

Active versus expectant management of the third stage of labour: the Hinchingsbrooke randomised control trial

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Articles

Active versus expectant management of third stage of labour: the Hinchingsbrooke randomised controlled trial

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Summary

Background This study tested the hypotheses that active management of the third stage of labour lowers the rates of primary postpartum haemorrhage (PPH) and longer-term consequences compared with expectant management, in a setting where both managements are commonly practised, and that this effect is not mediated by maternal posture.

Background 1512 women judged to be at low risk of PPH (blood loss >500 mL) were randomly assigned active management of the third stage (prophylactic oxytocic within 2 min of baby's birth, immediate cutting and clamping of the cord, delivery of placenta by controlled cord traction or maternal effort) or expectant management (no prophylactic oxytocic, no cord clamping until pulsation ceased, delivery of placenta by maternal effort). Women were also randomly assigned upright or supine posture. Analyses were by intention to treat.

Findings The rate of PPH was significantly lower with active than with expectant management (51 [6.8%] of 748 vs 126 [16.5%] of 764; relative risk 2.42 [95% CI 1.78–3.30], $p < 0.0001$). Posture had no effect on this risk (upright 92 [12%] of 755 vs supine 85 [11%] of 757). Objective measures of blood loss confirmed the results. There was more vomiting in the active group but no other important differences were detected.

Interpretation Active management of the third stage reduces the risk of PPH, whatever the woman's posture, even when midwives are familiar with both approaches. We recommend that clinical guidelines in hospital settings advocate active management (with oxytocin alone). However, decisions about individual care should take into account the weights placed by pregnant women and their caregivers on blood loss compared with an intervention-free third stage.

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See Commentary page

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Introduction

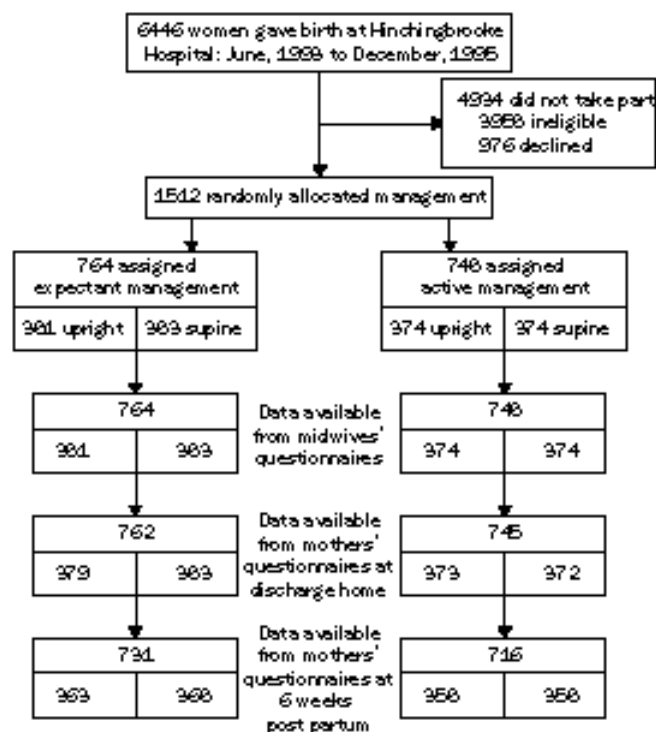
Delivery of the placenta and membranes (the third stage of labour) is potentially the most hazardous part of childbirth for the mother, mainly because of the risk of primary postpartum haemorrhage (PPH, defined as estimated maternal blood loss of 500 mL or more within 24 h of delivery) and its subsequent morbidity. This stage of labour can be managed actively or expectantly. Active management generally involves routine prophylactic administration of a uterotonic agent, early cord clamping and cutting, and controlled cord traction. In expectant management (sometimes called conservative or physiological management) uterotonic drugs are not given prophylactically, the cord is neither clamped nor cut early, and the placenta is expelled by maternal effort. An upright posture and early suckling have also been recommended.¹

A systematic review² of three controlled trials^{3–5} suggested that, compared with expectant management, active management of the third stage reduces the risk of PPH and the need for therapeutic uterotonics, particularly oxytocics. However, it also increases the risk of unpleasant and occasionally dangerous side-effects, such as nausea, vomiting, and hypertension, mainly due to the action of ergometrine used alone or in combination with oxytocin.

