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MAIN TEXT

# Heterogeneity in clinical practices for post-cardiotomy extracorporeal life support: A pilot survey from the PELS-1 multicenter study

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## Abstract

**Background:** High-quality evidence for post-cardiotomy extracorporeal life support (PC-ECLS) management is lacking. This study investigated real-world PC-ECLS clinical practices.

**Methods:** This cross-sectional, multi-institutional, international pilot survey explored center organization, anticoagulation management, left ventricular unloading, distal limb perfusion, PC-ECLS monitoring, and transfusion practices. Twenty-nine questions were distributed among 34 hospitals participating in the Post-cardiotomy Extra-Corporeal Life Support Study.

**Results:** Of the 32 centers [16 low-volume (50%); 16 high-volume (50%)] that responded, 16 (50%) had dedicated ECLS specialists. Twenty-six centers (81.3%) reported using additional mechanical circulatory supports. Anticoagulation practices were highly heterogeneous: 24 hospitals (75%) reported using patients bleeding status as a guide, without a specific threshold in 54.2% of cases. Transfusion targets ranged from 7 to 10 g/dL. Most centers used cardiac venting

List of PELS-1Investigators are available in Supplemental Materials.

on a case-by-case basis (78.1%) and regular distal limb perfusion (84.4%). Nineteen (54.9%) centers reported dedicated monitoring protocols, including daily echocardiography (87.5%), Swan-Ganz catheterization (40.6%), cerebral near-infrared spectroscopy (53.1%), and multimodal assessment of limb ischemia. Inspection of the circuit (71.9%), oxygenator pressure drop (68.8%), plasma free hemoglobin (75%), d-dimer (59.4%), lactate dehydrogenase (56.3%), and fibrinogen (46.9%) are used to diagnose hemolysis and thrombosis.

**Conclusions:** This study shows remarkable heterogeneity in clinical practices for PC-ECLS management. More standardized protocols and better implementation of the available evidence are recommended.

**KEYWORDS**

cardiac surgery, clinical practices, extracorporeal life support, heart failure, post-cardiotomy shock, survey

## 1 | INTRODUCTION

The application of veno-arterial extracorporeal life support (V-A ECLS) in post-cardiotomy shock has been reported in 0.4% to 3.6% of cases[1] and has significantly increased in the past decades.[2,3] Nevertheless, data obtained from the Extracorporeal Life Support Organization (ELSO) registry indicate that, even with improved successful weaning, survival to hospital discharge remains low.[2,4] Despite the growing number of patients and the data provided by observational studies, we still lack high-quality evidence to standardize post-cardiotomy ECLS (PC-ECLS) care. A first attempt has been made with the 2020 EACTS/ELSO/STS/AATS expert consensus paper on PC-ECLS in adults[5] and the ELSO interim guidelines for V-A ECLS in adult cardiac patients.[6] However, it is unclear how well these guidelines have been applied, and their release is very recent.[7] There is evidence that a standardized team-based approach for PC-ECLS can produce promising results,[8] but little is known about the extent of heterogeneity in PC-ECLS practices. The primary step to understanding this knowledge gap is to investigate current real-life clinical practices. The Post-cardiotomy Extra-Corporeal Life Support Study (PELS-1) collected data on adults suffering from post-cardiotomy cardiogenic shock and requiring ECLS support in cardiac surgery units worldwide.[9] The present article reports the results of a survey conducted among PELS-1 participating centers to highlight similarities and differences in terms of five key issues: (1) Characteristics of PC-ECLS hospitals; (2) Anticoagulation management and transfusion; (3) Left ventricular (LV) unloading; (4) Distal limb perfusion; (5) General ECLS monitoring practices.

## 2 | MATERIALS AND METHODS

### 2.1 | Development of the survey

The PELS-1 Working Group designed and conducted a multi-institutional, multi-national pilot survey with input from the specialists from adult ECLS units. The list of invited cardiac surgery units was populated from the PELS-1 participating centers. As this was a quality improvement survey, specific ethical approval was waived. However, the PELS-1 study was conducted in accordance with the Declaration of Helsinki, and Institutional Review Board approval was obtained (number: METC-2018-0788, date: December 19th, 2018). This pilot survey was conducted and reported according to the consolidated criteria for reporting qualitative studies (COREQ).[10]

### 2.2 | Design of the survey

The survey was designed based on 29 questions (Supplemental methods) including five essential themes: (1) characteristics of ECLS center and institution; (2) anticoagulation management and transfusions; (3) left ventricular unloading; (4) distal limb perfusion; (5) ECLS monitoring practices. The survey included multiple-choice and open-ended (free text) questions. The survey, once designed, was sent to an independent reviewer (MEDP) for critical review. Following feedback, the survey underwent revision and further testing by the PELS-1 Working Group representatives and was then accepted for distribution.

### 2.3 | Distribution of the survey

PELS-1 is an international, multi-center, retrospective study enrolling consecutive patients supported with ECLS in the postoperative phase (ClinicalTrials.gov: NCT03857217) in 34 centers from 16 countries. In September 2021, a researcher (SM) from the coordinating center distributed the above-mentioned questionnaire to the PELS-1 principal investigator of each center through email. In the event of no response, a reminder was sent after 4 weeks and after 8 weeks. No face-to-face interviews, repeated interviews, or audio/visual recordings were performed. In cases of missing data or unclear answers, questionnaires were returned to participants for comment and/or correction. If after 2 reminders, no answer was available, missing data were considered "not reported."

