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Effectiveness of Closed Blood-Sampling Devices in Critically Ill Adults: A Feasibility Trial

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ABSTRACT

Background: Anaemia in critically ill patients is often worsened by diagnostic blood sampling. Closed blood sampling devices (CBSDs) may reduce iatrogenic blood loss and transfusion needs. However, robust evidence of their effectiveness and feasibility in the intensive care unit (ICU) setting is lacking.

Aim: To assess the feasibility of conducting a multicentre randomised controlled trial (RCT) evaluating the effectiveness of CBSDs in reducing transfusion requirements in critically ill adults.

Study Design: A two-centre, open-label, feasibility RCT was conducted in two Spanish university hospitals between November 2024 and March 2025. Patients with an ICU stay of 24 h who were expected to have an arterial catheter for at least 72 h longer were randomised to either a CBSD group (intervention) or standard practice (control). Primary outcome was feasibility (recruitment rate, intervention fidelity and dropout). Secondary outcomes included transfusion rates, discard volume and catheter-related adverse events. Data were collected over a maximum of 21 days or until ICU discharge or catheter removal. As this was a feasibility study with a small sample size, no statistical inference analyses were performed.

Results: Of 678 patients screened, 9.3% ($n = 63$) were eligible, and of those eligible, 76.2% ($n = 48$) were enrolled. After exclusions and losses, 31 patients were analysed (12 intervention, 19 control). Low eligibility was mainly due to short catheter dwell times and advanced monitoring needs with a Flotrac system. Intervention fidelity was suboptimal in four patients in the intervention group because one of the ICUs routinely used a venous route for blood gas sampling, despite patients having the CBSD in an arterial line. Thirteen patients (27.1%) were lost to follow-up for the same reasons as the low eligibility findings. There were no missing data (0%). Transfusion rates per 100 catheter days were lower in the intervention group (5.2 vs. 15.6). Discard volume per 100 catheter days was substantially reduced (53.1 mL vs. 970.7 mL). No catheter-related bacteraemias occurred.

Conclusions: A full-scale RCT evaluating CBSDs in ICU patients is feasible with protocol modifications, including broader site participation and improved device integration with advanced monitoring systems. Preliminary data suggest that CBSDs may reduce transfusion requirements and blood loss in critically ill patients.
Relevance to Clinical Practice: Nurses' involvement in the prevention of iatrogenic anaemia is key. CBSDs appear to be a feasible strategy for reducing blood loss associated with blood tests, with preliminary results linking their use to a decrease in the need for transfusions. If this is confirmed in the final clinical trial, it would mean greater safety for patients by avoiding complications linked to transfusions and would contribute to environmental sustainability by reducing the production of carbon dioxide associated with the process of collecting, storing and distributing red blood cells.
Trial Registration: NCT06478160

1 | Introduction

Anaemia is a common condition in intensive care patients. According to a worldwide study, 26% of 9553 study participants had a haemoglobin (Hb) level of < 9 g/dL on admission to the intensive care unit (ICU), and this proportion increased to 44% during the ICU stay [1]. In critically ill patients, the cause of anaemia is multifactorial, triggered by nutritional deficiencies, erythropoietin deficiency, haemolysis or coagulation disorders, and is worsened by repeated blood sampling for diagnostic purposes [2].

Anaemia is usually treated with blood transfusion. Approximately 10% of patients in Spanish ICUs receive at least one transfusion during their ICU stay. Furthermore, receiving a transfusion is associated with higher mortality [3]. Various studies have found an association between blood-product exposure and poor clinical outcome, with complications such as infections, multi-organ dysfunction, thrombotic events, heart failure and acute respiratory distress [4]. In addition, transfusions are a financial burden, requiring resources to collect, store and distribute the blood [5], and have a negative environmental impact. In 2019, the UK Blood and Transplant service emitted around 15 000 tonnes of carbon dioxide [6]. In 2010, the World Health Organization called on its member states to promote the rational use of blood products and implement alternatives to transfusion [7].

Patient Blood Management programmes were initially developed not only for surgical patients but have also been applied to critically ill patients. These programmes are based on three pillars: improving the clinical management of anaemia, optimising patient physiological tolerance of anaemia and minimising iatrogenic blood loss [8].

Nurses play a key role in leading environmentally sustainable healthcare policies by engaging with patients and fellow healthcare professionals [9]. It is estimated that the volume of blood collected for laboratory tests may actually exceed 40 times the volume required [10].

