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Full length article

Prevention of postpartum haemorrhage: Economic evaluation of the novel butterfly device in a UK setting

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ABSTRACT

Objectives: To explore the cost-effectiveness of a novel PPH device as compared with usual care.
Design: A decision analytical model was used to explore the cost-effectiveness of the PPH Butterfly device compared with usual care. This was part of a United Kingdom, UK, clinical trial ISRCTN15452399 using a matched historical cohort who had standard PPH management without the use of the PPH Butterfly device. The economic evaluation was conducted from a UK National Health Service (NHS) perspective.
Setting: Liverpool Women's Hospital, UK.
Participants: 57 women with 113 matched controls.
Intervention: The PPH Butterfly is a novel device that has been invented and developed in the UK to facilitate bimanual compression of the uterus in the treatment of PPH.
Main outcome measures: Main outcome measures included healthcare costs, blood loss, and maternal morbidity events.
Results: Mean treatment costs in the Butterfly cohort were £3,459.66 as compared with standard care £3,223.93. Treatment with the Butterfly device resulted in decreased total blood loss in comparison with standard care. The Butterfly device had an incremental cost-effectiveness ratio of £3,795.78 per PPH progression avoided (defined as $\leq$ 1000 ml additional blood loss from device insertion point). If the NHS is prepared to pay £8,500 per PPH progression avoided, then the Butterfly device is cost-effective with a probability of 87 percent. In the PPH Butterfly treatment arm there were 9% fewer cases of massive obstetric haemorrhage (severe PPH of more than 2000mls or more than 4 units of blood transfusion required) recorded as compared with the standard care historical cohort. As a low-cost device, the PPH Butterfly device is cost-effective but can be cost-saving to the NHS.
Conclusion: The PPH pathway can result in high-cost resource use such as blood transfusion or high dependence unit hospital stays. The Butterfly device is a relative low-cost device in a UK NHS setting with a high probability of being cost-effective. The National Institute for Health and Care Excellence (NICE) can use this evidence in considering the adoption of innovative technologies such as the Butterfly device in the NHS. Extrapolation on an international scale to lower and middle-income countries could prevent mortality associated with PPH.

Introduction

Postpartum haemorrhage (PPH) is a leading cause of maternal mortality and morbidity worldwide [1] and the second leading cause of maternal death in the United Kingdom (UK) [2]. Rates of PPH continue to rise steadily in the UK, occurring in 21% of all deliveries in the

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National Health Service (NHS) between 2017 and 2018 [3,4]. Although death due to PPH in the UK is rare [1], it continues to be an avoidable cause of death worldwide, particularly in lower and middle-income countries. PPH is likely to occur during the first 24 h after delivery but can take place anytime within the first 6 weeks after birth. Uterine atony is responsible for approximately 80% of primary PPH, while endometritis is the most frequent cause of secondary PPH [2].

The intervention

The PPH Butterfly device is a novel device (see Fig. 1) designed to facilitate compression of the uterus of women experiencing PPH as an alternative to bimanual compression. Although bimanual compression is effective, it causes significant discomfort to the woman and is a tiring maneuver for the doctor to maintain [5]. The intervention device is a smooth, streamlined plastic device with a perforated platform and folding handle. When inserted vaginally is provides a platform against which the uterus is compressed by the doctor through the abdominal wall [5].

Aims

To conduct early economic modelling to explore whether the PPH Butterfly device is likely to be cost-effective in comparison to standard treatment of PPH.

Methods

The non-randomised phase II clinical trial participant population studied included 57 women with clinically diagnosed primary PPH after vaginal births who did not respond to initial therapy. All women recruited to participate at Liverpool Women's Hospital in the UK were assigned the PPH Butterfly device. A retrospective cohort of two matched historical controls per trial participant were obtained from the same institution two years previously (the next woman to give birth after the same date two years previously with the same parity group, mode of birth and at least the same blood loss as the index case at device use).

The economic analysis was conducted from an NHS perspective following guidance on the economic evaluation of new medical devices [6].

