

Effect of a collector bag for measurement of postpartum blood loss after vaginal delivery: cluster randomised trial in 13 European countries

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ABSTRACT

Objective To evaluate the effectiveness of the systematic use of a transparent plastic collector bag to measure postpartum blood loss after vaginal delivery in reducing the incidence of severe postpartum haemorrhage.

Design Cluster randomised trial.

Setting 13 European countries.

Participants 78 maternity units and 25 381 women who had a vaginal delivery.

Interventions Maternity units were randomly assigned to systematic use of a collector bag (intervention group) or to continue to visually assess postpartum blood loss after vaginal delivery (control group).

Main outcome measures The primary outcome was the incidence of severe postpartum haemorrhage in vaginal deliveries, defined as a composite of one or more of blood transfusion, intravenous plasma expansion, arterial embolisation, surgical procedure, admission to an intensive care unit, treatment with recombinant factor VII, and death.

Results Severe postpartum haemorrhage occurred in 189 of 11 037 of vaginal deliveries (1.71%) in the intervention group compared with 295 of 14 344 in the control group (2.06%). The difference was not statistically significant either in individual level analysis (adjusted odds ratio 0.82, 95% confidence interval 0.26 to 2.53) or in cluster level analysis (difference in weighted mean rate adjusted for baseline rate 0.16%, 95% confidence interval -0.69% to 1.02%).

Conclusion Compared with visual estimation of postpartum blood loss the use of a collector bag after vaginal delivery did not reduce the rate of severe postpartum haemorrhage.

Trial registration Current Controlled Trials
ISRCTN66197422.

INTRODUCTION

Worldwide, postpartum haemorrhage remains one of the leading causes of maternal mortality¹ and the main component of severe morbidity,²⁻⁵ jeopardising women's fertility, exposing them to risks of transfusion and intensive care, and incurring costs. From reports in

developed countries, about 1% of deliveries are associated with severe postpartum haemorrhage.³⁻⁶

Decreasing the prevalence of severe postpartum haemorrhage remains a challenge. This seems all the more important given the recent increase in the incidence of postpartum haemorrhage reported in several developed countries.^{2,7,8} Individual risk factors have been described but they poorly predict the occurrence of postpartum haemorrhage.^{9,10} Interest has focused on care processes, as they are potentially amenable to change. Studies of maternal deaths show that most deaths due to postpartum haemorrhage involve delayed and substandard care in the diagnosis and management of blood loss.¹¹⁻¹³ Similar findings were drawn from a population based study of severe non-lethal postpartum haemorrhage.¹⁴

Delay in the diagnosis and treatment of postpartum haemorrhage may result from an underestimation of blood loss at delivery. Assessment of postpartum blood loss, particularly after vaginal birth, is recognised as difficult. Many studies found that visual estimates of peripartum blood loss are often inaccurate,¹⁵⁻²¹ showing an overestimation of blood loss at low volumes and an underestimation at larger volumes, the magnitude of underestimation typically increasing with the volume of haemorrhage.

We hypothesised that if blood loss is monitored and objectively measured by collection in a transparent plastic bag rather than by visual assessment, the response of a care giver will be triggered more rapidly when excessive blood loss occurs. Specifically, when bleeding is excessive but before haemorrhage has become catastrophic, appropriate management will take place without delay, so reducing the incidence of severe postpartum haemorrhage. A preliminary study has shown that a plastic collector bag constitutes a simple instrument for diagnosing haemorrhage in the delivery room.²² The impact of its use on health outcomes related to postpartum haemorrhage has, however, never been tested. Despite lacking evidence, the bag is routinely used in many maternity units in Belgium, France, Italy, and Portugal (European Union

Table 1 | Number of maternity units and women in baseline and trial periods by allocation and by country*

