880)
			N.S. (t=0.50, p=0.6)	
Length 2nd stage (mins)	19.01	(1–153)	19.93	(1–130)
			N.S. (t=0.88, p=0.4)	
	N	%	N	%
Sex (male)	355	50	363	50
			N.S. (z=0.08, p=0.9)	
Syntocinon infusion	194	27	197	27
			N.S. (z=0.13, p=0.9)	
Pethidine	327	46	374	52
			Sig. (z=2, p<0.05)	
Birthing chair	19	3	16	2
			N.S. (z=0.6, p=0.6)	
Episiotomy/tear—sutured	144	20	144	20
			N.S. (z=0.25, p=0.8)	
Previous retained placenta	14	2	16	2
			N.S. (z=0.29, p=0.8)	
Previous secondary PPH	7	1	8	1
			N.S. (z=0.22, p=0.8)	

N.S. = No significant difference Sig. = Significant difference

the drug were either 'excessive blood loss' or 'relaxed uterus'. The placenta was delivered by maternal effort in 32% and by controlled cord traction in 66%. The upright posture suggested for use in this group was achieved by 80 women (11%). The cord was left unclamped until pulsation had ceased in 304 of the deliveries (42%) (Table 3).

Retained placenta

The outcome of the two types of management are shown in Table 4. Manual removal of the pla-

Table 3
Process variables

	Active N=705		Physiological N=724	
	N	%	N	%
Posture in third stage (lying)	659	93	644	89
Cord clamped at delivery	624	89	420	58
Cord left to pulsate	81	11	304	42
Placenta—controlled cord traction	653	93	479	66
Placenta—maternal effort	32	5	234	32
Ergometrine given following birth (before delivery of placenta)	705	100	6	1

Table 4
Outcomes in the two study groups

	Active N = 705				Physiological N = 724					
	Mean	SD	Range	Median	Mean	SD	Range	Median	Sig. level	95% Confid. interval
Blood loss (ml)	148.90	(127.10)	0.0–1000	100	234.80	(223–90)	0.0–1500	180	$p<0.00005$ ($t=7.85$)	—
Length: third stage (min)	11.26	(19.62)	1.0–225	7	11.56	(8.41)	1.0–105	10	$p<0.00005$ ($t=7.53$)	—
P/N Hgb (gm)	12.59	(1.13)	8.6–16.7	12.7	12.09	(1.23)	7.8–15.7	12.1	$p<0.00005$ ($t=7.47$)	0.38–0.62
	N	%			N	%				
Manual removal	19	3			1	0.1			$p<0.0005$ ($Z=4.12$)	0.01–0.04
PPH	14	2			60	8			$p<0.0005$ ($Z=5.37$)	0.04–0.09
P/N Hgb. <10 gm	8	1			27	4			$p<0.002$ ($Z=3.17$)	0.01–0.04
Atonic haemorrhage req. IV/IM Ergo.	14	2			93	13			$p<0.0005$ ($Z=7.89$)	0.08–0.14
B/P >95 mmHg	35	5			5	1			$p<0.0001$ ($Z=4.91$)	0.03–0.06
After-birth pains—IM analgesia	8	1			1	0.14			$p<0.02$ ($Z=2.39$)	0.002–0.018

centa was required by 19 women (3%) in the 'active' group and 1 woman (0.1%) in the 'physiological' group. This difference in rates was highly significant ($p<0.0005$). The one woman in the 'physiological' group who had a retained placenta actually had Ergometrine following delivery of the baby.

Postpartum haemorrhage occurred in 6 women (30%) requiring manual removal and a blood transfusion was necessary for 1 woman (5%). Five women (25%) required treatment for heavy, offensive lochia or bleeding within the 6-week period following delivery. The obstetricians performing the manual removals felt that blood loss was not, and could not be, accurately assessed during the procedure so that the given measurements are probably under-estimated.

A history of previous retained placenta was noted in 14 women in the 'active' group and 16 in the 'physiological'. Retained placenta recurred in 3 women (21%) in the 'active' group and none in the 'physiological'. The rate of retained placenta for primiparae in the 'active' group was 3% (4 out of 160) and 2% (12 out of 531) for parous women who had no previous history of retention. This difference between the rates for women with and without a previous history of this problem is significant (chi-square = 12.52, d.f. = 1, $p<0.0005$, using a chi-square test with Yate's correction). These findings support those of Hall et al (1985) who stated that the risk of repetition of the problem was 2.4 times the risk for those without a previous history of retained placenta.