Model structure

A decision tree (see Fig. 2) was developed to capture the patient treatment pathways and model the cost-effectiveness of the PPH Butterfly device compared with usual treatment when managing PPH. The model was constructed using a mixture of participant data from the trial and data sourced from a matched historical cohort, obtained from patient records.

Model inputs

The range of NHS costs measured and valued were discussed with clinicians working in obstetrics. The costs consisted of:

(i) PPH Butterfly device: As a novel device which is not yet available to purchase, a proxy cost of the most comparative medical device was used for the base case analysis. Detailed information on the potential cost of future manufacturing was obtained and the value of the device against alternatives was considered.
(ii) Resources used by patients through the PPH management treatment pathways including blood transfusion, examination in theatre under anaesthetic, and details of inpatient stay.

Resources were costed using national reference costs and reported in pounds sterling, for the year 2017/18 using national unit costs guide of hospital resources [7,8]. Where national reference costs were unavailable direct hospital finance data was obtained from Liverpool Women's NHS Foundation Trust. In accordance with the National Institute for Health and Care Excellence (NICE) guidelines as the intervention follow-up period was less than one year no discounting of costs or outcomes was necessary [9,10].

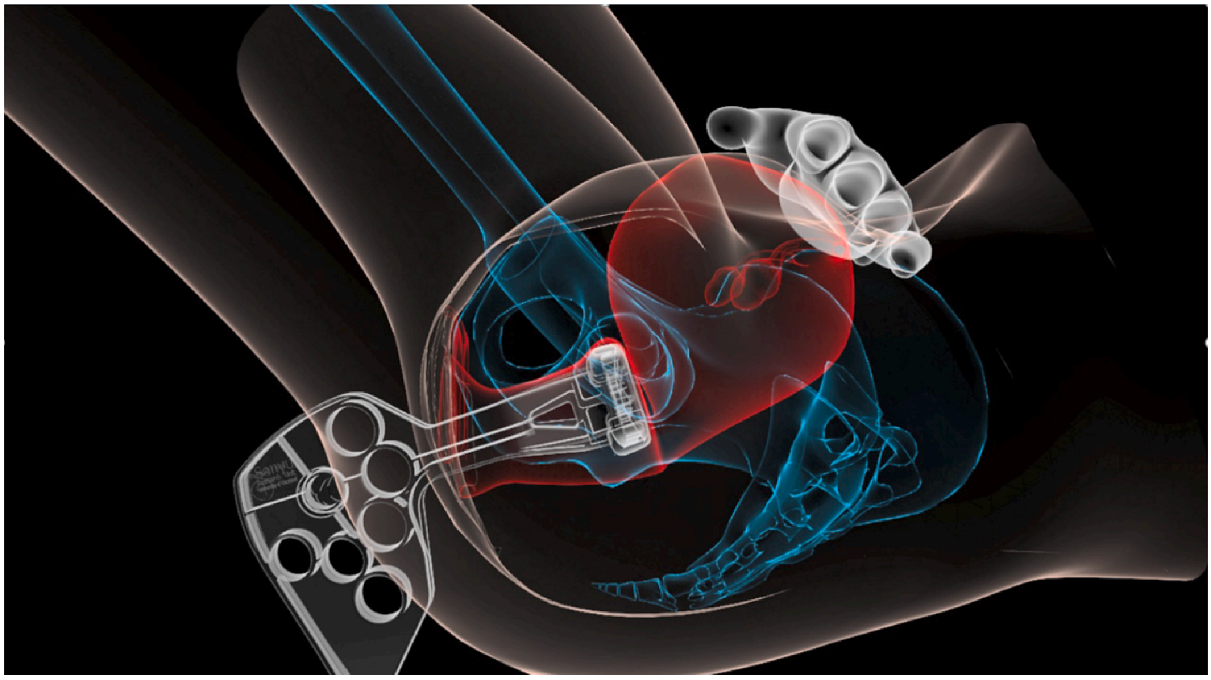

Fig. 1. The novel postpartum haemorrhage device.