To minimise iatrogenic anaemia, nurses should use blood-saving techniques such as point-of-care testing, small volume/paediatric tubes and closed blood sampling devices (CBSDs) [11].

Although there is no evidence regarding which is the most effective of these techniques, CBSDs appear to be the most feasible to introduce into clinical practice [12]. Small volume tubes reduce the amount of blood needed for laboratory testing, but have no impact on discard volume (blood diluted with flush solutions and drugs that has to be discarded prior to sampling). These tubes also have the disadvantage that laboratory techniques have to be adapted to test smaller blood volumes [13]. On the contrary, CBSDs have zero discard volume because all the diluted blood is returned to the venous or arterial circulation. Although these devices can cause catheter-related adverse events (including infection and obstruction), according to the literature, such events have very low prevalence [14]. Despite this, it is essential to train healthcare professionals to use CBSDs and remind them of measures to prevent catheter-related infections [15].

While the use of paediatric tubes and CBSDs reduce blood sampling volume, current evidence does not show that they prevent haemoglobin loss or reduce transfusion needs [16]. Only one recent study associated the use of smaller volume tubes with a decrease in blood transfusion units per patient [17]. Of seven experimental studies evaluating the effectiveness of CBSDs in the prevention of anaemia and/or the need for transfusion, all of which were published before 2014, five (71.4%) excluded patients with active bleeding and yet it is these patients who might benefit most from the blood-sparing strategy achieved with a CBSD [18].

Furthermore, the recent clinical practice guideline published on transfusion strategies in critically ill patients by the European Society of Intensive Care Medicine (ESICM) [5] mentions that there are no cost-effectiveness studies of CBSDs. The ESICM task force judged that CBSDs could be used in long-stay ICU patients exposed to multiple blood draws since the devices may reduce the need for transfusions. According to a survey conducted in Argentina, Ecuador, Colombia and Spain, CBSD uptake is still low in adult ICUs. In Spain specifically, CBSDs were used in only 11.3% (22/194) of ICUs surveyed [19]. In a multicentre prevalence study in Australia and New Zealand among patients with arterial catheters, open transducer systems (requiring a stopcock and syringe method) were used in 65.7% (414/630) of cases [20].

In view of the lack of studies on CBSD effectiveness in critically ill medical and surgical adult patients, we conducted a two-centre feasibility randomised controlled trial (RCT) to compare transfusion needs and adverse event incidence in CBSDs versus standard practice. The aim was to assess recruitment rate, intervention fidelity and dropout.

Impact Statements

- What is known about the topic?
  - Anaemia in ICU patients is worsened by blood sampling, leading to risky consequences.
  - CBSDs are blood-sparing systems that return the initial discard volume to the patient.
  - Robust evidence for CBSD effectiveness is lacking, and their clinical uptake remains low.
- What this paper adds?
  - Preliminary data suggest CBSDs reduce blood waste and may lower transfusion rates and patient morbidity.
  - The feasibility trial helps provide specific protocol modifications to ensure a future definitive trial is successful.
  - Furthermore, key barriers to a larger trial are identified, including low eligibility and equipment incompatibility.

2 | Design and Methods

2.1 | Design

Study reporting followed the CONSORT guideline extension to randomised pilot and feasibility trials (Table S1).

A two-centre, two-arm, parallel-group, 1:1 randomisation feasibility RCT was conducted, comparing an intervention group (IG) (with a CBSD for blood sampling) and a control group (CG) (without a CBSD, following standard practice of discarding blood drawn before obtaining the laboratory sample). For the CBSD, we used the two models marketed in Spain with CE marking: Safedraw (Merit Medical) [21] and VAMP (Edwards) [22]. The study protocol was registered as NCT06478160 on ClinicalTrials.gov.

2.2 | Setting and Sample

The feasibility RCT was conducted at two public university hospitals, Hospital Universitario Virgen Macarena (HVUM, Seville) and Hospital Universitario 12 de Octubre (HUOC, Madrid), both in Spain. One has 30 beds for medical-surgical patients and admits 1378 patients/year with an average 6.26-day stay per patient. The other has 60 beds, also for medical-surgical patients, an average of 2600 admissions/year and a 4.6-day stay per patient. In Spain, nurses all hold a Bachelor Degree in Nursing, and the nurse:patient ratio in both ICUs is 1:2. The two ICUs are part of the Spanish Society for Intensive and Critical Care Medicine and Coronary Units (SEMICYUC), which, together with the Spanish Society for Intensive Care and Coronary Unit Nursing (SEEIUC), promote the evaluation of quality indicators for critical-care patients [23], the purpose of which is to encourage evidence-based practice, including avoiding red blood cell transfusions in patients with pre-transfusion haemoglobin (Hb) > 7 mg/dL and complying with hand hygiene measures.