### 2.4 | Data analysis

The data were exported in a dedicated file format into Microsoft Excel (Washington, USA, Version 16.35) and reviewed by three researchers (SM, GB, and JMR). Variables are expressed as numbers (valid percent based on available data, excluding missing values) for categorical variables. All descriptive statistics were performed on the original data, and no imputations were performed. Categorical data were compared between groups with Pearson's Chi-Square, Fisher's exact test, or the Fisher–Freeman–Halton Exact Test, as appropriate. The descriptive analysis addressed differences between low-volume (≤30 V-A ECLS cases per year) and high-volume (>30 V-A ECLS cases per year) centers.[11-13] We considered a 2-sided $p$-value <0.05 statistically significant. All data were merged from de-identified files into SPSS 26.0 (IBM, New York, USA) and R 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria) for data management and statistical analysis. The final report was shared with all participants before publication.

## 3 | RESULTS

### 3.1 | Characteristics of the participating centers

Thirty-two centers (94.1%) responded to the PELS-1 Survey. Two centers did not submit their questionnaires despite 2 reminders. Most centers were in Europe ($n=22$, 68.8%; Table 1), academic hospitals ($n=24$, 75%), and referral centers for transplants and ventricular assist devices (VAD, $n=23$, 71.9%). High-volume centers were academic hospitals ($n=16$, 100%, $p=0.002$). The annual surgical volume, intensive care unit bed capacity, and V-A ECLS volume ranged widely (Figure 1). Sixteen centers (50%) treated more than 30 V-A ECLS cases per year, and two centers (6.3%) declared a V-A ECLS volume >100 cases per year. Most centers ($n=26$, 81.3%) reported the availability of other types of mechanical circulatory support. ECLS specialists were present in 16 (50%) hospitals, equally distributed between high- and low-volume centers (Table 1).

### 3.2 | Anticoagulation management and transfusion

Most hospitals declared to administer a full dose of protamine ($n=16$, 52%) at the end of the cardiac operation when an intra-operative ECLS is required, especially high-volume hospitals ($n=11$, 69%, Figure 2A). Anticoagulation is mostly started at a variable time based on the patient's bleeding ($n=24$, 75%, Figure 2B). Thirteen centers (54.2%) did not report a specific bleeding monitoring protocol, but they disclosed that they start anticoagulation based on a subjective judgment of reduced post-operative bleeding (Table S1). Centers that reported a specific bleeding threshold showed a high heterogeneity (Table S1). The main first choice of anticoagulation drug was continuous infusion of unfractionated heparin ($n=31$, 96.9%, Table 2), while the most popular second choices were bivalirudin ($n=15$, 43%) and argatroban ($n=8$, 23%). Most hospitals ($n=25$, 43.9%) declared to use activated partial thromboplastin time (aPTT) for anticoagulation monitoring. However, frequency and target values (Table 2 and Table S2) differed widely. Heterogeneity was observed regarding other anticoagulation monitoring methods, such as activated clotting time (ACT, $n=9$, 15.8%), anti-Xa activity ($n=8$, 14%), TEG/ROTEM ($n=8$, 14%) or prothrombin time ($n=4$, 7%). The hemoglobin threshold to transfuse patients ranged from 7 to 10 g/dL (Table 3).

### 3.3 | LV unloading and distal limb perfusion

Only 4 (12.5%) centers routinely use LV unloading strategies in all PC-ECLS cases (Table 3). Most centers ($n=25$, 78.1%) reported considering LV unloading on a case-by-case basis. Intra-aortic balloon pump remains the most common unloading strategy ($n=18$, 56.3%). Most centers ($n=27$, 84.4%) declared to regularly use distal limb perfusion with femoral cannulation.

### 3.4 | ECLS monitoring

Nineteen centers (59.4%) reported specific PC-ECLS monitoring protocols (Table 4). Limb perfusion is frequently