Fig. 2. A decision tree pathway showing a schematic representation of the clinical pathway for patients with postpartum haemorrhage.

Economic analysis

A dichotomous analysis of blood loss ≤1000mls or >1000mls (from point of insertion) was investigated. In the primary analysis the incremental cost-effectiveness was calculated as the ratio of the difference between the costs and the number of women in the PPH Butterfly arm and the standard care matched historical cohort were the PPH progresses by more than 1000 ml after insertion of the device. The device insertion point for the historical controls was modelled to be the same as the blood loss at insertion in the index case. The primary analysis calculates the cost per PPH progression avoided (defined as ≤ 1000 ml additional blood loss from the device insertion point).

Secondary outcomes included the probability of experiencing a range of maternal morbidity events, including transfer to theatre, blood transfusion, admission to an intensive unit, high dependency/specialist unit, progression to massive obstetric haemorrhage (defined as total blood loss since childbirth of more than 2000 ml or transfusion of 4 units or more) or maternal death (within 6 weeks of giving birth). The incremental cost per 'maternal morbidity avoided' outcome was analysed as a composite of secondary outcomes included in the clinical trial. This has previously been used in other childbirth research [11]. Further analysis using a 'shifting the curve' approach was conducted to investigate distribution of the total blood loss of each treatment arm across cohorts [12].

The economic evaluation took an intention to treat (ITT) approach and analysis was conducted for the full set of patients in the intervention and control arms.

In the primary analysis, variation to input parameters to test the assumptions and to account for uncertainty were considered using sensitivity analysis [13]. Bootstrapping of 1000 data replications [14] was used to produce cost-effectiveness planes from which the cost-effectiveness acceptability curves (CEAC) were plotted to provide evidence to healthcare policymakers and stakeholders of the probability of cost-effectiveness at different payer thresholds.

Statistical analysis was conducted using Microsoft Excel Office 365. For validation and reporting see Appendix 1 [15–18].

Budget impact assessment (BIA)

In accordance with ISPOR guidelines [19], a preliminary BIA was conducted to examine the total NHS costs of the widespread use of the PPH Butterfly device if rolled out nationally. BIAs are economic assessments used to explore the financial consequences of implementing a new health technology [20,21].

Results

As a novel medical device, value-based pricing considered factors such as true innovation, unmet need, strong patient demand and first to market [22–25], and has informed the development of a costing framework for a future economic evaluation of the PPH Butterfly device. Costs of surgical instruments used during childbirth vary considerably, however the Bakri intrauterine balloon tamponade [26] with a unit cost of £270 was applied as a proxy cost for the intervention device in the base case economic analysis (see Table 1). The deterministic sensitivity analysis included varying the device cost using alternative proxy device costs ranging from £5 to £400.

Mean treatment costs in the Butterfly arm was £3,459.66 as compared with standard care which cost £3,223.93. Treatment with the Butterfly device resulted in PPH progressing beyond 1000mls after device use in 1(1.75%) case compared with standard care where 9(7.97%) cases where PPH progressed. See Table 2 for mean costs and effects.

The Butterfly device had a mean ICER of £3,795.78 per PPH progression avoided (defined as > 1000 ml blood loss after point of device use). See Table 3 for a summary.

The probabilistic sensitivity analysis result is presented in Fig. 3 showing the cost-effectiveness plane, where the majority of the ICER values fall on the North-East plane indicating that the Butterfly device has higher costs but is more effective than standard care.

From the cost-effectiveness simulation the CEAC is plotted in Fig. 4 to show the probability of cost-effectiveness at different willingness-to-pay (WTP) thresholds.

At a WTP of £8,500 per PPH progression avoided, the Butterfly intervention has a cost-effectiveness probability of 0.87. Various probabilities can be obtained for different price thresholds from the CEAC curve in Fig. 4.

Table 1
Summary of cost data used in the model.