In a multicentre survey of 194 ICUs in Spain, 69.1% of ICUs were unaware of the existence of a protocol regulating the discard volume (DV) needed for each catheter type [19]. In the two ICUs participating in this study, no protocol was in place.

A sample was taken of consecutive critically ill patients fulfilling the inclusion and exclusion criteria shown in Table 1. These criteria were based on a review of the literature published to date [24–27].

2.3 | Intervention

Two types of blood draw techniques were compared. In the IG, a CBSD was used in an arterial catheter, with zero DV because the blood containing flush solution was reinfused into the patient. In the CG, the standard technique was followed, discarding blood before drawing the sample for testing. In both groups, if blood was collected via other routes apart from the arterial catheter, this was logged in the case report form (CRF) in order to determine the patient's total blood loss. All the ICU nurses were trained in correct CBSD use as per the device instruction leaflet. Safedraw CBSDs were used in ICU-HUVM [21] and Edwards CBSDs [22] in ICU-HUOC, ensuring that a single device technique would be used at each hospital. All the ICU nurses were reminded about arterial catheter care procedures (transducer position at the level of the right atrium or

TABLE 1 | Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Over 18 years of age • Recruited during the first 24 h of ICU stay • Arterial catheter inserted in the first 24 h of ICU stay and expected to be used at least 72 h after recruitment	• Limitation of life-sustaining therapies • Express refusal of transfusion • Admission for: • Trauma • Burns • Liver surgery • Orthopaedic surgery • Chronic kidney failure • Active gastrointestinal bleeding • Haematological cancer • Menstruation on admission or during enrolment into study • Pregnancy

Abbreviation: ICU: intensive care unit.

midaxillary line, transducer zeroing to reference atmospheric pressure, and 8-hourly system pressurisation checks). They were also trained on how to log arterial catheter-related adverse events in the study CRF: fast flush test [28], criteria for possible catheter obstruction [29] and steps to follow for suspected catheter-related bacteraemia [30].

2.4 | Study Outcomes

The primary outcome was to examine the study feasibility criteria (Table 2), and secondary outcomes were number of blood units transfused, DV and catheter-related adverse events.

2.5 | Sample Size

Since the goal of pilot trials is not to estimate or test intervention efficacy or effectiveness, traditional sample size calculations for definitive trials are not directly applicable [31]. We estimated we needed to enrol at least 59 patients, according to Viechtbauer's formula [32]. The sample size of the multicentre RCT was calculated using data from the Riessen study [33], anticipating a reduction in the number of patients needing transfusion of 32% in the CG and of 8% in the IG. With a 95% confidence level and 80% power, and adding 20% to allow for expected losses, we estimated that we needed to enrol 54 patients in each study group. However, assuming that the outcome would differ between medical and surgical patients, according to the Riessen study data [33], we planned to analyse the variables by medical or surgical subgroup, and it was therefore necessary to enrol 54 medical and 54 surgical patients in both the CG and IG. In short, we needed 108 patients in total for the CG and 108 for the IG. The feasibility study duration was 4 months so that we could determine the recruitment rate and be able to plan the time needed to collect the data for the final sample.

2.6 | Allocation and Randomisation

A randomisation sequence was created by a statistician, using computer-generated coded lists, stratified by ICU and by medical or surgical admission diagnosis, varying the block length to ensure the randomisation sequence was concealed prior to patient enrolment. The coded list was delivered to the ICU in sealed envelopes and kept in a locked box. Blinding to the type of intervention performed was impossible as the presence or absence of CBSD was visible, making this an open-label study. Indication for blood transfusion was decided by other professionals (the ICU physicians responsible for the patients) who were not involved in the study, following clinical transfusion guidelines and quality indicators established by scientific societies [23, 34].

