Contemporary outcomes of cardiac surgery patients supported by the intra-aortic balloon pump

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Key question
What are contemporary outcomes of cardiac surgery patients supported by IABP in terms of morbidity and mortality?

Key finding(s)
Mortality was 12.7%. Vascular complications, peripheral arterial disease and dialysis requirement were associated with mortality.

Take-home message
IABP proved to be a safe support modality and was associated with a relatively low complication rate.

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Abstract

OBJECTIVES: Although the intra-aortic balloon pump (IABP) has been the most widely adopted temporary mechanical support device in cardiac surgical patients, its use has declined. The current study aimed to evaluate the occurrence and predictors of early mortality and complication rates in contemporary cardiac surgery patients supported by an IABP.

METHODS: A multicentre, retrospective analysis was performed of all consecutive cardiac surgical patients receiving perioperative balloon pump support in 8 centres between January 2010 to December 2019. The primary outcome was early mortality, and secondary outcomes were balloon-associated complications. A multivariable binary logistic regression model was applied to evaluate predictors of the primary outcome.

RESULTS: The study cohort consisted of 2615 consecutive patients. The median age was 68 years [25th percentile 61, 75th percentile 75 years], with the majority being male (76.9%), and a mean calculated 30-day mortality risk of 10.0%. Early mortality was 12.7% (n = 333), due to cardiac causes (n = 266), neurological causes (=22), balloon-related causes (n = 5) and other causes (n = 40). A composite end point of all vascular complications occurred in 7.2% of patients, and leg ischaemia was observed in 1.3% of patients. The most important predictors of early mortality were peripheral vascular disease [odds ratio (OR) 1.63], postoperative dialysis requirement (OR 10.40) and vascular complications (OR 2.57).

CONCLUSIONS: The use of the perioperative IABP proved to be safe and demonstrated relatively low complication rates, particularly for leg ischaemia. As such, we believe that specialists should not be held back to use this widely available treatment in high-risk cardiac surgical patients when indicated.

Keywords: Intra-aortic balloon pump • Cardiac surgery • Postcardiomy shock • Mechanical circulatory support

ABBREVIATIONS

| Abbreviation | Description                        |
|--------------|------------------------------------|
| CABG         | Coronary artery bypass grafting    |
| CI           | Confidence intervals               |
| CPB          | Cardiopulmonary bypass             |
| CT           | Computed tomography                |
| EuroSCORE    | European System for Cardiac Operative Risk Evaluation |
| IABP         | Intra-aortic balloon pump          |
| IRB          | Institutional review board         |
| LV           | Left ventricular                   |
| OR           | Odds ratio                         |

INTRODUCTION

The intra-aortic balloon pump (IABP) has traditionally been the most widely adopted temporary mechanical circulatory support device in cardiac surgical patients [1] and is particularly applied in patients undergoing coronary artery bypass grafting (CABG) because of its effects on coronary blood flow and reduced left ventricular (LV) end-diastolic pressure [2]. However, during the past decade, the IABP has gained some negative attention, primarily due to the absence of a beneficial effect over conventional therapy in randomized trials of patients with myocardial infarction complicated by cardiogenic shock [3, 4], while these patients were subjected to an increased complication rate [3]. These results have been incorporated in most recent guidelines, discouraging the use of IABP in this specific patient category [5]. Unfortunately, this attention also led to the seeming underuse of this important device in cardiac surgery patients, which could be unjustified.

In cardiac surgery, the IABP has a plethora of indications in the perioperative phase, all based on either the reduction of LV afterload, or the improvement of coronary perfusion [2]. Indeed, these indications are not limited to the traditional cardiogenic shock patient with myocardial infarction. Furthermore, the device has been demonstrated to improve survival when implanted preoperatively in high-risk patients [6, 7] but can also be used as a first-line widely available therapy when patients cannot be weaned from cardiopulmonary bypass (CPB) in the direct postoperative phase. Therefore, the use of IABP in these conditions is still the mainstay and first approach to postcardiotomy shock (PCS), as outlined in a recent expert consensus statement by the various European and American surgical societies [8].

One of the perceived limitations of the IABP is the associated complication rate, which comprises device-related bleeding, limb ischaemia, mesenterial ischaemia, stroke and vascular lacerations [9]. Still, this perception is based on rather outdated studies, and contemporary data on this matter are lacking, particularly with regard to more recent series describing perioperative IABP outcomes. Therefore, the current multicentre study aimed to evaluate (i) the mortality associated with perioperative IABP implantation, (ii) major complications associated with perioperative IABP implantation and (iii) predictors of early of these adverse events, in contemporary cardiac surgery patients supported by IABP counterpulsation.

MATERIALS AND METHODS

Study design

The current study comprises a retrospective analysis of partly retrospectively and partly prospectively collected data. Only patient charts and operative reports were used for data collection.

Ethical statement

The institutional review board (IRB) of the leading center approved the current (IRB approval number: 0020038, date: 7 March 2014), after which this was sent to all participating centres for confirmation and re-approval. The need for written informed consent was waived by the IRB.