	Value (£*)	Source
Base case cost of PPH Butterfly device[1]	270.00	A proxy value of a comparable medical device used as no market price available. Cost of Bakri balloon provided by Liverpool Women's NHS Foundation Trust.
Blood Transfusion (first unit)	179.15	NICE (2015b).
Blood Transfusion (subsequent unit of blood)	170.72	NICE (2015b).
Transfer to a higher level of care (high dependency unit stay per day)	992.87	National Reference Costs 2017/18 [8].
Examination in theatre under anaesthetic	1231.00	Estimated cost[2] from National Reference Costs 2017/18 [8].
Base case cost for normal or assisted delivery (excluding post-partum surgical intervention)	2689.00	National Schedule of Reference Costs 2017/18 [8].

*All costs are reported in pounds sterling inflated to cost year 2017/18 where necessary. [1]Cost of the PPH Butterfly was varied as part of the sensitivity analysis. [2]Theatre costs were estimated from subtracting the base case cost for normal or assisted delivery without postpartum surgical intervention from the unit cost of normal or assisted delivery with postpartum surgical intervention.

Table 2
Mean cost and proportion distribution for blood loss from point of device use in the intervention compared with additional blood loss from index case point of insertion in the standard care arm.

	PPH Butterfly (n = 57)	Standard Care (n = 113)	Change (%)	ΔE (Odd Ratio)
Effects – proportion (%)				
≤1000	56(98.25)	104(92.03)	6.21	0.21
>1000	1(1.75)	9(7.97)	−6.21	
Blood Loss (Mean) (mls)				
Before Device use	968.95	955.40	13.55	
After Device use	280.00	383.08	−103.08	
Total	1248.95	1338.49	−89.53	
Cost (Mean) (£)				
≤1000	3459.73	3163.55	296.18	
>1000	3455.44	3921.67	−466.24	
Total	3459.66	3223.93	235.73	

Table 3
Summary of results from the base case cost-effectiveness analysis to calculate the mean ICER value per PPH progression avoided.

PPH Butterfly		Standard care		
Mean Costs (£)	**Effect**	**Mean Costs (£)**	**Effect**	**ICER (Cost/Effect)**
3459.66	0.98	3223.93	0.92	3795.78

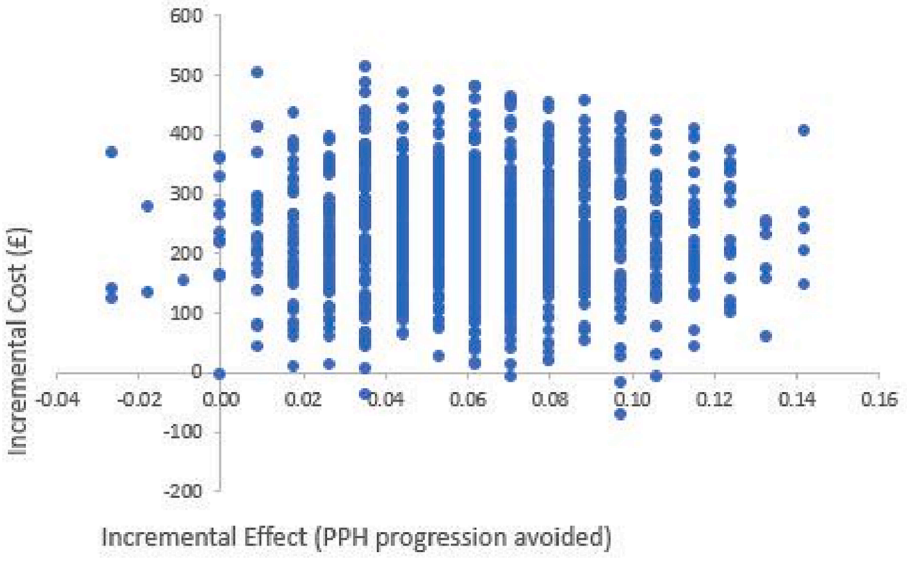

Fig. 3. Cost-effectiveness analysis plane.