2.7 | Data Collection

Nurses from the participating ICUs were trained as collaborating investigators for the study and formed part of the Blood-Sparing Research Group. Every day from November 2024 to March 2025, the nurses reviewed patients admitted to the ICU to check if they met the inclusion and exclusion criteria during the first 24 h of their stay and, if appropriate, patients were asked to consent to participate in the study. If they consented, they picked an envelope from the box for randomisation.

A baseline data record was created for patient enrolment in the study and another for daily follow-up. Patients remained in the study for a maximum of 21 days after randomisation (day 22 of ICU admission), until ICU discharge or death, or until the arterial catheter was removed definitively.

The collaborating investigators (nurses in the Blood-Sparing Research Group) logged the study, demographic and clinical data at the time of patient enrolment: study group allocation (control or intervention), Safedraw or VAMP device (in the case of the IG), age, sex, diagnosis on admission, place admitted from, SAPS 3 score and Charlson comorbidity score.

They also logged daily follow-up data: haemoglobin and haematocrit (lowest values in 24 h), blood transfusion units, cumulative daily dose of drugs inducing anaemia and/or haemolysis or bone marrow suppression, administration of coagulation factors, erythropoietin, iron and vitamin B12, and ICU stay and hospital stay in days.

The nurses responsible for each patient logged the following data in the CRF related to the blood draw technique: DV via the arterial catheter in the CG, DV via other routes apart from the arterial catheter in both groups, blood volume (mL) drawn for testing, blood loss associated with renal clearance therapies and/or extracorporeal membrane oxygenation (ECMO), fast flush test result (worst in 24 h), presence of signs of bleeding (drainage output (mL/day), rectal bleeding and haematemesis).

TABLE 2 | Study outcomes.

Primary outcome (feasibility criteria)	Secondary outcomes (clinical data)
1. Eligibility: ≥ 50% screened were eligible for allocation 2. Allocation: ≥ 70% of eligible patients are randomised 3. Intervention fidelity: ≥ 95% receive care as per study protocol 4. Retention: < 10% loss to follow-up 5. Missing data: < 5%–10% of study outcomes	1. Number of blood units transfused per patient per 100 arterial catheter days 2. Discard volume per patient per 100 arterial catheter days 3. Incidence of arterial catheter-related adverse events per 100 catheter days

They also recorded arterial catheter-related adverse events: bacteraemia, CBSD malfunction, loss of arterial pressure waveform monitoring, catheter change and reason.

2.8 | Data Analysis

Data collected in the CRFs were reviewed and cleaned as per trial protocol criteria. Missing data were retrieved when possible through the patients' electronic medical records. Qualitative variables (sex, diagnosis, place admitted from, feasibility outcomes) were described using absolute frequencies and percentages, and quantitative variables using mean and standard deviation or median and interquartile range, depending on the data distribution. Variables were tested for normality using the Kolmogorov–Smirnov test. As this was a feasibility study with a small sample size, no statistical inference analyses were performed. Statistical analyses were performed using IBM SPSS Statistics for Windows (version 26.0. IBM Corp.).

3 | Ethical Considerations

The research ethics committee of HUVM approved the study protocol in the 30 October 2024 (internal code: SRS-UCI-HUVM24) and the committee of HUOC issued a favourable feasibility report. Patients were asked to participate in the study and if they agreed, they gave their written informed consent; if