Three criticisms have been raised and have led to disagreements over the application of these results in routine practice. First, since a survey by Garcia and Garforth⁶ indicated that a policy of active management (with intramuscular Syntometrine [oxytocin plus ergometrine], Sandoz Pharmaceuticals, Camberley, UK) was almost universal throughout England and Wales, and since active management was the norm in hospitals involved in the three controlled trials, women assigned expectant management might have been at a disadvantage because midwives were less experienced in this approach.

Second, many women who choose expectant management of the third stage are encouraged to expel the placenta by adopting an upright posture. Thus, the differences in blood loss between active and expectant management could be due to position rather than other factors. In a trial comparing upright with recumbent position for the second stage of labour, Spiby⁷ found that the adoption of a maternal posture aiding gravity predisposed women to greater blood loss.

Third, the significance of PPH per se in a healthy population delivered in a hospital setting has also been questioned.⁸ Inch⁹ proposed that the hazards of expectant management in the short term may be outweighed by physical and psychological advantages for the mother in the months after childbirth.



Trial profile

We report here a randomised controlled trial that compared the effects of active and expectant management of the third stage of labour on maternal and neonatal morbidity and attempted to address these three issues. The trial was carried out in a setting where the philosophy of care was to place emphasis on helping women to give birth with minimum intervention, including during the third stage of labour. In this context midwives were similarly confident with active and expectant management for women at low risk of PPH. To take account of maternal posture, participants were simultaneously randomised to upright or supine position for the third stage of labour. Women were followed up at 6 weeks post partum.

Methods

The trial was carried out in the Maternity Unit of Hinchingbrooke Healthcare NHS Trust, a district general hospital in Cambridgeshire, UK, with an annual birth rate of about 2500. Approval was obtained from the local research ethics committee.

Before the trial began, an advisory group was established with membership from lay and professional representatives of the local maternity service. The principal investigators (JR and JW) wrote to all local midwives inviting them to participate; none declined. Midwives were then surveyed to report their own assessment of their confidence of using each method of third-stage management. The few who identified themselves as requiring further training in either method were assisted by experienced midwives who remained present until the completion of the third stage. Several meetings were held to prepare staff for their roles in the study.

Pregnant women were eligible to take part if they expected to deliver at Hinchingbrooke Hospital and were judged to be at low risk of haemorrhage. The criteria for exclusion were placenta praevia, previous PPH, antepartum haemorrhage after 20 weeks'

gestation, anaemia (haemoglobin <10 g/dL or mean corpuscular volume <75 fL), non-cephalic presentation, multiple pregnancy, intrauterine death, epidural anaesthesia, parity greater than five, uterine fibroid, oxytocin infusion, anticoagulation therapy, intended instrumental/operative delivery, duration of gestation less than 32 weeks, and any other circumstances judged by the clinician in charge to be overwhelming contraindications to any of the managements. Giving birth underwater did not exclude women from participating, although we emphasised that the mother would be expected to get out of the pool to deliver the placenta. Between 24 and 32 weeks of pregnancy women were invited to join the trial in a letter given to them by the community midwife. Written consent was obtained at a subsequent antenatal visit. Reasons for ineligibility or declining were recorded in the woman's notes. When women were admitted in established labour, eligibility and consent were confirmed by the attending midwife. Women who had not previously been invited or given consent were invited to join the study when admitted in labour if the midwife judged that this invitation was appropriate.

Random allocation was to one of four policies for the management of the third stage of labour (expectant management, upright posture; expectant management, supine posture; active management, upright posture; active management, supine posture). The randomisation schedule used variably sized balanced blocks, and the randomisation envelopes were prepared in advance in the National Perinatal Epidemiology Unit (NEPU). Allocation was by selection of the next sequentially numbered, opaque, sealed envelope stored on the ward, which included a card detailing one of the four policies. (Copies of the information given on the four cards are available from *The Lancet* and on the journal's website <http://www.thelancet.com>.) On admission to the labour ward, each eligible woman was given the next available envelope. Entry to the trial occurred only when an envelope was opened, which was when the midwife expected a normal delivery uncomplicated by any of the exclusion criteria. Unused envelopes were returned to the NEPU. Once the envelope was opened, the mother was included in the trial whether or not the policy indicated on the card was followed. The clinician was asked to carry out the randomly allocated management unless there were good reasons for deviation from these instructions.