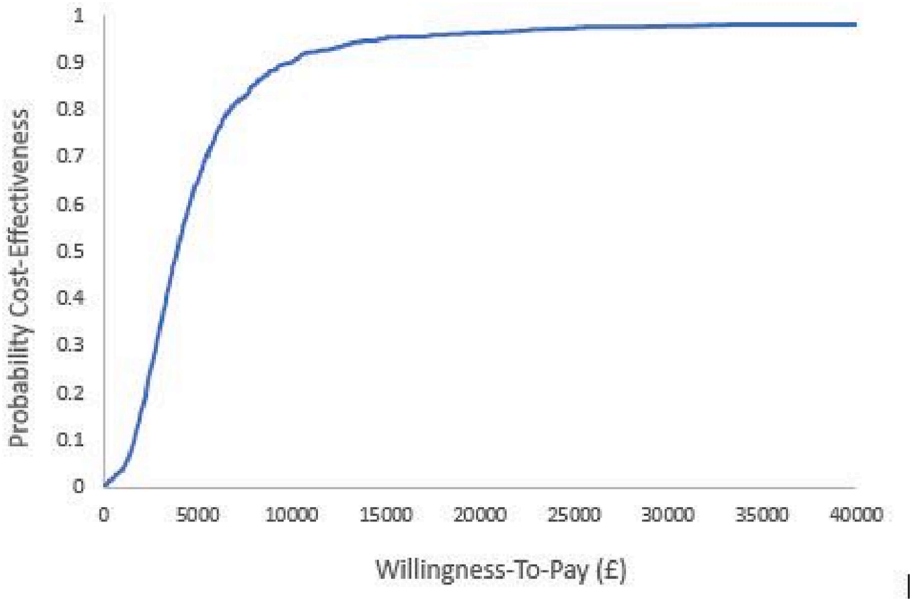

Fig. 4. CEAC curve showing the probability of cost-effectiveness at different willingness-to-pay thresholds (in pounds Stirling £).

Secondary analysis indicated that the standard care historical control had more maternal morbidity events, although the Butterfly intervention arm had a greater percentage of participants with at least one event. See Table 4 for rates of maternal morbidity events.

The mean ICER value was -£1,413.70 per maternal morbidity event (composite) avoided for women experiencing PPH. The PPH Butterfly arm, though having more cost than the standard arm, showed a negative composite maternal morbidity result. A similar analysis was conducted for patients who had at least one morbidity event. This gave a mean ICER value of £17,059.67 per event. The result per event shows the Butterfly arm is cost-effective irrespective of the event.

Secondary analysis

Treatment with the Butterfly device resulted in an average blood loss of 1248.95mls in comparison with standard care which had an average blood loss of 1338.49mls, which shows a decrease of 89.54mls in the Butterfly device intervention arm (see Table 5). The intervention arm had 9% fewer cases of massive obstetric haemorrhage (severe PPH of more than 2000mls or more than 4 units of blood transfusion required) recorded as compared with the standard care historical cohort.

Fig. 5 shows a comparison of total blood loss between the intervention and control groups. The smoothed distribution curves show an increase in the level of severity of blood loss in the control group as the control curve is more to the right while the intervention curve is more to the left. A shift to the left in the curve shows a reduction in blood loss and would result in savings to the NHS in avoiding health care resources that would have been expended due to higher blood loss.

Impact of variation

A variation of market price range for the novel PPH Butterfly device is shown in Fig. 6 with its corresponding ICER value (using the primary outcome of serious PPH progression averted as the measure of effect).

Table 4
Rates of maternal morbidity events for each treatment arm represented as total numbers and in percentages N (%).