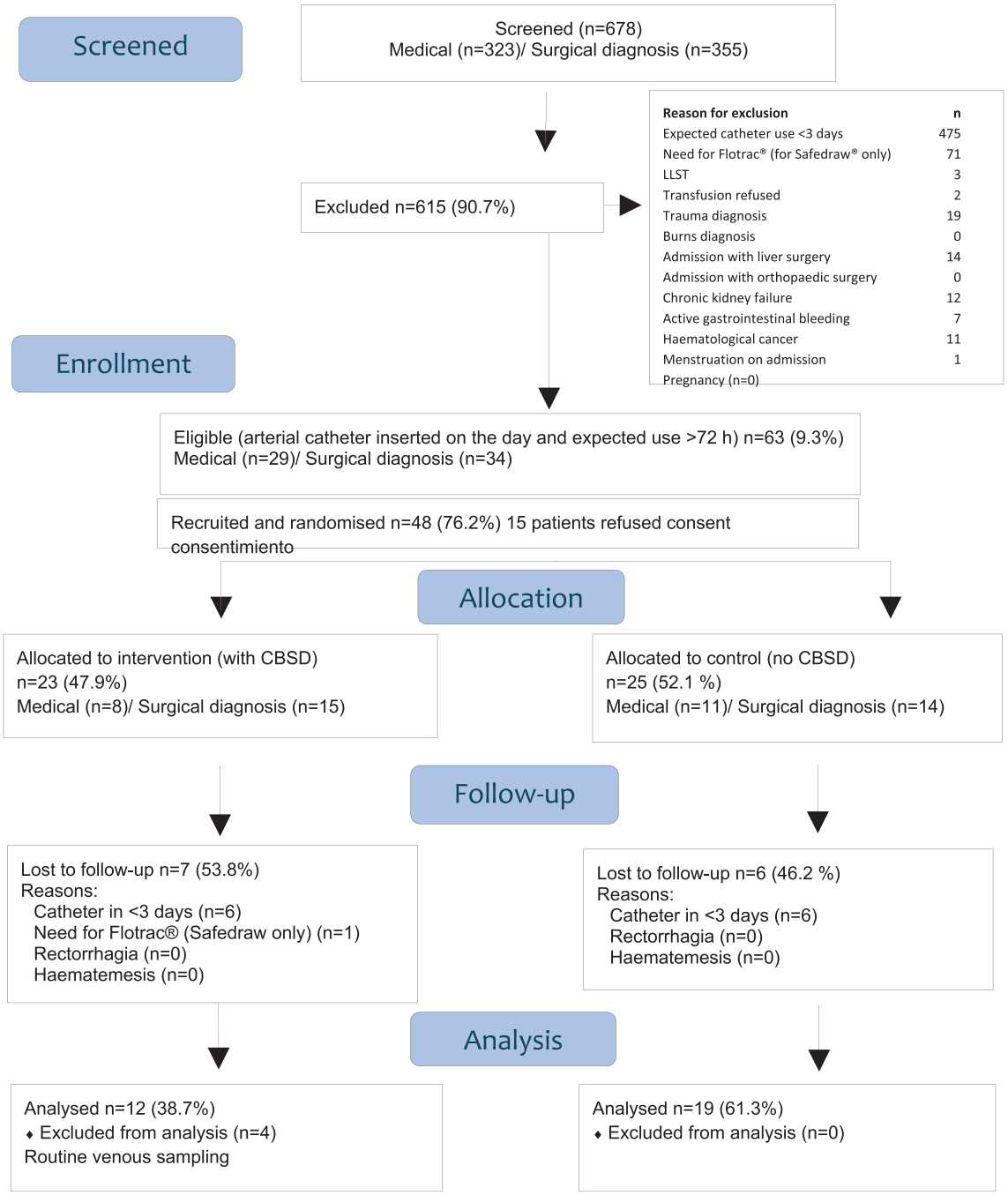

FIGURE 1 | Flowchart.

their clinical situation did not allow it, family members were asked for their consent. When patients regained consciousness, they received an explanation about the arterial device that had been placed in situ and were given the opportunity to revoke the family member's consent if they wished.

4 | Results

From 24 November 2024 to 21 March 2025, 678 patients were screened, of whom 63/678 (9.3%) were found to be eligible. A total of 48/63 (76.2% of the eligible patients) consented to participate in the study and were randomised (Figure 1). Thirteen patients (13/48, 27.1%) were lost to follow-up: 12 due to having an arterial catheter dwell time < 3 days and one who was withdrawn from the study due to advanced monitoring needs with a Flotrac system. Four patients in the IG were excluded from the analysis for receiving off-protocol care. The final sample consisted of 31 patients, 12 patients (12/31, 38.7%) in the IG (6 medical and 6 surgical) and 19 patients (19/31, 61.3%) in the CG (10 medical and 9 surgical).

Clinical data were logged for a total of 115 arterial catheter days in the IG and 167 days in the CG.

4.1 | Primary Outcome: Feasibility Criteria

Two feasibility criteria were met (Table 3): allocation (48/63, 76.2%) and missing data (0%). The eligibility criterion was met by only 63/678 (9.3%), mainly because most patients (475/615; 77.2%) were expected to have a catheter dwell time of < 3 days on the day of randomisation (day 1 of ICU admission). In addition, 71/615 patients (11.5%) could not be enrolled in the ICU that used Safedraw because they needed advanced haemodynamic monitoring with Flotrac. Intervention fidelity was 91.7% (44/48), with four patients having blood drawn via routes other than the arterial line with the CBSD. In the CRFs, it was observed that one of the ICUs routinely used a venous route for blood gas sampling, despite patients having the CBSD in an arterial line. This approach increased the DV, which was expected to be almost zero in the IG (except for DV prior to sampling for blood cultures). Furthermore, more losses to follow-up were observed than expected (27.1%). The reason was catheter dwell time < 3 days, and in one case, the need for Flotrac during study participation.