**TABLE 1** Centers characteristics.

| | Overall ($n=32$) | Low volume ($n=16$) | High volume ($n=16$) | $p$-value |
|---|---|---|---|---|
| Continent | | | | 0.754 |
| Asia | 3 (9.4%) | 1 (6.3%) | 2 (12.5%) | |
| Australia | 3 (9.4%) | 2 (12.5%) | 1 (6.3%) | |
| Europe | 22 (68.8%) | 10 (62.5%) | 12 (75%) | |
| North America | 2 (6.3%) | 1 (6.3%) | 1 (6.3%) | |
| South America | 2 (6.3%) | 2 (12.5%) | 0 (0%) | |
| Center type | | | | 0.550 |
| VAD center | 5 (15.6%) | 3 (18.8%) | 2 (12.5%) | |
| Transplant and VAD center | 23 (71.9%) | 10 (62.5%) | 13 (81.3%) | |
| Non-transplant non-VAD center | 4 (12.5%) | 3 (18.8%) | 1 (6.3%) | |
| Hospital type | | | | 0.002 |
| Academic | 24 (75%) | 8 (50%) | 16 (100%) | |
| Non-academic | 3 (9.4%) | 3 (18.8%) | 0 (0%) | |
| Private hospital | 4 (12.5%) | 4 (25%) | 0 (0%) | |
| Other | 1 (3.1%) | 1 (6.3%) | 0 (0%) | |
| Overall beds | | | | 0.352 |
| 0–499 | 8 (25%) | 6 (37.5%) | 2 (12.5%) | |
| 501–1000 | 11 (34.4%) | 5 (31.3%) | 6 (37.5%) | |
| >1000 | 13 (40.6%) | 5 (31.3%) | 8 (50%) | |
| ICU beds | | | | 0.395 |
| 0–30 | 7 (21.9%) | 5 (31.3%) | 2 (12.5%) | |
| 31–60 | 16 (50%) | 8 (50%) | 8 (50%) | |
| 61–90 | 2 (6.3%) | 0 (0%) | 2 (12.5%) | |
| >90 | 7 (21.9%) | 3 (18.8%) | 4 (25%) | |
| ICU type | | | | 0.719 |
| Only cardiac | 19 (59.4%) | 9 (56.3%) | 10 (62.5%) | |
| Mixed | 13 (40.6%) | 7 (43.8%) | 6 (37.5%) | |
| Operations/year | | | | 0.180 |
| 0–500 | 4 (12.5%) | 2 (12.5%) | 2 (12.5%) | |
| 501–1000 | 13 (40.6%) | 9 (56.3%) | 4 (25%) | |
| >1000 | 15 (46.9%) | 5 (31.3%) | 10 (62.5%) | |
| Other ECLSs/year | | | | 0.220 |
| 0–30 | 24 (75%) | 14 (87.5%) | 10 (62.5%) | |
| >30 | 8 (25%) | 2 (12.5%) | 6 (37.5%) | |
| Other MCS available | 26 (81.3%) | 13 (81.3%) | 13 (81.3%) | 1.000 |
| Other MCS type | | | | 0.643 |
| Nothing | 6 (14%) | 3 (14%) | 3 (13%) | |
| Impella | 23 (52%) | 10 (48%) | 13 (57%) | |
| Levitronix | 5 (11%) | 4 (19%) | 1 (4%) | |
| TandemHeart-ProtekDuo | 4 (9%) | 2 (10%) | 2 (9%) | |
| VAD | 6 (14%) | 2 (10%) | 4 (17%) | |
| Other | 0 (0%) | 0 (0%) | 0 (0%) | |
| ECLS specialists | 16 (50%) | 7 (43.8%) | 9 (56.3%) | 0.480 |

*Note*: Data are reported as $n$ (% as percentage excluding missing values). $p$ values by chi squared indicate statistically significant differences between low-volume and high-volume centers.

Abbreviations: ECLS, extracorporeal life support; ICU, intensive care unit; MCS, mechanical circulatory support; VAD, ventricular assist device.

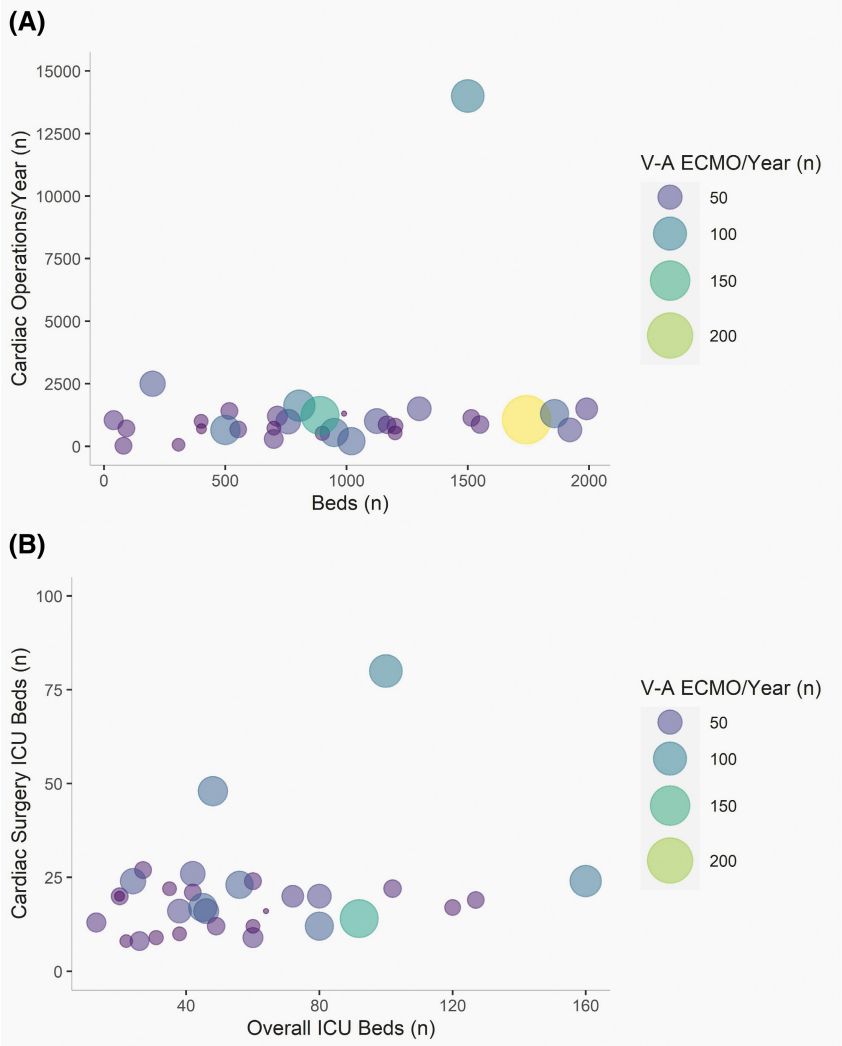


**FIGURE 1** Bubble chart representing (A) overall bed capacity, annual cardiac operations and veno-arterial extracorporeal life support (V-A ECLS) annual use. (B) overall intensive care units (ICU) beds, cardiac surgery ICU beds and V-A ECLS annual use.