Full active management was defined as the administration of a prophylactic uterotonic as soon as possible after delivery of the anterior shoulder (within 2 min of birth) followed by immediate clamping and cutting of the cord and delivery of the placenta by controlled cord traction or maternal effort. Full expectant management meant no use of uterotonic drugs, no clamping of the cord until pulsation had ceased, and delivery of the placenta within 1 h by maternal effort. If care was not as allocated, the midwife recorded the reasons for the deviation on the datasheet. The assessment of overall third-stage management was based on the combination of the midwives' responses to closed questions about particular components of management as recorded on the first datasheet.

The primary outcome for the trial was PPH (blood loss >500 mL, as estimated by the attending midwife) since this was deemed to be an important factor in decision-making about clinical management on the labour ward. Greater blood loss (≥ 1000 mL), need for blood transfusion, and need for iron tablets were also recorded. A more objective measure of blood loss was haemoglobin concentration 24–48 h post partum. The longer-term effects of postpartum blood loss, for example maternal fatigue and depression, were assessed by self-completed questionnaires at 6 weeks post partum. Other outcomes were side-effects such as nausea and vomiting, headache, and hypertension (diastolic >100 mm Hg or systolic >160 mm Hg); manual removal of placenta and evacuation of products of

Characteristic	Expectant (n=764)	Active (n=748)
Sociodemographic characteristics		
Mean (SD) maternal age at delivery (years)	28.5 (4.4)	28.7 (4.9)
Primiparous	280 (36.6%)	295 (39.4%)
Known history of depression	115 (15.1%)	114 (15.2%)
Rhesus negative	117 (15.3%)	117 (15.6%)
Expectation of good support at home*	760 (99.7%)	739 (99.2%)
Haematology		
Mean haemoglobin at 32 weeks (g/dL)*	11.1 (0.9)	11.1 (0.9)
MCV at 32 weeks (fL)*	88.9 (4.9)	88.9 (4.6)
Induction		
	158 (20.7%)	125 (16.7%)
Median (IQR) duration of labour (min)		
First stage	300 (195-450)	310 (190-460)
Second stage	20 (10-43)	21 (10-45)
Use of meptazinol/pethidine		
	275 (36.0%)	302 (40.4%)
Delivery		
Spontaneous vaginal	754 (98.7%)	746 (99.7%)
Upright position	230 (30.1%)	202 (27.0%)
In water	13 (1.7%)	11 (1.5%)
Perineal damage requiring sutures		
None	324 (42.4%)	311 (41.6%)
Sutured tear	351 (45.9%)	345 (46.1%)
Episiotomy	89 (11.6%)	92 (12.3%)
Initial confidence of midwife conducting delivery about active management†		
Very confident	519 (82.5%)	510 (87.2%)
Fairly confident	109 (17.3%)	73 (12.5%)
Not very confident	1 (0.2%)	2 (0.3%)
Not at all confident	0	0
Initial confidence of midwife conducting delivery about expectant management†		
Very confident	344 (54.7%)	344 (58.8%)
Fairly confident	202 (32.1%)	163 (27.9%)
Not very confident	57 (9.1%)	55 (9.4%)
Not at all confident	26 (4.1%)	23 (3.9%)
Baby		
Gestational age <37 weeks	15 (2.0%)	23 (3.1%)
Male	404 (52.9%)	382 (51.1%)
Mother intending to breastfeed	528 (69.1%)	512 (68.4%)

Data are number of women unless otherwise stated. MCV=mean corpuscular volume. *Data not available for all women: expectation of support at home n=762 expectant, 745 active; haemoglobin n=721, 704; MCV n=706, 690. †n=629 for expectant group, 585 for active group.

Table 1: Characteristics at entry to the trial

conception; neonatal outcomes; and the views of mothers and staff about third-stage management.

We could not conceal the treatment allocation because active and expectant management require different actions on the part of both midwife and mother. The technicians who did antenatal and postnatal blood tests were unaware of allocation.

Five questionnaires were used for data collection. These were piloted on a small sample of mothers and midwives before recruitment started. The first questionnaire, completed by the midwife present at the birth, gave details of labour and postnatal events before transfer to the postnatal ward. The second, completed by the midwife who discharged the mother home, outlined relevant events since delivery. Each mother answered a very brief questionnaire just before discharge home, describing her perceptions of the management of the third stage and her expectations of support at home. Additional information on antenatal characteristics and postnatal outcomes (including blood-test results) was collected from the casenotes by the principal investigators on a separate datasheet. 6 weeks after the birth, a questionnaire about the woman's physical and emotional wellbeing since the birth and a freepost envelope were sent to each participant. If there was no response after 3 weeks, a follow-up letter and duplicate questionnaire were sent. A final telephone reminder was given after a further 2 weeks. The Child Health Department contacted the principal investigators to notify them about infant deaths during the period of data collection, so that inappropriate follow-up could be avoided. In areas where the Edinburgh postnatal depression scale (EPDS)¹⁰ was routinely administered, these scores were collected from local health visitors for women participating in the trial.