	Butterfly (n = 57)	Standard care (n = 113)
Theatre		
Minimal (≤1000)	1 (1.75)	1 (0.88)
Moderate (>1000)	3 (5.26)	6 (5.31)
Severe (>2000)	2 (3.51)	3(2.65)
All	6 (10.53)	10 (8.85)
HDU		
Minimal (≤1000)	1 (1.75)	2 (1.77)
Moderate (>1000)	19 (33.33)	26 (23.01)
Severe (>2000)	4 (7.02)	18 (15.93)
All	24 (42.11)	46 (40.71)
Blood Transfusion		
Minimal (≤1000)	0 (0.00)	2 (1.77)
Moderate (>1000)	4 (7.02)	19 (16.81)
Severe (>2000)	4 (7.02)	6 (5.31)
All	8 (14.04)	27 (23.89)
Massive Obstetric Haemorrhage		
Blood Transfusion (≥4 units)	0 (0.00)	0 (0.00)
Severe (≥2000mls)	10 (17.54)	31 (27.43)
All	10 (17.54)	31 (27.43)
Death	0 (0.00)	0 (0.00)

Table 5
Mean cost and proportion distribution for total blood loss in the intervention and control treatment arms.

	PPH Butterfly (n = 57)	Standard care (n = 113)	Change
Mean total Blood Loss (mls)	1248.95	1338.49	−89.54
Proportion (%)			
Minimal (≤1000)	26(45.61)	48(42.48)	3.14
Moderate (>1000)	27(47.37)	47(41.59)	5.78
Severe (>2000)	4(7.02)	18(15.93)	−8.91
Mean cost (£)			
Minimal (≤1000)	3025.44	2756.69	268.75
Moderate (>1000)	3668.17	3448.03	220.14
Severe (>2000)	4874.56	3884.73	989.83
Effect			**ΔE (Odd Ratio)**
(≤1000)	26(46%)	48(43%)	0.88
(>1000)	31(54%)	65(57%)	

There is a positive linear correspondence between the price and the ICER values. At a price below £34.40 the intervention device is not only cost-effective but also cost-saving and at prices above £34.40 the intervention is still cost-effective.

Budget impact assessment (BIA)

Between 2017 and 2018, there were 626,203 deliveries in NHS hospitals in England [27]. Of these, 118,978 (19%) women experienced PPH [27]. Caesarean section delivery accounted for 16% of all deliveries in England in 2017/18 [27] and these births incur some of the highest risk of PPH [28]. In addition, 16.2% of PPH cases will fail to respond to first line treatments (such as Oxytocin) [29] equating to 16,191 births in 2017/18 in England (once caesarean section delivery births are excluded). These were potentially suitable for treatment with the PPH Butterfly device. Table 6 shows scenario testing for the Butterfly device varying the cost of the device and varying the percentage of PPH cases where it might be used. If the intervention device had been used to treat all eligible PPH cases in England in 2017/18 (n = 16,191) it would have cost the NHS between £80,955 and £4.37 million (considering the PPH Butterfly costs alone).

Resources related to the delivery and implementation of the PPH Butterfly device were obtained using a short resource diary, separating out any research and development related resources. Training costs included a one-off session averaging 25 min (including staff travel time). The training session incorporated 10 min of practical muscle memory development on a specially engineered mannequin. Staff training was estimated to cost a total of £1,503.90 to train 34 clinicians, with a cost per clinician of £44.23 or £26.38 per patient use in this study (n = 57). While the training mannequin was specifically developed for this study, comparable simulators for teaching bimanual compression exist and are marketed at £200 [30] which is comparable to the costs used in the estimates of training resources for the intervention device (see Appendix 2 Table A for supplementary training unit costs).

The latest minor adaptations of the PPH Butterfly device may reduce some of the risks identified during these early trials and thereby reduce some of the specific training requirements.

Discussion

There is a high cost of the PPH pathway including increased rates of high-cost resource use such as blood transfusion or high dependency unit (HDU) hospital stays. The PPH Butterfly device produced at a cost similar to other surgical instruments used during childbirth has high probability of being a cost-effective device for improving maternal morbidity outcomes following PPH in the UK NHS setting.

Strengths and weaknesses

There are no economic evaluations of bimanual compression and, as a new medical device, this is the first economic evaluation to assess the evidence of the cost-effectiveness of the PPH Butterfly device. This economic evaluation used volume of blood loss to calculate the primary outcome. This limits its comparability to other published studies. Published estimates suggests that utility value of having blood loss ≤1000mls could be estimated at 0.87 while the utility values for having a blood loss >1000mls at 0.75 [31,32]. The inclusion of generic outcome such as quality adjusted life years (QALYs) can be applied so that thresholds for various WTP of PPH progression can be compared to the commonly cited threshold of between £20,000 and £30,000 set by NICE [33].