monitored with a multi-modality approach including clinical observation ($n=25$, 78.1%), ultrasound ($n=22$, 68.8%) and skin temperature evaluation ($n=18$, 56.3%). Neuromonitoring is mainly based on near-infrared spectroscopy (NIRS; $n=17$, 53.1%), especially in low-volume centers ($p=0.013$). Echocardiography is performed daily in most centers ($n=28$, 87.5%), while Swan-Ganz catheterization is used in 40.6% of centers ($n=13$). Other organs are rarely monitored routinely (Table 4) and lung ultrasound is used only in low-volume centers ($p=0.043$). Most centers evaluate hemolysis through concentrations of free hemoglobin ($n=24$, 75.0%) and thrombosis by direct inspection of the circuit ($n=23$, 71.9%), oxygenator pressure drop ($n=22$, 68.8%), D-dimer (59.4%), lactate dehydrogenase (56.3%), and fibrinogen (46.9%).

## 4 | DISCUSSION

This pilot PELS-1 survey is the first cross-sectional, multi-institutional, international survey on clinical practices for PC-ECLS management. This descriptive work reports responses from 32 ECLS centers from 16 countries, with 68.8% being European centers. Half of the participants represented high volume (>30 V-A ECLS cases/year) units, and about three quarters were academic hospitals and referral centers for heart transplantation and VAD. The inclusion of different types of ECLS units from different countries makes this pilot survey representative of PC-ECLS practices. Extreme heterogeneity in all five major PC-ECLS themes was observed.

Post-cardiotomy cardiogenic shock represents one of the most common ECLS indications in adults.[2,3,4,5,14] The current clinical scenario pushes every cardiac surgery unit to provide an ECLS service besides the normal cardiac surgery activity, regardless of the center's ECLS case load. Nevertheless, to optimize outcomes, it is recommended that centers performing ECLS for cardiac failure achieve a minimum ECLS volume of 30 cases per year, with a substantial proportion being for cardiac failure.[11,12,13,15] This survey revealed that several hospitals

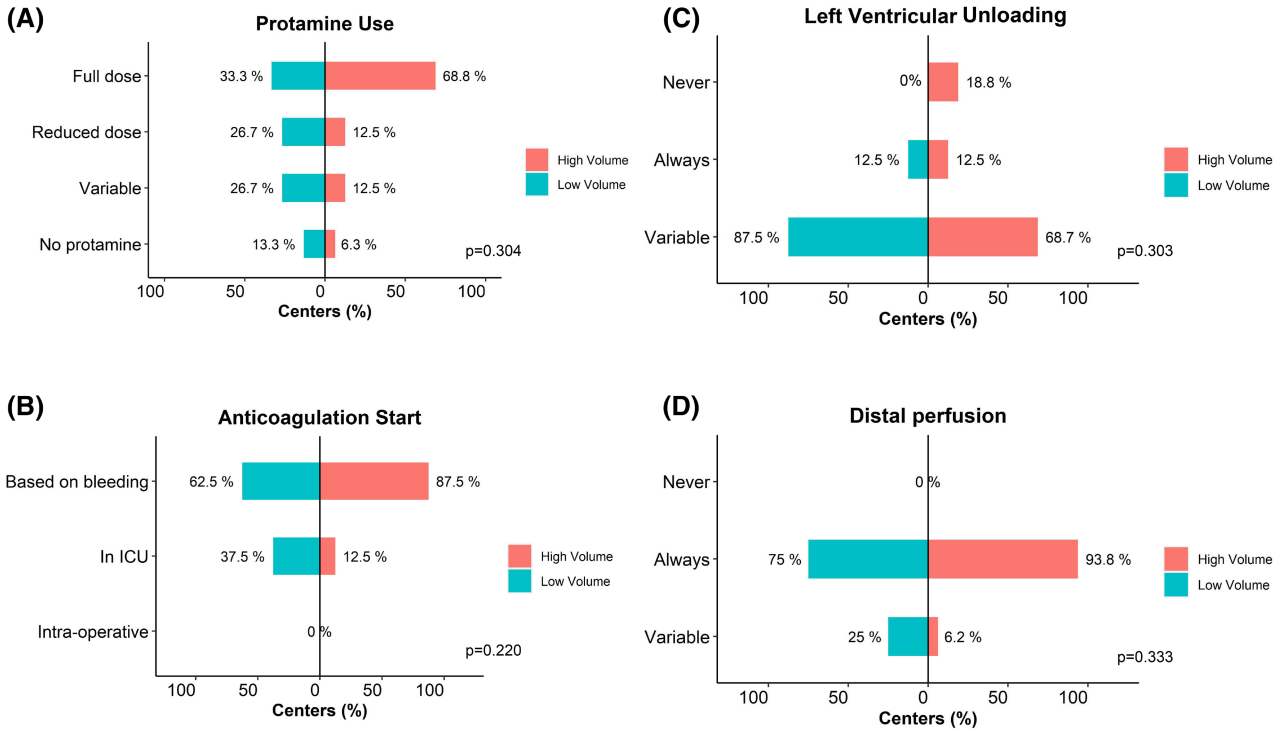


**FIGURE 2** Bar charts representing the reported practices regarding protamine administration (A), left ventricular vent (B), anticoagulation initiation (C), and placement of a distal perfusion cannula (D).