Before the trial, the rate of PPH for women at low risk of this complication at Hinchingsbrooke Hospital was about 8%. The sample size was calculated accordingly. We postulated that active management would lower the PPH rate to 6% (under active management) from 10% (under expectant management). A sample size of about 2000 women would have a 90% chance of detecting this reduction at the 5% level of significance.

The principal investigators and research assistants entered the data. Disks and datasheets were transferred to the NPEU for second entry and comparison. Data analysis was carried out at the NPEU according to random allocation (ie, by intention-to-treat analysis). The primary comparison was between women randomly allocated expectant or active management. Two stratified analyses were also prespecified: by allocation to upright or supine maternal posture for the third stage; and by the initial confidence of individual midwives with expectant management, as ascertained from the pretrial survey. Statistical tests used include two-sided *t* tests and median tests for continuous data, and χ^2 tests for categorical data.

Results

Recruitment and randomisation for the trial began in June, 1993. After the trial had been under way for 15 months, an independent data-monitoring committee looked at the data from an interim analysis based on the 700 women randomised by June, 1994. There was no significant difference between the two trial groups but the overall PPH rate was higher than expected. The power calculations were revised accordingly, suggesting that a sample size of about 1500 women would be sufficient.

The trial finished in December, 1995. During the recruitment phase, 6446 women gave birth at Hinchingsbrooke Hospital. Of these, 1512 (23.5%) entered the trial, the remainder (4934) being ineligible or declining to participate (figure). Most of the 976 women who refused to take part did so because they wanted to specify a particular form of management; 385 requested active and 504 expectant management. The primary reasons for exclusion in the other women were: placenta praevia in 14, previous PPH in 160, antepartum haemorrhage after 20 weeks' gestation in 135, anaemia in 243, non-cephalic presentation in 119, multiple pregnancy in 90, intrauterine death in 12, epidural anaesthesia in 463, parity above five in 50, uterine fibroid in 12, oxytocin infusion for induction or augmentation of labour in 519, anticoagulant therapy in 9, intended instrumental/operative delivery in 854, gestation less than 32 weeks in 43, request of staff (including rare obstetric and medical problems) in 96, request of general practitioner in 57, language difficulties in 19, error in 66, too far advanced in labour in 470, other reasons in 6, and no reason specified in 521.

Among the 1512 women randomised into the trial, there was a high return rate for datasheets in both study groups (figure).

The groups generated by random allocation were similar at entry to the trial (table 1). 92 (60%) of the 153 midwives surveyed at the start of the trial completed a questionnaire. Of these, 84% felt very confident about active management, 15% felt fairly confident, and only one midwife felt not very confident. By contrast, 41% felt very confident about expectant management, 37% felt fairly confident, and 22% felt not very or not at all confident. The number of deliveries each midwife conducted in the trial ranged from 0 to 38. 113 midwives were responsible for the 764 women allocated expectant management, and 114 midwives were responsible for the

	Expectant (n=764)	Active (n=748)
Prophylactic oxytocic given <2 min after birth of baby		
Oxytocin	5 (0.7%)	146 (19.5%)
Oxytocin plus ergometrine	14 (1.8%)	561 (75.0%)
Total	19 (2.5%)	707 (94.5%)
Cord clamping		
Median (IQR) time between birth and cord clamping (min)	9 (1-15)	1 (1-1)
Clamping before placental delivery	556 (72.8%)	748 (100%)
Clamping and cutting before pulsation stopped	226 (29.6%)	699 (93.4%)
Controlled cord traction		
Within 2 min of birth	13 (1.7%)	59 (7.9%)
At any time	92 (12.0%)	347 (46.4%)
Baby put to breast		
Within 10 min of birth	61 (8.0%)	13 (1.7%)
10-120 min after birth	436 (57.1%)	474 (63.4%)
Posture		
Upright initially and when placenta delivered	269 (35.2%)	249 (33.3%)
Upright initially but not when placenta delivered	124 (16.2%)	41 (5.5%)
Not upright initially but upright when placenta delivered	56 (7.3%)	81 (10.8%)
Not upright initially or when placenta delivered	314 (41.1%)	377 (50.4%)
Not known	1 (0.1%)	0
Insertion of urinary catheter during third stage		
	39 (5.1%)	26 (3.5%)
Actual management		
Fully active*	19 (2.5%)	699 (93.4%)
Fully expectant†	488 (63.9%)	2 (0.3%)
Mixture	257 (33.6%)	47 (6.2%)
Primary reason why allocated management was not fully achieved		
Became ineligible after envelope opened	15	1
Instructions followed but oxytocic given after 1 h	16	..
Therapeutic oxytocic because of bleeding	38	0
Mother's or midwives' request or mother's tiredness or distress	34	11
Baby's health	115	9
Other	17	8
No reason given	41	20