Country	Maternity units		Women						
	Intervention	Control	Total No (%)	Baseline period			Trial period		
				Total	Intervention	Control	Total	Intervention	Control
Austria	3	3	1067 (3.0)	371	219	152	696	359	337
Belgium	8	8	6013 (17.1)	1552	728	824	4461	1867	2594
Denmark	3	3	1657 (4.7)	507	272	235	1150	562	588
Finland	2	2	4805 (13.7)	1347	656	691	3458	1551	1907
France	3	3	3702 (10.6)	972	544	428	2730	1351	1379
Hungary	4	4	2230 (6.4)	562	268	294	1668	784	884
Ireland	2	2	3971 (11.3)	950	300	650	3021	946	2075
Italy	3	3	926 (2.6)	196	138	58	730	491	239
Netherlands	1	1	1084 (3.1)	301	130	171	783	322	461
Norway	1	1	668 (1.9)	143	72	71	525	241	284
Portugal	2	3	3274 (9.3)	810	338	472	2464	901	1563
Spain	4	3	4351 (12.4)	1595	1097	498	2756	1239	1517
Switzerland	3	3	1328 (3.8)	389	175	214	939	423	516
Total	39	39	35 076 (100)	9695	4937	4758	25 381	11 037	14 344

*Baseline data were unavailable in one maternity unit in intervention group.

Project of Obstetric Haemorrhage Reduction: Attitude, Trial and Early Warning System (EUPHRATES) survey,²³ unpublished data).

We evaluated the effectiveness of systematic use of a transparent plastic collector bag to measure postpartum blood loss after vaginal delivery in reducing the incidence of severe postpartum haemorrhage.

METHODS

We used a cluster randomised design with maternity unit as the unit of randomisation. Given the logistics of clinical practice on the delivery suite, contamination seemed to be inevitable in an individual patient randomised trial setting. The sites we selected for the trial comprised 78 maternity units in 13 European countries (table 1). Maternity units were eligible if they had more than 200 vaginal deliveries annually (excluding water births) and no previous policy for routine use of collector bags. In addition, to ensure that the standard of care for management of the third stage of labour was similar across all participating units, the units had to comply with the EUPHRATES consensus statement on the prevention and management of postpartum haemorrhage,²⁴ a minimum standard, not a detailed guideline.

In all maternity units of participating countries except Denmark, we included all women undergoing a vaginal delivery during the study period. In Denmark, enrolment into the study in each maternity unit depended on the midwife; if a midwife agreed to participate, we included all of the vaginal deliveries that she or he took care of in their maternity unit.

The random allocation was produced centrally by the National Perinatal Epidemiology Unit, Oxford. A stratified design was used to ensure that the two arms of the trial were as similar as possible at baseline for the stratification factors of country and size of maternity unit (median split within country). The maternity units were randomly allocated to either systematic

use of a collector bag after vaginal delivery (intervention arm) or no use of the bag (control group).

Intervention

The trial was implemented between January 2006 and May 2007, depending on the country. Before participation, each centre was visited by the national coordinator. At the visit, staff were reminded of the EUPHRATES consensus statement on the prevention and management of postpartum haemorrhage and familiarised with the processes and the data collection instrument.

A second visit from the national coordinator took place in the intervention group after randomisation, when use of the collector bag was explained to birth attendants with the aid of standard written instructions and a training video. The bag was to be placed under the mother's pelvis as soon as the baby was born and before delivery of the placenta. The bag was transparent and graduated, allowing continuous monitoring of blood loss. It did not require sterilisation and could be used in the dorsal, lateral, or lithotomy positions. Women delivering standing or crouching could be offered the opportunity to lie down for the third stage, allowing the bag to be placed under their pelvis. The bag was to be left in situ until the birth attendant was no longer concerned about blood loss, such as when a sanitary towel was applied to the vulva. Bags were purchased centrally and provided to each cluster in the intervention arm.

No collector bag was used in the control group, with postpartum blood loss being assessed visually. The control group was monitored during the study period to assess compliance with allocation.

Outcomes

The primary outcome was the incidence of severe postpartum haemorrhage after vaginal deliveries, defined as a composite of all women who experienced one or