The PPH Butterfly treatment resulted in fewer cases of serious haemorrhage, a reduction in blood transfusion and an increase in breastfeeding when compared with the historical control group. These differences were however not statistically significant (see Weeks at al., 2023) [34]. There was also an increase in the number of other treatments received in the PPH Butterfly arm and overall the treatment costs were higher in this arm.

The control data came from a matched historical cohort. This comparison is therefore prone to various biases and may not be strictly comparable.

A longer time horizon and more detailed costing of resource use in the postnatal period at a patient data level could help capture the high level of care needs for patients experiencing complications. While data from literature such as Bowers and Cheyne [35] provide a useful breakdown of the costs of postnatal stay into fixed (i.e. admission and discharge) and variable costs (length of stay), this is unlikely to represent the full use of postnatal resources by women experiencing PPH.

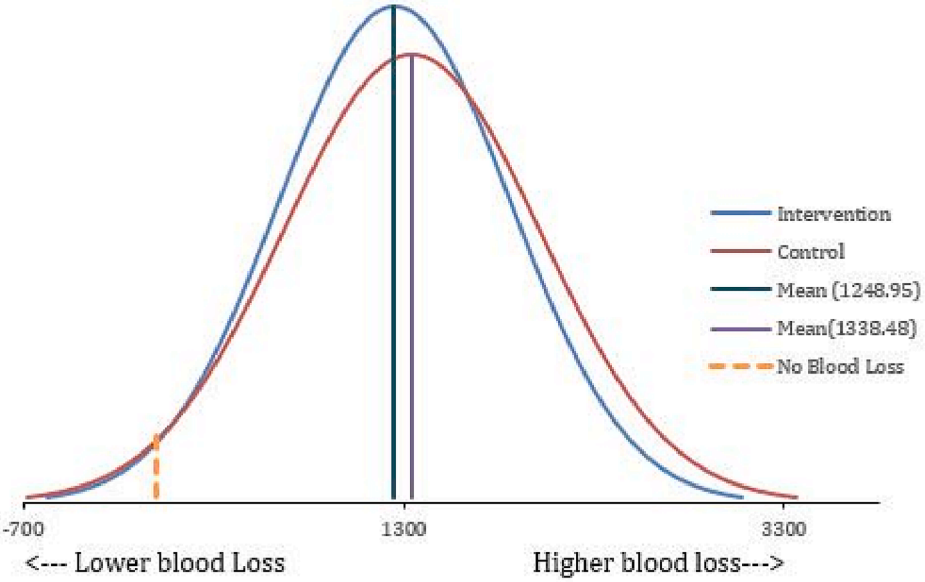

Fig. 5. A shifting the curve distribution showing total blood loss between the intervention (PPH Butterfly) and historical control group (standard care).