*Administration of prophylactic oxytocic <2 min after birth of baby; immediate clamping and cutting of cord; and delivery of placenta by controlled cord traction or maternal effort.

†No oxytocic drug given in third stage of labour; no clamping of cord until pulsation ceased; delivery of placenta within 1 h by maternal effort.

Table 2: **Third-stage management**

748 women allocated active management. 66% of these midwives (attending 629 and 585 women in the expectant and active groups, respectively) had completed a survey questionnaire. Information about their initial level of confidence with the two managements is shown in table 1.

Reported compliance with the randomly allocated managements was high (table 2). 94.5% of women in the active-management group received a prophylactic uterotonic, 93.4% had the cord clamped before pulsation ceased, and 46.4% had controlled cord traction at some time; the corresponding proportions in the expectant-management group were 2.5%, 29.6%, and 12.0% (table 2). More babies in the expectant-management group breastfed within 10 min of birth, and 65.1% of women in both groups had suckled the baby within 2 h. 35.2% of the expectant-management group and 33.3% of the active-management group adopted an upright posture throughout the third stage, but a larger proportion of the expectant-management group were upright for at least part of the third stage.

Overall, 93.4% of women in the active-management group received full active management of the third-stage compared with 2.5% in the expectant-management group. 63.9% of women in the expectant-management

	Expectant (n=764)	Active (n=748)
Blood loss on labour ward		
<500 mL	638 (83.5%)	697 (93.2%)
500-999 mL	106 (13.9%)	38 (5.1%)
≥1000 mL	20 (2.6%)	13 (1.7%)
Estimated mean (SE) blood loss on labour ward (mL)	336.5 (8.8)	268.5 (9.0)
Therapeutic oxytocic (≥2 min after birth of baby)		
	161 (21.1%)	24 (3.2%)
Duration of third stage		
Median (IQR) in min	15 (10-25)	8 (5.3-11.0)
>30 min	125 (16.4%)	25 (3.3%)
Manual removal of placenta		
Total	13 (1.7%)	15 (2.0%)
Trapped	7 (0.9%)	8 (1.1%)
Blood pressure		
Systolic >160 mm Hg	3 (0.4%)	8 (1.1%)
Diastolic >100 mm Hg	1 (0.1%)	6 (0.8%)
Side-effects		
Nausea	45 (5.9%)	86 (11.5%)
Vomiting	17 (2.2%)	47 (6.3%)
Headache	3 (0.4%)	5 (0.7%)
Women's perceptions*		
Satisfied with third-stage management	718 (94.2%)	721 (96.8%)
Felt in control during third stage	667 (87.5%)	621 (83.4%)
Mean (SE) postnatal stay (days)	2.1 (0.1)	2.0 (0.7)
Haemoglobin on second postpartum day		
Mean (SE) in g/dL*	10.7 (0.05)	11.2 (0.04)
Mean (SE) change from 32 weeks' gestation*	-0.4 (0.06)	0.9 (0.05)
≤10 g/dL*	204 (28.4%)	107 (15.2%)
Bleeding		
Blood transfusion on labour/postnatal ward	20 (2.6%)	4 (0.5%)
Antibiotics before discharge	7 (0.9%)	9 (1.2%)
Bleeding problems reported after discharge	145 (19.8%)	125 (17.5%)
Readmitted for bleeding problems	5 (0.7%)	12 (1.7%)
Antibiotics for bleeding, discharge to 6 wk	36 (4.9%)	39 (5.4%)
Mean (SE) duration of postnatal bleeding (days)*	23.5 (0.4)	23.8 (0.4)
Evacuation of retained products of conception	6 (0.8%)	9 (1.2%)
Iron tablets, delivery to 6 weeks*	205 (28.0%)	121 (16.9%)
General health at 6 weeks post partum*		
Worse than prepregnancy	66 (9.0%)	64 (8.9%)
Exhausted since birth	175 (23.9%)	163 (22.8%)
Exhausted at 6 weeks	113 (15.5%)	105 (14.7%)
Blues	343 (46.9%)	313 (43.7%)
Depressed	46 (6.3%)	55 (7.7%)
Help for depression	104 (14.2%)	107 (14.9%)
Admission to hospital for depression	0	1 (0.1%)
No health problems as reported at 6 weeks*	566 (77.4%)	529 (73.9%)