providing V-A ECLS for post-cardiotomy shock perform ≤30 V-A ECLS cases per year, and these low-volume centers are mainly non-academic. Both low-volume and high-volume centers seem to be aligned on several clinical practices, including access to other mechanical circulatory support devices or the presence of ECLS specialists. Overall, it is advised, when possible and depending on the center-specific caregiver model, to have fully trained ECLS specialists as part of the team.[11] However, this practice was reported only in 50% of the included centers. Interestingly, low-volume centers tend to use more or different monitoring strategies, such as NIRS or lung ultrasound, compared to high-volume centers. Given the current reality, differences in terms of ECLS case load and team organization among centers are still relevant.[11,12]

The highest degree of heterogeneity was observed regarding anticoagulation policies, including timing of initiation, monitoring, and intensity of anticoagulation. According to the 2020 EACTS/ELSO/STS/AATS expert consensus paper on PC-ECLS,[5] reversing intraoperative heparin with protamine after cardiopulmonary bypass termination may be considered (Class of recommendation: IIb, level of evidence: C).[5] However, no evidence is available regarding the optimal amount of protamine to be administered. About half of the surveyed centers use a full dose of protamine, while 38% use a reduced or variable dose based on the patient's bleeding.[16] Similarly, available guidelines support the initiation of ECLS without anticoagulation until bleeding has diminished to acceptable levels (Class of recommendation: I, level of evidence: C), indicating a threshold of <100 mL/h within 24–48 h after cardiopulmonary bypass.[5] Despite these recommendations, most participating centers did not report a specific protocol regarding bleeding thresholds or start the anticoagulation based on their clinical judgment on patient's bleeding. Furthermore, reported protocols were extremely heterogeneous indicating an urgent need of scientific evidence on this topic. While awaiting new evidence in this field, it is advisable to establish institutional protocols and standardize the clinical practice according to the available 2020 EACTS/ELSO/STS/AATS expert consensus paper.[5]

Similarly, anticoagulation monitoring is still debated, and the effects of this uncertainty are reflected by the variability in monitoring methods, timing, and target values reported by the PELS-1 centers. The general ELSO guidelines are currently noncommittal about appropriate monitoring, advocating a tailored strategy for each patient.[17] This statement can support the different approaches established by each institution based on local experience and resource availability. Nevertheless, the 2020 EACTS/ELSO/STS/AATS expert consensus paper on PC- ECLS clearly recommends monitoring anticoagulation with a target ACT of 160–220 s and a target aPTT of 50–80 s (Class of recommendation:I, level of evidence:C).[18] The 2021 ELSO anticoagulation guidelines suggest an anticoagulation

**TABLE 2** Anticoagulation management.

| | Overall ($n=32$) | Low volume ($n=16$) | High volume ($n=16$) | $p$-value |
|---|---|---|---|---|
| Protamine use | | | | 0.304 |
| No protamine | 3 (10%) | 2 (13%) | 1 (6%) | |
| Full dose | 16 (52%) | 5 (33%) | 11 (69%) | |
| Reduced dose | 6 (19%) | 4 (27%) | 2 (13%) | |
| Variable | 6 (19%) | 4 (27%) | 2 (13%) | |
| Anticoagulation start | | | | 0.220 |
| Intraoperative | 0 (0%) | 0 (0%) | 0 (0%) | |
| ICU | 8 (25%) | 6 (37.5%) | 2 (12.5%) | |
| Based on bleeding | 24 (75%) | 10 (62.5%) | 14 (87.5%) | |
| Anticoagulation first line drug | | | | 1.000 |
| Continuous unfractionated heparin IU/h | 31 (96.9%) | 15 (93.8%) | 16 (100%) | |
| Subcutaneous heparin | 0 (0%) | 0 (0%) | 0 (0%) | |
| Argatroban | 0 (0%) | 0 (0%) | 0 (0%) | |
| Bivalirudin | 1 (3.1%) | 1 (6.3%) | 0 (0%) | |
| Other | 0 (0%) | 0 (0%) | 0 (0%) | |
| Anticoagulation second line drug | | | | 0.278 |
| None | 7 (20%) | 5 (29%) | 2 (11%) | |
| Continuous unfractionated heparin IU/h | 0 (0%) | 0 (0%) | 0 (0%) | |
| Subcutaneous heparin | 4 (11%) | 3 (18%) | 1 (6%) | |
| Argatroban | 8 (23%) | 2 (12%) | 6 (33%) | |
| Bivalirudin | 15 (43%) | 7 (41%) | 8 (44%) | |
| Other | 1 (3%) | 0 (0%) | 1 (6%) | |
| Anticoagulation monitoring[a] | | | | 0.582 |
| ACT | 9 (15.8%) | 3 (9.4%) | 6 (24%) | |
| aPTT | 25 (43.9%) | 14 (43.8%) | 11 (44%) | |
| PT | 4 (7%) | 4 (12.5%) | 0 (0%) | |
| INR | 3 (5.3%) | 2 (6.3%) | 1 (4%) | |
| TEG/ROTEM | 8 (14%) | 5 (15.6%) | 3 (12%) | |
| Anti-Xa activity | 8 (14%) | 4 (12.5%) | 4 (16%) | |
| ACT frequency | | | | 0.500 |
| 4–6 h | 7 (77.8%) | 3 (100%) | 4 (66.7%) | |
| 12–24 h | 2 (22.2%) | 0 (0%) | 2 (33.3%) | |
| aPTT frequency | | | | 0.341 |
| 4–8 h | 20 (80%) | 10 (71.4%) | 10 (90.9%) | |
| 12–24 h | 5 (20%) | 4 (28.6%) | 1 (9.1%) | |
| PT frequency | | | | n.a. |
| 4–8 h | 2 (50%) | 2 (50%) | 0 (0%) | |
| 12–24 h | 2 (50%) | 2 (50%) | 0 (0%) | |
| INR frequency | | | | n.a. |
| 4–8 h | 0 (0%) | 0 (0%) | 0 (0%) | |
| 12–24 h | 3 (100%) | 2 (100%) | 1 (100%) | |
| TEG/ROTEM frequency | | | | 1.000 |
| 12–24 h | 3 (37.5%) | 2 (40%) | 1 (33.3%) | |
| When needed/other | 5 (62.5%) | 3 (60%) | 2 (66.7%) | |