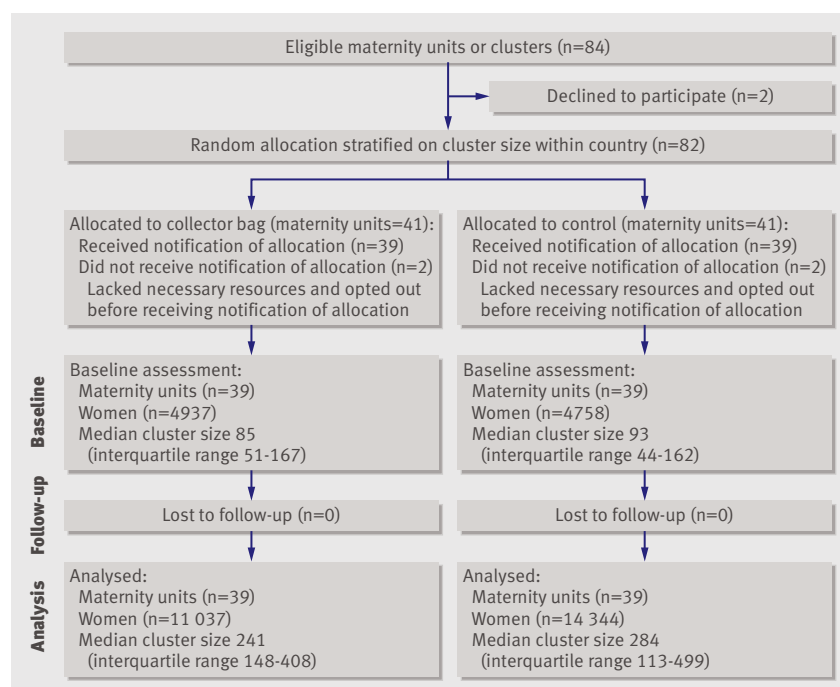


Fig 1 | Flow diagram of trial

more of blood transfusion, intravenous plasma expansion, arterial embolisation, surgical procedure, admission to an intensive care unit, treatment with recombinant factor VII, and death. Secondary outcomes were each of the components of the primary outcome, manual removal of the placenta, and administration of prostaglandins after delivery.

Data collection

Each participating centre was asked to collect data for four months from all women who had had a vaginal delivery: for one month before randomisation (baseline period) and for three months after randomisation in the control group (trial period). The three month period of data collection in the intervention group followed a two week training period during which the unit started using the collector bag.

Data were collected using a form filled in by the birth attendants for each vaginal delivery. Information was collected on maternal age, induction of labour, mode of delivery, number of babies, birth weight, use of prophylactic uterotonics, and outcome data. A second form was used for deliveries with severe postpartum haemorrhage, with information collected on the delivery and management of postpartum haemorrhage. This form was used to cross check criteria for the primary outcome.

Sample size

The sample size calculation took into account the cluster randomised design; we estimated the intracluster correlation coefficient to be 0.01. With the assumption of an event rate for the primary outcome of 2.5% in the control group, 82 clusters (41 in each arm of the trial) were required to detect a decrease in the event rate to

1.5% (a 40% relative risk reduction) with 80% power, a two sided significance level of 5%, and an average cluster size of 300 women.²⁵

Statistical analysis

The participants and maternity units were analysed in the groups to which they were assigned regardless of the management received by individual women or deviation from the protocol.

We summarised the baseline characteristics of the maternity units and individual women using counts (percentages) for categorical variables, means (standard deviations) for normally distributed continuous variables, or medians (interquartile ranges) for other continuous variables. Comparative statistical analysis was done at both individual and cluster level and took into account the effect of clustering. All statistical tests were two sided (5% significance level) and not adjusted for multiple comparisons. Statistical analyses were done using SPSS version 17 and Stata v10.0 software.

For analysis at the individual level we compared primary and secondary outcomes between the two study groups both unadjusted and adjusted for the effect of clustering. To determine the magnitude and direction of any differences in outcomes between the two groups, we calculated crude odds ratios and 95% confidence intervals. We also used logistic regression to adjust for clustering and key prognostic factors. The cluster randomised design imparts a data structure that facilitates the calculation of a valid intracluster correlation coefficient, ρ .

Cluster level analysis was carried out only on the primary outcome. Some hospitals contributed fewer events than others and some recruited fewer women. We allowed these hospitals to have less effect on the treatment estimate by weighting the analysis on the basis of the precision—that is, we calculated the weighted mean difference for the treatment comparison. We used a weighted linear regression model to test the effect of the intervention on the rate of severe postpartum haemorrhage during the trial period, adjusting for the baseline rate, expressed as the weighted mean difference (95% confidence interval).

RESULTS

Figure 1 shows the flow of maternity units and women through the study. Of the 84 maternity units meeting the inclusion criteria, two declined to participate before allocation. Overall, 41 maternity units were randomised to the intervention group and 41 to the control group. Two maternity units in each group opted out before receiving notification of allocation owing to lack of necessary resources. Thirty nine in each group completed the trial. Table 1 shows the number of participating maternity units and women included in each country.