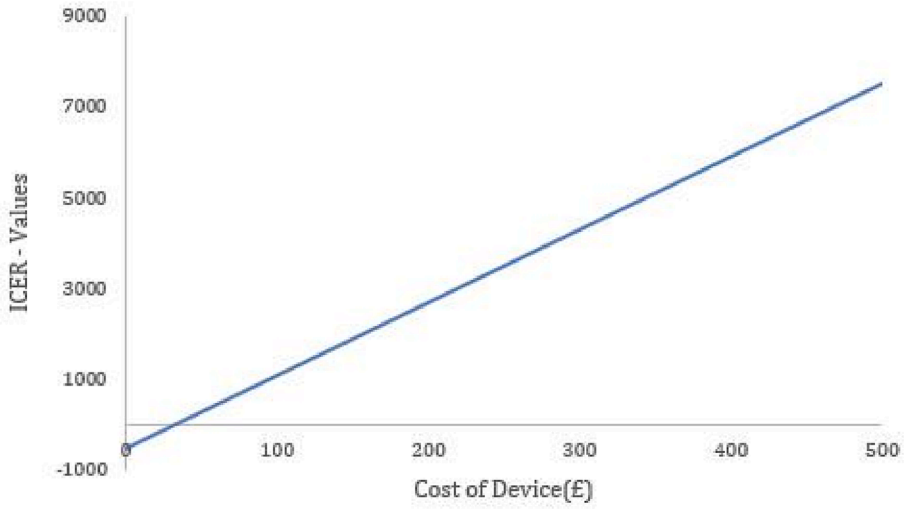

Fig. 6. A plot of the ICER values at different price range for the PPH Butterfly device.

Table 6
Hypothetical scenarios varying the number of PPH cases treated by the PPH Butterfly device and potential cost of the device.

Percentage of PPH cases treated	Cost of the PPH Butterfly device			
	£5	£50	£120	£270
100% (all cases)	£80,955	£809,550	£1.94million	£4.37million
75%	£60716.25	£607,162.50	£1.46million	£3.28million
50%	£40477.50	£404,775.00	£971,460	£2.19million
25%	£202387.75	£202,387.50	£485,730	£1.09million

Implications

NICE guidance supports the adoption of innovative medical devices should there be sufficient evidence to support the case for both clinical effectiveness and the potential for cost-savings or equivalence in cost [36]. NICE guidance acknowledges that diagnostic tools may have some additional benefits to patient health which may justify additional costs [36].

The aim of the PPH Butterfly device is to reduce the severity of PPH and in turn reduce the need for blood transfusions, which are a scarce and costly resource [37,38]. According to NHS, blood and transplant statistics, there has been an increase in the number of new blood donor registrations from 416,367 in 2015/16, to 509,009 in 2018/19 [39]. Despite this, blood products are often over prescribed and remain in constant short supply [40]. Moreover, blood transfusions have been associated with increased risk of morbidity and mortality [41–43]. NICE published guidance on blood transfusion [37,38] highlights the importance of preventing unwarranted blood transfusions and their accompanying risks, and to avoid the misuse of limited blood product resources [44]. More recently, Vogel et al. (2020) has acknowledged the lack of rigorous economic evaluation of uterine tamponade devices in general [48]. This paper addresses this need with respect to a novel device, the PPH Butterfly.

Conclusion

At costs similar to other devices used during childbirth, the PPH

Butterfly device offers value for money in the UK NHS setting. Extrapolating to the international context of lower and middle-income countries, the PPH Butterfly device could be widely introduced at low-cost to reduce avoidable maternal morbidity and mortality.

Authors' contributions

RTE co-wrote and finalised the manuscript and led the health economics work package as a co-applicant and guarantor of the health economics work reported in this paper. LB led drafting of manuscript and was lead researcher in the health economics study design, conduct and analysis. VE undertook the modelling and economic evaluation aspects of this economics study and co-wrote the manuscript. BFA was involved in the health economics costings, budget impact assessment analysis and co-wrote the manuscript. JMC was involved in the health economics study design and conduct providing maternity cover for LB in the middle of the study. AW was the study Principal Investigator. All authors contributed to, read, and approved the final manuscript.

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Clinical trial registration

https://doi.org/10.1186/ISRCTN15452399.

Condensation

Investment in effective medical devices that prevent serious postpartum haemorrhage (PPH) could improve maternal outcomes and offer value for money in the UK NHS setting.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: ADW is the co-inventor of the PPH Butterfly, whose patent is held by the University of Liverpool (with a royalty-sharing agreement with the inventors). None of the other authors declare any conflict of interest.

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Availability of Data and Material

The data analysed for the study will be made available to researchers on request to the corresponding author (RTE) or the principal investigator (AW) upon appropriate and reasonable request. Data will be shared after approval from the Trial Steering Committee with a signed data access agreement.

Ethical Approval

Ethical approval for the clinical trial was obtained from the Health Research Authority (HRA), the North West - Liverpool Central Research Ethics Committee (Ref 17/NW/0373).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejogrb.2023.02.020.

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