*Data not available for all women; women's perceptions n=762 expectant, 745 active; haemoglobin on second day n=718, 702; change in haemoglobin n=677, 659; duration of postnatal bleeding n=726, 712; health at 6 weeks post partum n=731, 716.

Table 3: **Primary and secondary maternal outcomes**

group and 0.3% in the active-management group had fully expectant management, and a further 33.6% had a mixture of both types of management. The commonest reasons why fully expectant management was not achieved were the need for neonatal resuscitation and heavy bleeding.

The overall rate of the primary outcome—PPH—was 11.7% (table 3), 126 (16.5%) in the expectant-management group and 51 (6.8%) in the active-management group (relative risk 2.42 [95% CI 1.78-3.30]; p<0.0001). The rate of more serious estimated blood loss (≥1000 mL) was also greater in the expectant-management group but this difference did not reach statistical significance (p=0.32). The increased risk was reflected in the other measures of blood loss such as postnatal haemoglobin below 10 g/dL (relative risk 1.86

	Expectant (n=764)	Active (n=748)
Mean (SE) birthweight	3521 (17)	3454 (17)
Infant's health		
Phototherapy for jaundice*	25 (3.4%)	32 (4.5%)
Admission to SCBU	20 (2.6%)	20 (2.7%)
No problems reported*	329 (45.0%)	312 (43.6%)
Breastfeeding at discharge		
Fully	531 (69.5%)	546 (73.0%)
Partially	11 (1.4%)	8 (1.1%)
Breastfed at 6 weeks		
Fully	272 (37.2%)	265 (37.0%)
Partially	120 (16.4%)	142 (19.8%)

SCBU=special-care baby unit.

*As reported by mother; n=731 expectant, 716 active.

Table 4: Neonatal outcomes

[1.51–2.30], $p<0.0001$), blood transfusions (4.9 [1.68–14.25], $p=0.0024$), and use of iron tablets (1.66 [1.36–2.03], $p<0.0001$). Other risks of expectant management were increased use of therapeutic uterotonics (6.25 [4.33–9.96], $p<0.0001$) and a greater likelihood of a third stage longer than 30 min (4.90 [3.22–7.43], $p<0.0001$). Expectant management reduced the incidence of nausea (0.51 [0.36–0.72], $p=0.0002$) and vomiting (0.35 [0.21–0.61], $p=0.0002$). The effect on hypertension was not significant.

Apart from a slightly higher mean birthweight of babies in the expectant-management than in the active-management group, there was no evidence of any other differential effects of the two policies on maternal or neonatal outcomes either in the short term or at 6 weeks after the birth (tables 3 and 4).

In response to open-ended questions at 6 weeks post partum, 116 women commented specifically (either positively or negatively) on the third stage. Of these, 75% had been assigned expectant management.

A small sample of women (n=210) was assessed by means of the Edinburgh postnatal depression scale.¹⁰ The proportion who assessed themselves as depressed was similar to that in the whole population (6 vs 7%). 7% had a score of 13 or more (depressed) on the scale (9% expectant management, 5% active management; $p=0.33$).