One maternity unit in the intervention group did not collect baseline data. Deviating from the protocol, most maternity units (31 of 39) continued collecting data during the two week training period in the intervention arm. In these units, trial data collection started

Table 2 | Baseline characteristics of maternity units and individual women by allocation. Values are numbers (percentages) unless stated otherwise

Characteristics	Intervention group (n=38)*	Control group (n=39)
Maternity units:		
Median (interquartile range) rate of caesarean delivery (%)	21.1 (17.4-26.6)	21.7 (14.6-26.0)
>1600 deliveries annually	20 (52.6)	19 (48.7)
Maternal age (years):	(n=4937)	(n=4758)
Mean (SD)	29.6 (5.4)	29.7 (5.5)
Median (interquartile range)	30.0 (26-33)	30.0 (26-33)
No with missing data	31	23
Mode of delivery:		
Spontaneous vaginal	4104 (83.1)	4062 (85.4)
Operative vaginal	833 (16.9)	696 (14.6)
Induction	1080 (21.9)	1043 (21.9)
No of babies:		
Single	4833 (98.5)	4645 (98.6)
Multiple	76 (1.5)	68 (1.4)
No with missing data	28	45
Birth weight (g):		
Mean (SD)	3315 (566.4)	3349 (549.1)
Median (interquartile range)	3330 (3020-3660)	3370 (3050-3690)
No with missing data	26	29
Prophylactic uterotonics in 3rd stage:	3527 (71.4)	3153 (66.3)
No with missing data	0	5
Prostaglandin used after birth:	212 (4.3)	218 (4.6)
No with missing data	0	5
Manual removal of placenta:	204 (4.1)	121 (2.5)
No with missing data	0	5
Severe postpartum haemorrhage†	60 (1.22)	90 (1.89)

*Baseline data unavailable in one maternity unit.

†One of following: maternal death, transfusion, plasma expansion, surgery or embolisation, admission to intensive care unit, or treatment with recombinant factor VII.

after the first month of baseline data collection. Four units in the control group collected trial data for more than three months (up to five months). Only the three month period of data collection specified in the protocol was considered for all units. In some Austrian hospitals the number of women included was low, given the total expected number of deliveries. The national coordinator confirmed that the missing data were all caesarean deliveries and that in some hospitals the caesarean rate was high. Nevertheless, sensitivity analyses were carried out and showed that the results were not influenced by excluding these hospitals or even the entire Austrian dataset.

Baseline data were collected for 4937 vaginal deliveries in the intervention group and 4758 in the control group. The characteristics of the maternity units and women (table 2) in both groups were broadly similar for all factors except manual removal of the placenta and use of prophylactic uterotonics, which were more common among women in the intervention group.

Primary outcome

Individual level analysis

A total of 25 381 women were included in the analysis (11 037 in the intervention group, 14 344 in the control

group). The greater number of women in the control group resulted from a larger median cluster size (241 in the intervention group, 284 in the control group).

The incidence of severe postpartum haemorrhage was 189 of 11 037 vaginal deliveries (1.71%) in the intervention group compared with 295 of 14 344 in the control group (2.06%). The difference was not statistically significant (table 3). The crude odds ratio for the effect of the intervention was 0.83 (95% confidence interval 0.69 to 1.00). The odds ratio adjusted for clustering was 0.83 (0.27 to 2.60); after further adjustment for maternal age, use of prophylactic uterotonics in the third stage, mode of delivery, and birth weight, the odds ratio was 0.82 (0.26 to 2.53). Sensitivity analyses were done to test the robustness of this result excluding units that deviated from the protocol, and also by country and baseline rate of severe postpartum haemorrhage (median split by country). The results of these analyses were similar.

Cluster level analysis

The weighted mean rate for severe postpartum haemorrhage was 1.71% (SD 2.51%) in the intervention group and 2.06% (SD 3.52%) in the control group. The intraclass correlation coefficient for severe postpartum haemorrhage was 0.023. The rate of severe postpartum haemorrhage did not differ significantly between the groups: weighted mean difference -0.34% (95% confidence interval -2.56% to 1.87%); $P=0.75$. Adjusting for the baseline rate of severe postpartum haemorrhage resulted in a slight change in this result: adjusted weighted mean difference 0.16% (-0.69% to 1.02%); $P=0.70$. Rates of severe postpartum haemorrhage in the baseline and trial periods for each maternity unit were heterogeneous across units in different countries (fig 2).