TABLE 3 | Feasibility results.

Criterion and target	Result	Target achieved
Eligibility		
• ≥ 50% screened were eligible for allocation	63/678 (9.3%)	No
Allocation		
• ≥ 70% of eligible patients are randomised	48/63 (76.2%)	Yes
Intervention fidelity		
• ≥ 95% receive care as per study protocol	44/48 (91.7%)	No
Retention		
• < 10% loss to follow-up	13/48 (27.1%)	No
Missing data		
• < 5% transfusion records	0 (0%)	Yes
• < 10% discard volume records	0 (0%)	Yes
• < 10% fast flush test record	0 (0%)	Yes

4.2 | Secondary Outcomes: Clinical Data

The baseline data of the patients assigned to each study group were comparable (Table 4). For every 100 arterial catheter days, 5.2 blood units were transfused in the IG versus 15.6 units in the CG; DV was 53.1 mL IG versus 970.7 mL CG; suboptimal arterial pressure waveform monitoring was 12.2 IG versus 6.7 CG, loss of arterial pressure waveform monitoring was 3.5 IG versus 0.6 CG and catheter malfunction was 3.5 IG versus 1.2 CG. There were no episodes of catheter-associated bacteraemia (Table 5).

TABLE 4 | Baseline sample characteristics ($n = 31$).

	Intervention group ($n = 12$)	Control group ($n = 19$)
Age (years), Median [P25–P75].	62 [55–70]	63 [60–73]
Sex, female, *n* (%)	4 (33)	8 (42)
Diagnosis on admission, *n* (%)		
Medical	6 (50)	10 (53)
Surgical	6 (50)	9 (47)
Place admitted from, *n* (%)		
Ward	—	5 (26)
Operating theatre	5 (42)	7 (37)
Other ICU/other hospital	—	—
Emergency department	6 (50)	7 (37)
Out-of-hospital	1 (8)	—
Chronic hospital care	—	—
SAPS 3, Median [P25–P75]	58 [49–64]	54 [47–66]
Charlson, Median [P25–P75]	3 [1–3]	4 [2–5]

Abbreviation: SAPS, Simplified Acute Physiology Score Median [25th percentile–75th percentile].

TABLE 5 | Clinical results.

	Intervention group ($n=12$)	Control group ($n=19$)
Number of blood units transfused per patient per 100 arterial catheter days	5.2	15.6
Discard volume (DV) per patient per 100 arterial catheter days (mL)	53.1	970.7
Suboptimal arterial pressure waveform monitoring per 100 catheter days	12.2	6.7
Arterial catheter-related bacteraemia per 100 catheter days	0	0
Loss of arterial pressure waveform monitoring per 100 catheter days	3.5	0.6
Catheter malfunction per 100 catheter days	3.5	1.2

Abbreviation: DV: Discard volume (blood diluted with flush solutions and drugs that is discarded prior to blood drawn for laboratory tests).

5 | Discussion

A total of 31 patients were analysed in this feasibility study and the intervention with CBSD was found to be safe, with no serious adverse events associated with the arterial catheter. However, more ICU participants need to be recruited in the definitive RCT because eligibility was lower than expected since few patients require an arterial catheter for more than 3 days during an ICU stay.

Experts' recommendations in the ESICM clinical practice guideline [5] state that 'the effects of CBSD upon blood transfusion are probably small, especially in patients for whom ICU stay and arterial catheter duration of use are short' (p. 685). We reviewed the study inclusion criteria: patients with an ICU stay of 24 h who are expected to have an arterial catheter for at least 72 h longer. We decided to maintain the inclusion criterion of expected arterial line use of at least 72 h, as assessed on the day of recruitment (during the first 24 h of the ICU stay), despite the low eligibility rate detected in the feasibility study. As a result, we decided to add two more ICUs to the main RCT and train the nurses in those ICUs in the use of CBSDs. In addition, the Safedraw device is now used alongside Flotrac systems after implementing a specific connection line set-up protocol to make the two systems compatible. This set-up might alter the fast flush test, and therefore use of a Flotrac system will be recorded in the patient's CRF. We believe these measures will increase the eligibility rate and reduce loss to follow-up.