Postpartum haemorrhage

Fourteen women (2%) in the 'active' group and 60 (8%) in the 'physiological' had a PPH, defined as a blood loss of greater than 500 ml. This difference was highly significant ($p<0.0005$). If this overall term 'postpartum haemorrhage' is further clarified by subdividing the women into groups according to amount of blood lost, a picture of the severity of the problem can be obtained. Thirty-five (58%) of the PPHs in the 'physiological' group and 12 (86%) of those in the 'active' group can be classed as 'mild' (501–750 ml). Fourteen (23%) in the 'physiological' group and 1 (7%) in the 'active' were in the 'moderate' PPH class (751–1000 ml), while 'severe' PPH (1001–1500 ml) occurred in 11 (18%) of the 'physiological' and 1 (7%) of the 'active' group. Two of the severe haemorrhages in the 'physiological' group occurred in women who had been given Ergometrine before the delivery of the placenta, one of whom subsequently required a manual removal of placenta and the other required an evacuation of retained products immediately after delivery.

The majority of PPHs in both groups are in the mild or moderate category, with a small proportion (11 women, (2%) of the 'physiological' deliveries and 1 woman (0.1%) of the 'active' deliveries) in the category of 'severe'. This difference is significant ($z=2.86$, $p<0.005$).

The postnatal haemoglobin levels for the three categories of PPH are interesting to note. Those who had a blood loss of 501–750 ml (48) had a mean haemoglobin of 11.24 gm (5 women did not have a postnatal haemoglobin sample taken), compared with means of 10.75 gm for those with a blood loss of 751–1000 ml (15), and 10.35 gm for those with a loss of 1001–1500 ml (12). A comparison of the haemoglobin levels in these three groups using one-way analysis of variance shows a significant difference in the distributions ($F=3.45$, d.f. = 2, 69, $p=0.05$). This demonstrates that mean postnatal haemoglobin is lowered in relation to mean blood loss at time of delivery, and supports the overall measurement of blood loss with an objective and unbiased test of haemoglobin.

Mean blood loss

The mean blood loss was 148.9 ml (S.D. 127.1) in the 'active' group and 234.8 ml (S.D. 223.9) in the 'physiological'. This was a highly significant difference, ($p<0.00005$) using a two-sample, two-tailed 't' test following logarithmic transformation of the data. This procedure was necessary as the data were positively skewed and normal statistical tests could not be carried out. In this situation the logarithmic values of the data are often normally distributed and inferential tests may then be applied (Bourke et al, 1985).

The effect of perineal trauma on mean blood loss was examined. In the 'physiological' group

the mean blood loss in primiparae following episiotomy, laceration and intact perineum was 269, 237 and 297 ml respectively. In the 'active' group the blood loss was 197, 169 and 185 ml respectively. No difference was found between these losses in either group. The multiparous women had mean blood losses of 296, 246 and 199 ml in the 'physiological' group and 174, 149 and 129 ml in the 'active' group, for episiotomy, laceration and intact perinea respectively. These differences were statistically significant (K–W = 16.05, d.f. = 2, 538, $p < 0.0005$ ('physiological') and (K–W = 7.43, d.f. = 2, 544, $p < 0.03$ ('active'), using Kruskal–Wallis analysis of variance technique (Hicks, 1988). This is a non-parametric statistical test using the chi-square distribution, and is necessary as the blood loss in the groups is not normally distributed.

Reducing the use of episiotomy when delivering multiparous women may help to reduce blood loss and lessen the chances of PPH.

Length of the third stage

The mean length of the third stage of labour in the 'active' group was 11.3 min (S.D. 19.6), and in the 'physiological' group was 11.6 min (SD 8.4). Following logarithmic transformation of the data the means show a highly significant difference ($p < 0.00005$).

The mean postnatal haemoglobin was 12.6 gm (SD 1.1) in the 'active' group and 12.09 gm (SD 1.23) in the 'physiological'. This difference was also highly significant ($p < 0.00005$). There were 8 postnatal haemoglobins less than 10 gm in the 'active' group and 27 in the 'physiological', giving incidences of 1% and 4% respectively. This difference in rates of anaemia was significant ($p < 0.002$).