Figure 3 shows the difference in baseline and trial rates of severe postpartum haemorrhage for each unit in the intervention group, according to compliance with bag use. No relation was found between the difference in severe postpartum haemorrhage rates (baseline and trial) and the proportion of bag use. Analysis of the intervention effect on the primary outcome, including in the intervention arm only maternity units where the bag was used in at least 50% of vaginal deliveries, showed no significant difference between the two groups: individual level analysis adjusting for cluster and individual characteristics, adjusted odds ratio 0.59 (95% confidence interval 0.23 to 1.53).

Secondary outcomes (individual level analysis)

Analyses were done to test the effect of the intervention on the main components of the primary outcome (table 3). The proportion of women who had blood transfusion, surgical procedure, embolisation, or manual removal of placenta did not substantially differ between the intervention and control groups, whether after adjustment for cluster or after further adjustment for other prognostic factors. No maternal deaths occurred.

Table 3 | Main outcomes. Values are numbers (percentages) unless stated otherwise

Outcomes	Intervention (n=11 037)	Control (n=14 344)	ICC (ρ)	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI) [†]	Adjusted odds ratio (95% CI) [‡]
Primary outcome:						
Severe postpartum haemorrhage*	189 (1.71)	295 (2.06)	0.023	0.83 (0.69 to 1.00), P=0.05	0.83 (0.27 to 2.60), P=0.8	0.82 (0.26 to 2.53), P=0.7
Secondary outcomes:						
Blood transfusion	86 (0.78)	135 (0.94)	0.011	0.83 (0.63 to 1.68), P=0.2	0.83 (0.35 to 1.96), P=0.8	0.80 (0.33 to 1.90), P=0.6
Plasma expander	127 (1.15)	222 (1.55)	0.022	0.74 (0.59 to 0.92), P=0.007	0.74 (0.20 to 2.72), P=0.7	0.95 (0.62 to 1.46), P=1.0
Surgical procedure or embolisation	50 (0.45)	76 (0.53)	0.012	0.85 (0.60 to 1.22), P=0.9	0.85 (0.20 to 3.63), P=0.9	0.78 (0.18 to 3.40), P=0.7
Manual removal of placenta	326 (2.95)	366 (2.55)	0.016	1.16 (1.00 to 1.35), P=0.05	1.16 (0.76 to 1.77), P=0.5	1.09 (0.72 to 1.67), P=0.7
Prostaglandins	501 (4.54)	766 (5.34)	0.129	0.84 (0.75 to 0.95), P=0.004	0.84 (0.40 to 1.77), P=0.7	0.85 (0.40 to 1.80), P=0.7

ICC=intracluster correlation coefficient.

*Defined by one of following: maternal death, transfusion, plasma expansion, surgery or embolisation, admission to intensive care unit, or treatment with recombinant factor VII.

[†]Adjusted for clustering (maternity unit).[‡]Adjusted for clustering (maternity unit), age of mother, prophylactic uterotonics used in third stage, mode of delivery, and birth weight.

The proportion of women in receipt of intravenous plasma expanders or prostaglandins differed between intervention and control groups, but the differences were not significant after adjustment for clustering effect.

DISCUSSION

In this cluster randomised trial of 25 381 vaginal deliveries in 78 maternity units of 13 European countries, the systematic use of a collector bag after vaginal delivery did not modify the rate of severe postpartum haemorrhage. There was no evidence of heterogeneity, the results not differing by country or size of hospital.

Strengths and limitations of the study

This trial provides new results on an unexplored although controversial aspect of care in the third stage of labour. Although objective measurement has been shown to increase the accuracy of assessing postpartum blood loss compared with visual estimation,¹⁵⁻²¹ the routine use of a collector bag was not associated with a significant decrease in severe postpartum haemorrhage. This result constitutes an important contribution to the ongoing debate on strategies to improve the care of women with postpartum haemorrhage and to decrease the incidence of severe cases. Additionally, the cluster randomised design and the large number of clusters and their diversity provide good external validity to this trial. Small deviations from the protocol did occur for data collection, but sensitivity analyses showed that none of these changed the internal validity of the trial.