(Continues)

TABLE 2 (Continued)

| | Overall ($n=32$) | Low volume ($n=16$) | High volume ($n=16$) | $p$-value |
|---|---|---|---|---|
| Anti-Xa activity frequency | | | | 0.229 |
| 4–6 h | 3 (37.5%) | 0 (0%) | 3 (75%) | |
| 12–24 h | 3 (37.5%) | 2 (50%) | 1 (25%) | |
| When needed/other | 2 (25%) | 2 (50%) | 0 (0%) | |

*Note*: Data are reported as $n$ (% as a percentage excluding missing values). $p$ values by chi squared indicate statistically significant differences between low-volume and high-volume centers.

Abbreviations: ACT, accelerated clotting time; aPTT, activated partial thromboplastin time; ICU, intensive care unit; INR, international normalized ratio; PT, prothrombin time; ROTEM, rotational thromboelastometry; TEG, thromboelastography.

[a]Percentages indicate the frequency of use for each monitoring strategy with respect to the pool of all reported monitoring strategies.

monitoring laboratory schedule.[17,19] As demonstrated by this pilot survey, these guidelines are still far from being widely applied.

There is a lack of studies to guide blood product transfusion practices in PC-ECLS patients, but general guidelines suggest a hemoglobin goal of >7–9 g/dL[17] to maintain a good oxygen delivery. A survey on anticoagulation and transfusion practices in adult ECLS demonstrated that 33.3% of centers use a hemoglobin transfusion trigger of 7.1–8 g/dL and 28.9% of them use a threshold of 8.1–10 g/dL.[20] The current survey on PC-ECLS showed that 53.1% of included hospitals use a hemoglobin trigger of 8 g/dL, in line with previous literature,[21] but pragmatic real-life studies are required to investigate whether this empirical threshold also has real benefits.

Regarding the LV unloading strategy, a minority of centers declared to avoid the use of any LV vent, while most hospitals apply a dynamic strategy based on the patient's needs and degree of LV distension, as also advised by the 2020 EACTS/ELSO/STS/AATS expert consensus paper on PC- ECLS.[5] Similarly, the current guidelines supporting a routine implant of a distal perfusion cannula with a femoral peripheral ECLS,[6] are implemented in most centers.

About 60% of surveyed centers declared to have specific monitoring protocols for PC-ECLS patients. While monitoring is endorsed by the literature,[5,6] specific indications on method choice and frequency are lacking. Overall, daily echocardiography (87.5%) and pulmonary artery catheter measurements (40.6%) are the most common methods for cardiovascular monitoring[22] while NIRS (53.1%) and brain computed tomography (28.1%) are the preferred methods for neurological monitoring.[23] Close monitoring of lower limb ischemia is widely applied by most centers, following guidelines.[5,6] Other organs are usually monitored upon patient's needs, while special attention is given to hemolysis and thrombosis, reflecting the international guidelines.[5,6,17] Notwithstanding, a certain degree of variability can still be observed among centers.

The findings of this pilot survey reflect the opinions of a cohort of physicians from 16 countries on 5 continents. However, a potential bias may be introduced based on the pilot nature of this survey, which was shared only among the PELS-1 participating centers. Despite that, the survey involved low- and high-volume programs, making this pilot survey representative of real-life PC- ECLS practices. We attempted to avoid nonresponse bias by sending the survey to institutions already involved in PELS-1. Given that a response of 20%–30% is generally considered acceptable for a survey,[24] we also attempted to increase the response rate by sending email reminders. Despite this, 2 centers did not reply, and the final response rate was 94.1%. Incomplete responses may have also been a limitation, although calculations were made as described above to accurately present the data. Even if the number of respondents is still considered to be small, data suggest an apparent variability of PC-ECLS practice that may, in and of itself, minimize nonresponse bias.[25] Finally, there might be variations in ECLS management modalities due to nonclinical factors, including financial, historical, cultural, and ethical factors.[26] However, exploring these was beyond the scope of this survey.

## 4.1 | Conclusions

As there is limited evidence regarding PC-ECLS management, each institution tends to develop different strategies, as shown by this pilot survey summarizing the approaches taken by 32 facilities worldwide. The survey demonstrates wide variability in ECLS service organization, practices regarding anticoagulation and transfusions, LV unloading, and monitoring. Moreover, this survey showed how several choices are still based on clinicians' personal judgment and not on institutional protocols or guidelines. The use of distal limb perfusion seems to be an exception in this scenario, as it is regularly applied in most centers.