Incidence of blood transfusion

Two women in the 'physiological' group required blood transfusion following delivery. One woman in the 'active' group, who had a manual removal of placenta required a transfusion. A second woman who was in the 'physiological' group but received active management and subsequently had an evacuation of retained products 4 hours after delivery also required a transfusion. Given the total number of transfusions in both groups, no possible division of transfusions between the groups would be significant at the 5% level.

Atonic haemorrhage or a 'relaxed uterus' requiring i.v. or i.m. Ergometrine occurred in 93 (13%) of the 'physiological' group and 14 (2%) of the 'active', a highly significant difference ($p < 0.0005$).

Side-effects of Ergometrine

The problems which have been described as side-effects of Ergometrine occurred more frequently in the 'active' group (Table 5). Hypertension (diastolic pressure of greater than 95 mmHg) was found in 35 (5%) of this group and 3 (9%) of those required drug treatment and observation for a 2–3 hour period in the labour ward. One woman in the 'active' group who had no previous hypertension either antenatally or in labour, had an eclamptic fit 4 hours after delivery. This is such a rare occurrence that no definite conclusions can be drawn but it is worth noting that another woman in the 'active' group of the pilot study also had an eclamptic fit post delivery. In the 'physiological' group 5 women (1%) had a diastolic blood pressure of greater than 95 mmHg, but none of them had a pressure greater than 100 mmHg or required drug treatment. This difference was significant ($p < 0.0001$).

After-birth pains requiring oral analgesia occurred more frequently in the 'active' group

Table 5
Problems in the first 1–2 hours post delivery in the two study groups

	Active N = 705		Physiological N = 724		Sig. level
	N	%	N	%	
After-birth pains:					
Oral analgesia	24	3	12	2	1
IM analgesia	8	1	1	0.14	2
Hypertension:					
B/P > 95 mmHg	26	4	5	1	3
B/P > 100 mmHg	9	1	0	0	4
Nausea	20	3	0	0	5
Vomiting	12	2	0	0	6
Headache	3	0.43	0	0	N.S.

N.S. = No significant difference
1 $z = 2.10$ ($p < 0.05$) 2 $z = 2.39$ ($p < 0.02$)
3 $z = 3.89$ ($p < 0.0005$) 4 $z = 3.07$ ($p < 0.005$)
5 $z = 4.57$ ($p < 0.0005$) 6 $z = 3.54$ ($p < 0.0005$)

Table 6
Bleeding-related problems in the first 5 days and first 6 weeks in the two study groups

	Active N=705		Physiological N=724		Sig. level
	N	%	N	%	
First 5 days					
Bleeding requiring—Ergometrine/Syntocinon	3	0.43	1	0.14	N.S.
Bleeding requiring ERPC, transfusion and anti-biotics	0	0	1	0.14	N.S.
Heavy/offensive lochia requiring anti-biotics/oral Ergometrine	11	2	4	1	N.S.*
First 6 weeks					
Attended OPD, bleeding—no treatment	6	1	1	0.14	N.S.**
Attended OPD, bleeding—anti-biotics	16	2	6	1	1
Admitted, bleeding—anti-biotics	5	1	0	0	2
Admitted, bleeding—ERPC	2	0.28	7	1	N.S.

N.S. = No significant difference
N.S.* $z=1.88$ ($p=0.06$) N.S.** $z=1.93$ ($p=0.54$)
1 $z=2.21$ ($p<0.05$) 2 $z=2.28$ ($p<0.05$)

and the incidence of women who required intramuscular analgesia for severe pain was higher in this group also ($p<0.02$) (Table 5). After-birth pain was defined as any pain complained of in the abdomen or back following delivery.

Nausea and vomiting also occurred with greater frequency in the 'active' management group. The incidence of these problems were taken from the data recorded by the midwives in each woman's computer record. It should be noted that some of the problems (e.g. nausea, headache) might not necessarily have been reported to the midwife, and vomiting may have occurred after the midwife had completed the recording of the delivery and the records may not have been subsequently altered. It was for this reason that a sub-study was carried out to ask women how they had felt following delivery, and the findings of this study will be reported in the future.

Problems related to bleeding in the first 5 days and first 6 weeks have been compared in Table 6, and generally show a higher incidence in the 'active' group. A total of 14 (2%) required treatment in the first 5 days for bleeding or heavy/offensive lochia compared with 6 (1%) of those in the 'physiological' group, a difference which does not reach statistical significance ($z=1.87$, $p=0.06$). In the first 6 weeks a total of 29 women (4%) from the 'active' group and 14 (2%) from the 'physiological' returned to the hospital, either as in- or out-patients, because of bleeding, a difference which is significant ($z=2.41$, $p<0.02$). Unfortunately, it was not possible to ascertain whether any women had attended their general practitioner with problems during this period, but the majority of women return to the hospital with problems and for their '6-week' check-up, rather than attend another doctor.