Two prestated stratified analyses were done. The first factor was random allocation to upright or to supine posture for the third stage of labour. 67% of women assigned upright posture actually achieved this posture during the third stage (irrespective of expectant or active management). Of the women allocated supine management, more in the active-management than in the expectant-management group were supine for the third stage (88.5 vs 72.6%). Overall, there was no evidence to support the hypothesis that upright posture causes significantly more PPH than supine posture in the third stage (table 5, 12 vs 11%). Irrespective of posture, expectant management resulted in a higher PPH rate (and longer duration of the third stage, data not shown),

	Expectant	Active	Relative risk (95% CI)
Randomly allocated posture			
Upright	59/381 (15.5%)	33/374 (8.8%)	1.76 (1.17–8.30)
Supine	67/383 (17.5%)	18/374 (4.8%)	3.36 (2.20–6.00)
Midwives' initial confidence with expectant management			
Very/fairly	86/546 (15.8%)	33/507 (6.5%)	2.42 (1.65–3.55)
Not very/not at all	16/83 (19.3%)	6/78 (7.7%)	2.51 (1.03–6.08)

Table 5: PPH by randomly allocated active or expectant management: stratified analysis

than did active management, and the differences were more pronounced in the supine group (χ^2 heterogeneity test $p=0.025$).

The second prestated stratified analysis was based on the initial confidence of the midwives with expectant management. Full compliance with the allocated third-stage management was similar irrespective of this confidence (data not shown). Although the rate of PPH was slightly higher among women attended by midwives who were initially less confident with expectant management (14 vs 11%), the relative risk of PPH with expectant rather than active management was 2.4 irrespective of this initial confidence (χ^2 heterogeneity test, $p=0.94$).

Discussion

Our findings are consistent with those of previous studies. Compared with expectant management, active management of the third stage of labour reduced the risk of PPH. The relative risk associated with expectant management (2.4) can also be expressed in terms of the need to treat ten women with active management to prevent one PPH. This trial shows in addition that this effect occurs even when expectant management is carried out by midwives already accustomed to this technique. In addition, the trial provided data to answer two other important questions: it showed that the effect on PPH is not due to the upright maternal posture often associated with an expectant-management policy, and it showed no evidence that the differential effects were evident beyond the short term.

The definitions of active and expectant managements we used were based on those used in the previous trials, as well as practice in Hinchingsbrooke Hospital. On this basis, the uterotonic for use in active management was oxytocin plus ergometrine. A recent overview¹¹ showed that this combination is associated with a slightly, but significantly, lower rate of PPH than oxytocin alone. The overview concluded that the choice between these two uterotonics depends on the relative weight placed on this reduction and the substantial increase in nausea and vomiting associated with the ergometrine component. In countries with a higher background prevalence of hypertensive disorders, the vasoconstrictive properties of ergometrine may be of greater clinical relevance. Both uterotonics must be given intramuscularly or intravenously. This requirement may have disadvantages in countries that lack sufficient health-care resources and where the general health of women is poorer. An oral alternative, misoprostol, a synthetic prostaglandin, is being evaluated by WHO. Meanwhile, oxytocin alone seems to be the drug of choice for active management.

Upright maternal posture was a part of the expectant-management policies in previous trials; in our trial, posture was included as a component of the randomisation. We found no evidence that upright posture leads to more PPH. The rate was lower in the actively managed supine group (table 5), perhaps because of another component of active management—controlled cord traction. In previous trials, controlled cord traction was an integral part of the active-management policy, but this approach is controversial.^{12,13} In Hinchingsbrooke Hospital, most midwives await signs of separation of the placenta before using either controlled cord traction or maternal effort, so this practice was incorporated into the

active-management policy for the trial. Use of controlled cord traction within 2 min of birth (2%) was rare in all the groups except that allocated active management and supine position (13%), in which an option to use controlled cord traction was explicitly part of the policy.

Nearly all the women allocated active management received it fully. 36% of the group allocated expectant management did not receive it fully because of such circumstances as the need for early neonatal resuscitation, as stated in the protocol. Nevertheless, 64% did achieve full expectant management. The high proportion probably reflects the greater familiarity with expectant management among the Hinchingsbrooke midwives than in previous trials.^{2,14} Although outcomes were slightly better for women attended by midwives who were initially more confident in this management, women were not allocated randomly to midwives as defined by their degree of confidence, so we cannot exclude the possibility of selection effects. Stratified analysis of the data did not support greater confidence as an explanation for the benefits of active management seen elsewhere. From this trial, it is difficult to assess the part played by midwives' confidence because the degree of confidence was high, and the small number of midwives who felt less confident were accompanied by a more confident colleague. However, the form of management (active or expectant) seems to have more influence on outcome than the confidence of the midwife in her practice. Based on actual (rather than intention-to-treat) management, the PPH rate was lowest in the fully active group (8%), and was 11% in the group that achieved a fully expectant placental delivery (data not shown). The highest rate (21%) was in the mixed management group; change of management (from expectant to active) was associated in many cases with complications such as heavy bleeding. We cannot say from these data whether active management should be fully instigated once expectant management has "failed"; this question merits further investigation.