Heterogeneity of baseline rates for severe postpartum haemorrhage was large between maternity units (0% to 13.4%). In theory such a variation should be an asset and reflect a broad range of levels of risk in the participating maternity units. Because these differences were strongly related to the country, however, some concern remains about the criteria in use for the management of postpartum haemorrhage in different parts of Europe. Sensitivity analysis showed that this aspect did not alter the results.

Baseline data showed some heterogeneity between the intervention and control groups. Heterogeneity in

postpartum haemorrhage related practices and rates has been reported across maternity units in Europe, both between and within countries.^{4,23} Randomisation should balance these differences between the two arms. However, given the number of units randomised, although large for a cluster randomised controlled trial, there is a slight possibility of residual imbalance. Analyses were, however, adjusted for the main determinants of postpartum haemorrhage (individual level analysis) and baseline rate of severe postpartum haemorrhage (cluster level analysis); in addition, sensitivity analysis indicated that the absence of a major effect of the intervention was similar whether the maternity units had a high or low baseline rate of severe postpartum haemorrhage. In consequence, any perceived or real imbalance in these characteristics should have little or no effect on the findings.

Hypotheses for the results

Different mechanisms may explain the absence of difference in the rates of severe postpartum haemorrhage between maternity units that used the bag and those that visually assessed blood loss. This may result from a lack of compliance to the intervention. This is, however, unlikely because of the persistent absence of difference between the two groups when the analysis was

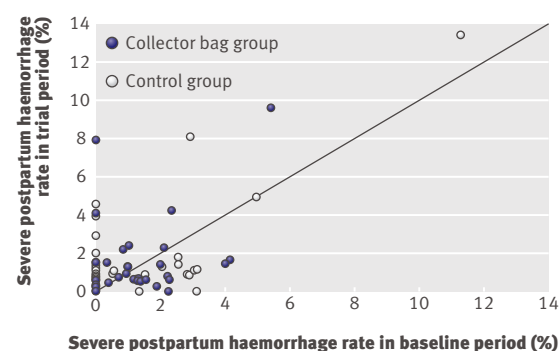


Fig 2 | Rate of severe postpartum haemorrhage during baseline and trial periods for each maternity unit. Each dot represents one maternity unit. Diagonal line denotes no change in rate of postpartum haemorrhage from baseline to trial period

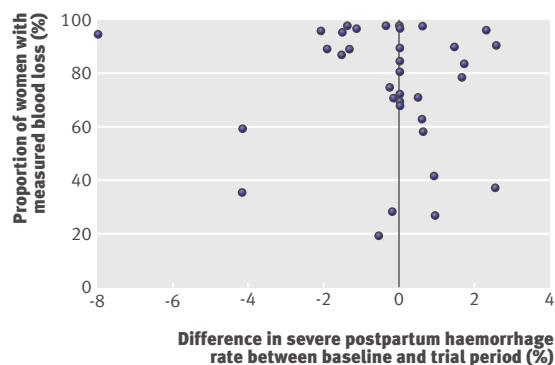


Fig 3 | Difference in rate of severe postpartum haemorrhage (baseline rate–intervention rate) according to compliance with intervention (percentage of women with measured blood loss) in 38 units in intervention group during trial

restricted to those maternity units that used the bag in a high proportion of deliveries.

One potential reason for the apparent ineffectiveness of the intervention might be incorrect use of the bags; in particular, that they were covered most of the time and thus could not be viewed. Such misuse is unlikely to explain the observed lack of effect as detailed oral and written instructions were provided and the training video clearly showed the care giver watching the bag and the graduations.

Participation in the study may indicate a particular interest in the management of postpartum haemorrhage so that existing management had little room for improvement. Such a selection process is, however, unlikely in these maternity units, owing to the variety of baseline rates of severe postpartum haemorrhage.

It may be hypothesised that the intervention has a double effect, in two opposite directions: increasing the rate of ascertainment through increased vigilance and decreasing the prevalence through timely management of excessive bleeding. If these two components were of the same order of magnitude, the global effect would be no effect. If this explanation was realistic, however, different effect sizes would be expected with different baseline rates or different degrees of compliance, or both. None of this occurred, making it unlikely that a benefit of the intervention in terms of decreased severe outcome was balanced by an equivalent increase in ascertainment. In fact the intervention seemed to increase the rates of postpartum haemorrhage, reflecting that the intervention was possibly more effective in improving ascertainment than in changing practice.