The other problems examined in the first 5 days are those which have been described as side-effects of Ergometrine, and are shown in Table 7. No statistically significant difference was found between the two groups, although it should be noted that in the 'physiological' group, the 3 women who had Ponston for after-birth pains and 2 of the women with leg cramps had had Ergometrine as a treatment.

Table 7
Problems in the first 5 days post-natal in the two study groups

	Active N=705		Physiological N=724		
	N	%	N	%	
Chest pain	5	1	1	0.14	N.S.
Leg cramps, oedema	14	2	6	1	N.S.*
Ponston for after-birth pains	1	0.14	3	0.41	N.S.

N.S. = No significant difference
N.S.* $z=1.87$, $p=0.06$

DISCUSSION

Sequelae of postpartum haemorrhage

Although postpartum haemorrhage has always been regarded as a serious complication the sequelae consequent upon PPH in this selected group of 'low-risk' women do not seem to be severe. The mean decrease in postnatal haemoglobin is the same (0.57 and 0.59 gm) in both groups, a decrease which appeared to be well tolerated by the majority of these women. Three (0.3%) women in the 'physiological' group required a blood transfusion (one had received Ergometrine before the placenta was delivered), compared with one in the 'active' (0.1%) group. It would appear that despite the increased incidence of PPH when physiological management is used, there is no significant increase in the need for blood transfusion.

None of the 60 women in the 'physiological' group who had PPH had any complications in the postnatal period whereas 4 of the 14 women from the 'active' group who had PPH (29%) went on to develop further problems, 3 within the first 5 days and 1 within the first 6 weeks. This difference in the rate of complications is highly significant ($p < 0.002$, using Fisher's exact test), with a 95% confidence interval of approximately 4.9% to 52.2%. This means that if 'active' management is used, we can be 95% confident that between approximately 4.9% and 52.2% more women will have complications following PPH than if 'physiological' management is used. A policy of physiological management of the third stage would certainly result in a higher incidence of PPH at the time of delivery, but the women do not appear to suffer any further consequences.

It would also appear from these findings that a PPH of between 501 and 750 ml does not, in fact, cause undue problems for normal healthy women with antenatal haemoglobin levels above 10.6 gm (capillary estimation). When one considers that the 500 ml of blood lost is equivalent to the amount withdrawn at a routine blood donation, and that expectant women are superbly prepared for blood loss by the haemodilution of pregnancy (Walters & Limm, 1975) it raises the question of whether the definition of PPH should be reviewed.

The postpartum haemorrhage rates for the 'physiological' group decreased considerably in the first four months, being at their highest in the pilot study (21%) and decreasing to a level of between 2% and 10% for the last eight and a half months. The difference in rates between the first four months (12%) and the last eight and a half months (7%) is significant ($z = 2.46$, $p < 0.02$). This would appear to indicate that the midwives who had not routinely used a physiological approach before needed a period of time to become accustomed to the new method. When routinely using Ergometrine and controlled cord traction, midwives become used to manipulating the uterus soon after delivery and exerting reasonably strong traction on the cord for delivery of the placenta. It requires practice and experience of physiological management to enable midwives to refrain from 'fundus-fiddling' and to develop the necessary patience and faith in the body's natural functions.

The mean loss of 234.8 ml in the 'physiological' group is considerably less than that found in other studies (Daley, 1951; Clarke & Douglas, 1962; Vaughan Williams et al, 1975; Sorbe, 1978), which reported levels of 344.1, 307.5, and 380 ml respectively. This may be due to the study population being truly 'at low risk' to haemorrhage, to changes in labour and delivery practice in the 1980s, such as active management of labour and reduced perineal trauma, or it may simply reflect difficulties in measuring blood loss.

Length of third stage

Using 'physiological' management the majority (93%) of third stages would end within 20 minutes and a prolonged third stage requiring manual removal of placenta would be a very rare occurrence. Should 'active' management be used routinely a slightly larger proportion (95%) of third stages would end within 20 minutes but approximately 3% of women would have a prolonged third stage requiring a manual removal of placenta with all the attendant factors which increase the workload of labour ward staff. Whether this difference in third stage lengths is clinically important or not is a matter for each

hospital or clinician to decide on the available evidence.