PPH was defined on a clinical estimation of blood loss, an imperfect measure of the actual amount of blood lost, but the basis on which clinical decisions are usually made. However, the results are supported by the more objective measurements—haemoglobin, need for iron tablets within 6 weeks of delivery, and need for blood transfusion within 48 h of delivery. Although women were about five times more likely to receive a blood transfusion if they were allocated expectant management, 48 women would need to receive active management to prevent one transfusion. Of women who had a PPH, a greater proportion in the expectant-management than in the active-management group (14 *vs* 8%) received a transfusion. This difference may be due to chance, a difference in the proportion meeting the transfusion criteria (clinical impression of pronounced anaemia or haemoglobin <8.0 g/dL within 48 h of delivery), or the unmasked nature of the interventions.

Concern that active management increases the likelihood of placental entrapment are not supported by our data.

Apart from the difference in the number of women prescribed or taking iron tablets, the postnatal progress (including the mean hospital stay) was similar for both groups of women after discharge from hospital. The mean duration of postnatal bleeding in the first 6 weeks was identical in the two groups.

About 7% of the women assessed themselves as depressed 6 weeks after the birth (6% in the expectant-management group, 8% in the active-management group). In the opportunistic sample taken from all postnatal women in areas where the Edinburgh postnatal depression scale was used routinely, similar proportions were depressed.

The only difference in neonatal outcomes was a higher mean birthweight of babies in the expectant-management group, which is probably due to the extra blood received before late cord clamping. This process might affect the iron status in the developing child.¹⁵ We plan to follow up these children in a future study.¹⁶

Our findings challenge practitioners to face two main issues. First, the need to give balanced information to women during the antenatal period, in line with the Department of Health's strategy for supporting informed choice.¹⁷ Second, to develop and maintain competence in both forms of practice.

The conclusions of the study may be used to enable individual women, together with their caregivers, to weigh up the relative importance of the various outcomes. However, the advantages and disadvantages of both managements will not be uniformly interpreted by clinicians or childbearing women. Some women, for example, may rate a small personal risk of PPH of little importance compared with intervention in an otherwise straightforward labour, whereas others may wish to take all measures to reduce the risk of PPH. Tolerance of blood loss varies widely, but more easily measurable outcomes—such as the risk of needing a blood transfusion or of vomiting after delivery—are likely to assist in decision-making.

Midwives need to be competent and confident in both approaches. Midwives practise in a variety of settings, and sometimes facilities for active management are not available. 976 women eligible for this trial declined to take part—of these, 504 made a specific request to have expectant management. When active management of the third stage is the far more commonly taught and practised method, women may be constrained in their choice because the staff are not conversant with expectant management. We suggest that practitioners confident in expectant management should be valued and used as teachers of this method. We also recommend that the principles of expectant management should form part of the initial education of midwives, as they are for other uncommonly encountered events in maternity care, such as shoulder dystocia. We also suggest that the emphasis should be on recognising insidious and subtle deviations from the normal, particularly with respect to identifying the early signs of compromise in maternal or fetal wellbeing, the expected length of third stage, the acceptable range of estimated blood loss, and watching for signs of separation before taking specific action.

Decisions about individual care should take into account the weights placed by pregnant women and their caregivers on PPH and blood transfusion compared with an intervention-free third stage. However, we recommend that clinical guidelines advocate the use of active management (with oxytocin alone) in similar hospital settings. Forthcoming data from a trial carried out in a primary-care setting in the Netherlands (K Herschderfer, personal communication) will broaden understanding of the relative implications of the two policies in industrialised countries. The next challenge is a trial of

expectant versus active management (perhaps with oral misoprostol) in a poorer country, where expectant management is the norm and the consequences of blood loss may lead to more serious maternal morbidity or even mortality.

Contributors

Juliet Wood and Jane Rogers are midwives in clinical practice and instigated the research and, with Diana Elbourne, obtained funding. All six investigators contributed to the design of the study and to the procedures for data collection and analysis. Sarah Ayers set up the randomisation programme and was responsible for all computing aspects of the trial. Diana Elbourne was responsible for statistical aspects. Juliet Wood and Jane Rogers were responsible for organising the practical outworking of the study during the training, recruitment, and data-collection phase. All six investigators contributed to the writing of the paper.

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