**TABLE 3** Transfusions, left ventricular venting, and distal perfusion.

| | Overall ($n=32$) | Low volume ($n=16$) | High volume ($n=16$) | $p$-value |
|---|---|---|---|---|
| Hb trigger for transfusions | | | | 0.417 |
| 7 g/dL | 4 (12.5%) | 1 (6.3%) | 3 (18.8%) | |
| 7.5 g/dL | 4 (12.5%) | 3 (18.8%) | 1 (6.3%) | |
| 8 g/dL | 17 (53.1%) | 8 (50%) | 9 (56.3%) | |
| 8.5 g/dL | 1 (3.1%) | 0 (0%) | 1 (6.3%) | |
| 9 g/dL | 4 (12.5%) | 3 (18.8%) | 1 (6.3%) | |
| 10 g/dL | 1 (3.1%) | 1 (6.3%) | 0 (0%) | |
| Not reported | 1 (3.1%) | 0 (0%) | 1 (6.3%) | |
| LV unloading | | | | 0.303 |
| No LV unloading | 3 (9.4%) | 0 (0%) | 3 (18.8%) | |
| Always LV unloading | 4 (12.5%) | 2 (12.5%) | 2 (12.5%) | |
| Variable | 25 (78.1%) | 14 (87.5%) | 11 (68.8%) | |
| LV unloading strategy (first line) | | | | 0.357 |
| Trans-aortic device | 3 (9.4%) | 0 (0%) | 3 (18.8%) | |
| Left ventricular (vent or cannula) | 5 (15.6%) | 3 (18.8%) | 2 (12.5%) | |
| Left atrium (direct or transseptal) | 5 (15.6%) | 2 (12.5%) | 3 (18.8%) | |
| Septostomy | 0 (0%) | 0 (0%) | 0 (0%) | |
| IABP | 18 (56.3%) | 10 (62.5%) | 8 (50%) | |
| Pulmonary artery cannula | 0 (0%) | 0 (0%) | 0 (0%) | |
| Other | 1 (3.1%) | 1 (6.3%) | 0 (0%) | |
| LV unloading strategy (second line) | | | | 0.478 |
| None | | | | |
| Trans-aortic device | 2 (6%) | 1 (6%) | 1 (6%) | |
| Left ventricular (vent or cannula) | 10 (28%) | 7 (39%) | 3 (17%) | |
| Left atrium (direct or transseptal) | 8 (22%) | 4 (22%) | 4 (22%) | |
| Septostomy | 7 (19%) | 4 (22%) | 3 (17%) | |
| IABP | 5 (14%) | 1 (6%) | 4 (22%) | |
| Pulmonary artery cannula | 0 (0%) | 0 (0%) | 0 (0%) | |
| Other | 4 (11%) | 1 (6%) | 3 (17%) | |
| Distal perfusion | | | | 0.333 |
| Never | 0 (0%) | 0 (0%) | 0 (0%) | |
| Always | 27 (84.4%) | 12 (75%) | 15 (93.8%) | |
| Variable | 5 (15.6%) | 4 (25%) | 1 (6.3%) | |

*Note*: Data are reported as *n* (% as percentage excluding missing values). *p* values by chi squared indicate statistically significant differences between low-volume and high-volume centers.

Abbreviations: IABP, intra-aortic balloon pump; LV, left ventricle.

This pilot survey encourages the development of larger qualitative research studies and clinical trials on specific patient management issues in PC-ECLS and a more widespread implementation of the available guidelines for PC-ECLS management. Finally, this survey highlights the importance of considering the variable "center" and its heterogeneity as an important factor in studies on PC-ECLS.

## AUTHOR CONTRIBUTIONS

**Silvia Mariani:** Concept/design, Data analysis /interpretation, Drafting the article, Critical revision of the article, Approval of the article, Statistics, and Data collection. **Gabor Bari:** Data analysis/interpretation, Drafting the article, Critical revision of the article, Approval of the article, and Statistics. **Justine M. Ravaux:** Concept/design, Data interpretation, Drafting the article, Critical revision of the article,