Postnatal haemoglobin

Haemoglobin levels have been found to be at their lowest level in pregnancy (mean 11.8 gm/100) at around 32 to 34 weeks, which is the time most of the antenatal samples were taken in this study, and rise to a mean of 12.4 gm/100 at term (Magee & Milligan, 1951). An increase over the immediate postpartum value occurs during the first 72 hours (Easterling & Herbert, 1975) and this rise in postnatal haemoglobin continues steadily for as long as a year postpartum (Magee & Milligan, 1951). Mean haemoglobin levels at 4 weeks post delivery were equivalent to the mean level at term (12.4 gm/100) and continued to rise to a level of 13.2 gm/100 at the 65th week. Lanzowsky (1960) has also shown that haemoglobin levels at 3 months postpartum are higher than the levels at term.

Thus women with haemoglobins of 7.8–9.9 gm/100 on the 2nd–3rd day should attain a level equal to their previous antenatal recording within the first 4 weeks. Iron supplementation will, of course, be necessary and will accelerate the rise of haemoglobin (Magee & Milligan, 1951. Women who have physiological management of the third stage will have a lower haemoglobin than those who receive Ergometrine routinely, but with iron supplementation their haemoglobin level should return to normal within the 6 week puerperal period.

The mean difference between antenatal and postnatal haemoglobin levels was an increase of 0.91 gm and 0.47 gm in the 'active' and 'physiological' groups respectively. Whether this result is of clinical importance or not is debatable. Blood viscosity has been shown to increase as haemoglobin increases (Hamilton, 1950) so that a high haemoglobin in the immediate postnatal period may predispose the woman to deep venous thrombosis.

Problems in the first 1 to 2 postnatal hours

Women in the 'active' group experienced higher rates of problems in the immediate postpartum period, with 8 women (1%) requiring i.m. Pethidine 50 mg for after-birth pains as opposed to one (0.1%) in the 'physiological' group, who actually had had Ergometrine as a treatment. Very few studies have considered this side-effect, one author merely noting uterine cramping as an effect of the drug without mentioning the degree of pain felt (Forman & Sullivan, 1952). Obviously a small minority of women feel the pain to be as severe as labour contractions if i.m. analgesia is warranted.

Hypertension, with a diastolic pressure of greater than 95 mmHg, was found in 26 (4%) of the 'active' group and 5 (1%) of the 'physiological' group, and a diastolic of greater than 100 mmHg also occurred in 9 (1%) of the 'active' group. These findings are in general agreement with those of other studies (Forman & Sullivan, 1952; Friedman, 1957; Hendricks & Brenner, 1970; Johnstone, 1972; Browning, 1974; Hacker & Biggs, 1979; Dommisse, 1980). Three women from the 'active' group required treatment for their hypertension in the form of Apresoline or Pethidine i.m., and remained under supervision in the labour ward for a further 1 to 2 hours post delivery.

Problems in the first 5 days and the first 6 weeks

The incidence of problems related to bleeding in the first five days was not significantly different between the two groups. This problem has not been adequately addressed in other studies although Martin and Dumoulin (1953) noted an increase in 'secondary PPH' in their 'Ergometrine' group which was also not statistically significant.

A higher incidence of complications in the first 6 weeks was shown in the 'active' group than in the 'physiological' with 4% and 2%, respectively, attending the hospital because of bleeding. The reason for this difference is debatable but it seems likely that a more aggressive type of management involving a stronger, drug-induced contraction and delivery by controlled cord traction may lead to the retention of small particles of placenta or membranes.

Conclusion

Routine administration of i.v. Ergometrine 0.5 mg following delivery is not necessary for women at 'low risk' to postpartum haemorrhage, and has many adverse effects. The main dis-

advantage of using physiological management is a greater mean blood loss and therefore an increase in the incidence of primary PPH and postpartum anaemia. The advantages of physiological management are a decrease in the incidence of manual removal of the placenta under general anaesthetic, a reduction in the incidence of secondary PPH and an absence of the unpleasant side-effects of Ergometrine.

Factors which may assist in decreasing blood loss at delivery (suckling at delivery, using an upright posture and maternal effort to deliver the placenta, leaving the cord to pulsate) should be examined in randomised trials comparing a 'totally physiological' management with one where oxytocics are not given but a more 'active' type of management is used.

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