A concomitant effect in the control group may also have contributed to the absence of difference between the two arms. Contamination of the intervention to control units is unlikely since participating units were not in contact, and no use of bags was reported in all the control maternity units. Participation in a research study, independently of any specific intervention, has been reported to change behaviours of participants (Hawthorne effect).²⁶ The hypothesis that the management of postpartum haemorrhage would have

improved in the control arm is, however, not supported by the absence of change in the rate of severe postpartum haemorrhage between the baseline and trial periods in this group.

The most plausible explanation of the negative result of this trial is that having a more accurate assessment of postpartum blood loss is not by itself sufficient to change behaviours of care givers and improve the management of postpartum haemorrhage. Lack of identification of women with excessive postpartum bleeding is a problem, potentially leading to higher levels of medical intervention if the bleeding progresses to severe haemorrhage. We designed a strategy to increase the awareness of care givers. The fact that this has not translated into a change in clinical outcomes probably reflects the complexity of decisions on management, which are influenced by multiple factors such as organisation of the delivery ward and how care givers perceive and cope with emergencies.

Comparison with other studies

We did not find any other published study assessing the effectiveness of the collector bag. We have, however, identified other large multicentre randomised trials in the specialty of maternal and child health where a diagnostic or screening test was evaluated but without any associated instructions about the management of abnormal results.^{27–29} None of these trials showed benefit with the introduction of the test. In addition one study showed that simple information is not sufficient to have an effect on the readiness of birth attendants to change.³⁰ These various reports suggest that the effect of enhanced diagnostic methods should include an accompanying protocol of management and may be a specific behavioural intervention, which in effect becomes a “complex intervention.”

Policy implications

The practical implication of these results for high income countries is that those units that are using a collector bag (cost per bag between €1 (88p; \$1.44) and €11 in Europe) need to reconsider their practice and possibly reallocate the resources to other aspects of care. Units that are not routinely using the bag should keep the same policy. For resource poor countries, positive results with the use of the “kanga collector” have been reported.³¹ This needs to be tested in a randomised design. In the current context of reported ongoing increase in the prevalence of postpartum haemorrhage, further research is needed to develop and test effective strategies to decrease the prevalence of severe postpartum haemorrhage through improvement of management. These will probably be multifaceted interventions, and in this context the collector bag may warrant further investigation.

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WHAT IS ALREADY KNOWN ON THIS TOPIC

Delay in the diagnosis and initial care of postpartum haemorrhage has been reported and may result from visual underestimation of blood loss

A collector bag has been proposed as a useful tool to measure blood loss but has not been tested despite being used routinely in many maternity units in Europe

WHAT THIS STUDY ADDS

The incidence of severe postpartum haemorrhage was not reduced by routine use of a collector bag to objectively measure postpartum blood loss after vaginal delivery, without specific guidelines on threshold and action

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Contributors: W-HZ designed data collection tools, monitored data collection for the whole trial, wrote the statistical analysis plan, cleaned and analysed the data, and drafted and revised the paper. She is guarantor. CD-T implemented the trial in France, analysed the data, and drafted and revised the paper. PB analysed the data and drafted and revised the paper. EJ wrote the statistical analysis plan, monitored data collection for the whole trial, and revised the draft paper. MJ designed data collection tools, monitored data collection for the whole trial, and revised the draft paper. SA initiated the collaborative project, designed data collection tools, implemented the trial for the all countries, monitored data collection for the whole trial, analysed the data, and drafted and revised the paper. All members of EUPHRATES designed the trial. Diogo Ayres-de-Campos, Istvan Berbik, Marie-Hélène Bouvier-Colle, Vicenç Cararach, Risto Erkkola, Mathias Klein, Walter Prendiville, Jos van Roosmalen, Babill Stray-Pedersen, and Carolyn Troeger implemented the trial in, respectively, Portugal, Hungary, France, Spain, Finland, Austria, Republic of Ireland, Netherlands, Norway, and Switzerland, and revised the draft paper. Gérard Bréart analysed the data and revised the draft paper. Alison Macfarlane and Clare Winter revised the draft paper.

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Data sharing: No additional data are available.

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