In addition, the study protocol was modified for the ICU that routinely takes venous samples for blood gases, due to routine medical practice in that ICU for monitoring cardiac output and tissue perfusion with venous oxygen saturation. The protocol now states that if patients are allocated to the CBSD IG, another CBSD will be placed in the venous line in order to eliminate DV from venous sampling. Placement of a second CBSD will be recorded in the CRF to take it into account in the cost-effectiveness analysis at the end of the clinical trial.

In this feasibility study, with just 31 patients analysed, we observed that the CG transfusion rate tripled the IG transfusion rate, and medical and surgical patients were represented equally in the two study groups. A meta-analysis published by Keogh et al. in 2023[25] also found a statistically significant decrease in transfusion requirements with the use of CBSDs in the only two studies that measured this outcome (RR: 0.65 [95% CI: 0.46, 0.92] $I^2=0\%$). The large volume of blood discarded in the CG of almost 1 L in only 100 arterial catheter days was unsurprising. Lack of a DV protocol explains the high variability of DV drawn via the arterial catheter [19], such that 55.2% of ICUs discard 2.1–5 mL of blood, 55.2% discard 5.1–8 mL and 12.9% discard 8.1–10 mL of blood.

With CBSDs, all this lost blood volume is spared, which reduces transfusion needs. However, CBSDs give a less reliable blood pressure reading, as noted in a scoping review on the effectiveness of CBSDs [16]. Recently, Lavault et al. [35] tested two alternative methods to the fast flush test to evaluate continuous arterial pressure waveform and concluded that in arterial systems with CBSDs, the natural frequency of the circuit decreases slightly while the damping coefficient remains stable, like arterial systems without CBSDs. Therefore, the longer term cost/benefit ratio of the intervention will have to be evaluated along with the final results of the trial, together with a cost-effectiveness analysis.

We have observed no episodes of arterial catheter-related bacteraemia to date, although an analysis of more catheter days is pending, since according to a review by Mariano Gomes et al. [36], the incidence of arterial catheter-related bacteraemia is 3.40 per 1000 catheters or 0.96 per 1000 catheter days.

5.1 | Strengths and Limitations

Training nurses to use the CBSDs by means of videos and bedside practice with low-fidelity simulators was optimal because no adverse events (bacteraemia, CBSD malfunction, loss of arterial pressure waveform monitoring or catheter change) occurred due to incorrect blood withdrawal practices. Training the nurse investigators participating in the study was effective because there was no unrecoverable data loss from the medical records. Although the study sample started with 48 randomised patients, the 27.1% loss to follow-up left only 31 patients (12 in the IG and 19 in the CG). This limits the interpretation of the clinical data, but we decided to proceed with the analysis in order to identify how the study protocol could be improved before adding two new ICUs. In addition, we took action to improve the percentage of eligibility and reduce loss to follow-up.

6 | Recommendations for Practice and/or Further Research

This study's data support CBSDs as a promising, nurse-led strategy to reduce the significant transfusion requirements and blood loss in critically ill patients. A large-scale trial to confirm these benefits is feasible, provided the protocol is modified to overcome the barriers identified. Future research should expand to more sites to enhance recruitment and address technical incompatibilities with monitoring systems. A definitive trial must also include a cost-effectiveness analysis to fully evaluate this intervention.

7 | Conclusions

A full-scale RCT evaluating CBSDs in ICU patients is feasible with protocol modifications to ensure that blood is not discarded via alternative routes apart from the arterial catheter in the IG, with broader site participation and improved device integration with advanced monitoring systems. Preliminary data suggest CBSDs may reduce transfusion requirements and blood loss in critically ill patients.

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Ethics Statement

The research ethics committee of HUVM approved the study protocol (SRS-UCI-HUVM24) and the committee of HUOC issued a favourable feasibility report.

Consent

Patients were asked to participate in the study with written informed consent; if their clinical situation did not allow it, family members were asked for their consent. When patients regained consciousness, they received an explanation about the arterial device that had been placed in situ and were given the opportunity to revoke the family member's consent if they wished.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Data S1:** CONSORT 2010 Extension Checklist for Pilot and Feasibility Trials.

Appendix A

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