**TABLE 4** General monitoring.

| | Overall ($n=32$) | Low volume ($n=16$) | High volume ($n=16$) | $p$-value |
|---|---|---|---|---|
| Limb perfusion | | | | |
| NIRS | 16 (50%) | 10 (62.5%) | 6 (37.5%) | 0.157 |
| Skin temperature | 18 (56.3%) | 10 (62.5%) | 8 (50%) | 0.476 |
| Capillary refilling | 17 (53.1%) | 6 (37.5%) | 11 (68.8%) | 0.077 |
| Ultrasound | 22 (68.8%) | 11 (68.8%) | 11 (68.8%) | 1.000 |
| Clinical observation | 25 (78.1%) | 13 (81.3%) | 12 (75%) | 1.000 |
| Nothing | 0 (0%) | 0 (0%) | 0 (0%) | n/a |
| Neuromonitoring | | | | |
| NIRS | 17 (53.1%) | 12 (75%) | 5 (31.3%) | 0.013 |
| EEG | 4 (12.5%) | 1 (6.3%) | 3 (18.8%) | 0.600 |
| Brain CT scan | 9 (28.1%) | 3 (18.8%) | 6 (37.5%) | 0.433 |
| Trans-cranial Doppler | 1 (3.1%) | 1 (6.3%) | 0 (0%) | 1.000 |
| Biomarkers | 3 (9.4%) | 0 (0%) | 3 (18.8%) | 0.226 |
| State entropy and bispectral index | 3 (9.4%) | 3 (18.8%) | 0 (0%) | 0.226 |
| Evoked potentials | 2 (6.3%) | 0 (0%) | 2 (12.5%) | 0.484 |
| Nothing | 7 (21.9%) | 1 (6.3%) | 6 (37.5%) | 0.083 |
| Cardiovascular | | | | |
| Swan-Ganz catheter | 13 (40.6%) | 8 (50%) | 5 (31.3%) | 0.280 |
| PiCCO | 2 (6.3%) | 1 (6.3%) | 1 (6.3%) | 1.000 |
| Daily echocardiography | 28 (87.5%) | 13 (81.3%) | 15 (93.8%) | 0.600 |
| Nothing | 2 (6.3%) | 1 (6.3%) | 1 (6.3%) | 1.000 |
| Other organs | | | | |
| Thorax CT scan | 10 (31.3%) | 3 (18.8%) | 7 (43.8%) | 0.127 |
| Lung ultrasound | 5 (15.6%) | 5 (31.3%) | 0 (0%) | 0.043 |
| Abdomen CT scan | 7 (21.9%) | 2 (12.5%) | 5 (31.3%) | 0.394 |
| Abdomen ultrasound | 6 (18.8%) | 3 (18.8%) | 3 (18.8%) | 1.000 |
| Kidney NIRS | 0 (0%) | 0 (0%) | 0 (0%) | n/a |
| Kidney ultrasound | 5 (15.6%) | 1 (6.3%) | 4 (25%) | 0.333 |
| Interleukins dosage | 1 (3.1%) | 0 (0%) | 1 (6.3%) | 1.000 |
| Nothing | 17 (53.1%) | 9 (56.3%) | 8 (50%) | 0.723 |
| Hemolysis | | | | |
| Free hemoglobin | 24 (75.0%) | 11 (68.8%) | 13 (81.3%) | 0.658 |
| Haptoglobin | 9 (28.1%) | 3 (18.8%) | 6 (37.5%) | 0.433 |
| ECLS oxygenator pressure drop | 17 (53.1%) | 7 (43.8%) | 10 (62.5%) | 0.288 |
| Other | 4 (12.5%) | 3 (18.8%) | 1 (6.3%) | 0.600 |
| Thrombosis | | | | |
| D-dimer | 19 (59.4%) | 10 (62.5%) | 9 (56.3%) | 0.719 |
| LDH | 18 (56.3%) | 9 (56.3%) | 9 (56.3%) | 1.000 |
| Fibrinogen | 15 (46.9%) | 7 (43.8%) | 8 (50%) | 0.723 |
| Thrombin | 5 (15.6%) | 2 (12.5%) | 3 (18.8%) | 1.000 |
| Lactate | 9 (28.1%) | 4 (25%) | 5 (31.3%) | 1.000 |
| Direct inspection of circuitry | 23 (71.9%) | 10 (62.5%) | 13 (81.3%) | 0.433 |
| ECLS oxygenator pressure drop | 22 (68.8%) | 11 (68.8%) | 11 (68.8%) | 1.000 |
| Other | 2 (6.3%) | 1 (6.3%) | 1 (6.3%) | 1.000 |

*Note*: Data are reported as *n* (% as a percentage excluding missing values). *p* values by chi squared indicate statistically significant differences between low-volume and high-volume centers.

Abbreviations: CT, computer tomography; ECLS, extracorporeal life support; EEG, electroencephalogram; LDH, lactate dehydrogenase; NIRS, near-infrared spectroscopy; PiCCO, pulse contour cardiac output.

Approval of the article, and Data collection. **Bas C.T. van Bussel:** Data analysis/interpretation, Drafting the article, Critical revision of the article, Approval of the article, and Statistics. **Maria Elena De Piero:** Concept/design, Data interpretation, Critical revision of the article, Approval of the article, and Data collection. **Ann-Kristin Schaefer, Khalil Jawad, Matteo Pozzi, Antonio Loforte, Nikolaos Kalampokas, Agne Jankuviene, Erwan Flecher, Xiaotong Hou, Jeroen J.H. Bunge, Kogulan Sriranjan, Leonardo Salazar, Bart Meyns, Michael A Mazzeffi, Sacha Matteucci, Sandro Sponga, Kollengode Ramanathan, Alessandro Costetti, Francesco Formica, Pranya Sakiyalak, Antonio Fiore, Chistof Schmid, Giuseppe Maria Raffa, Roberto Castillo, I-wen Wang, Jae-Seung Jung, Tomas Grus, Vin Pellegrino, Giacomo Bianchi, Matteo Pettinari, Alessandro Barbone, José P. Garcia, Mariusz Kowalewski, Kiran Shekar, Glenn Whitman:** Data interpretation, Critical revision of the article, Approval of the article, and Data collection. **Roberto Lorusso:** Concept/design, Data interpretation, Critical revision of the article, Approval of the article, and Data collection.

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## CONFLICT OF INTEREST STATEMENT

RL is consultant for Medtronic, Getinge, Abiomed, and LivaNova; Advisory Board Member of Eurosets, Hemocue, and Xenios (honoraria are paid as research funding). KR has received honorarium from Baxter and Fresenius for educational lectures not related to this topic.

## DATA AVAILABILITY STATEMENT

Data will be shared on reasonable request with the corresponding author with the permission of all PELS-1 participating centers.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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