Study population

The cohort comprised all consecutive adult patients (>18 years of age) treated by IABP in the perioperative phase (either pre- or intraoperatively) undergoing a cardiac surgical procedure in 8
cardiac surgery centres and was conducted by the ‘Gruppo Italiano di Ricerca sugli Outcome in Cardiochirurgia’ investigators. Inclusion criteria were patients treated by perioperative IABP between January 2010 and December 2019, undergoing cardiac surgery. Exclusion criteria were non-adult patients, patients undergoing congenital cardiac surgery. To determine surgical risk, the European System for Cardiac Operative Risk Evaluation (EuroSCORE, logistic) [10] was calculated manually based on the available baseline and procedural characteristics.

Timing of and indications for implantation

IABP catheter implantation was performed either in the intensive care unit, catheterization lab or operating room, depending on the timing and urgency of implantation. This decision was made preoperatively (prophylactic) [6] or intraoperatively based on 4 stratified reasons: ‘LV dysfunction’, ‘haemodynamic instability’, ‘prevention of ischaemia/diffuse coronary disease’ and ‘other reasons’. Generally, when implanted preoperatively for haemodynamic instability, IABP was implanted immediately and surgery was performed the next day. For all other preoperative implantation reasons, IABP implantation was planned in the catheterization lab just prior to surgery. Appropriate IABP placement and localization was confirmed using chest X-ray or fluoroscopy, depending on the implantation location, in all cases.

Implantation technique and intra-aortic balloon pump balloon size

Either a classical sheathed technique or the sheathless technique was used for IABP implantation [9, 11]. IABP balloon sizes were dependent on the patient’s height (<152 cm: 25 cc, 152–163 cm: 34 cc, 164–183 cm: 40 cc, >183 cm: 50 cc) [12].

Outcomes

All baseline and procedural characteristics warranted for calculation of the logistic EuroSCORE were collected. In addition, symptomatology (based on the New York Heart Association classification for dyspnoea), type of surgery, extent of coronary artery disease and IABP characteristics were collected. Surgery types were presented separately as well as in a binary form (isolated CABG or other cardiac surgical procedures). ‘Other cardiac surgical procedures’ were then subdivided into ‘non-CABG procedures’ and ‘cardiac surgical procedures with concomitant CABG’. The primary outcome was early mortality (either inhospital or 30-day). Secondary outcomes were vascular complications and IABP-related complications.

Definitions

Vascular complications were defined as ipsilateral ischaemia (radiologically and clinically confirmed), IABP-site bleeding, non-implantation-site bleeding (such as pericardial or thoracic bleeding), stroke (radiologically and clinically confirmed), peripheral emboli (radiologically and clinically confirmed), vascular laceration and retroperitoneal bleeding. Of note, vascular laceration comprised non-(overt)-bleeding vascular complications, such as perforation, rupture, dissection or stenosis, based on contemporary recommendations [13]. IABP-related complications were defined as IABP balloon rupture or IABP balloon dysfunction warranting replacement. IABP-related death comprised all causes of death potentially related to the use of the IABP, such as retroperitoneal bleeding or aortic dissection. LV dysfunction was defined as preoperative LV ejection fraction <30%. Finally, thrombocytopenia was defined as severe if platelet count was reduced below <50 x 10^9/l [14].

Statistical analysis

Data and statistics were reported according to guidelines provided by experts in our specialty [15]. Categorical variables were presented as numbers and corresponding percentages (%). Continuous variables were presented as mean and standard deviation or median and [25th and 75th percentile], depending on distribution of data. Distribution of these continuous variables was assessed for normality using the Kolmogorov–Smirnoff test (given the large sample size) and assessed visually by inspection of histograms and standardized normal probability (P–P) plots. Predictors for the primary outcome (early mortality) were identified using binary univariable logistic regression analysis, after which covariates with a P-value of <0.20 were included in a multivariable model. As a rule of thumb, and advocated by experts in our field, >10 events would be required per tested parameter in a multivariable model [16]. For all other analyses, P-values <0.05 were considered statistically significant. Results of binary logistic regression analyses were presented in odds ratios (OR) and corresponding 95% confidence intervals (CI). Hosmer and Lemeshow test was performed to evaluate goodness-of-fit of the model, in which P <0.05 was considered to indicate poor fit. In addition, model discrimination was tested in a receiver operating characteristic analysis, of which an area under the curve (AUC) indicated poor discrimination, 0.7–0.8 acceptable discrimination and >0.8 excellent discrimination. Collinearity was tested using variance inflating factors. Finally, different compositions of the model were tested and the model with lowest Akaike information criterion was chosen. All statistical analyses were performed using commercially available software (IBM SPSS Statistics for Windows, Version 27.0, Armonk, NY).

Missing data

When case volume is sufficient and amount of data is relatively low, multiple imputation serves as the method providing less biased results to cope with missing data [17]. For the current study, 76% of variables were 100% complete, 52% of cases were 100% complete and 99% of all values were complete. Ten multiple imputation datasets (multiple imputation based on single value regression analysis) were produced using SPSS version 27, imputed for 19 variables with missing data. The pooled datasets were used for analyses. For transparency reasons, a list of missing variables with corresponding frequencies is provided in Supplementary Material S1.

RESULTS

Patient population

The current multicentre cohort consisted of 2615 consecutive cardiac surgery patients treated with IABP in the perioperative phase.


Table 1: Baseline characteristics of the complete cohort

| Patient characteristics          |       |
|----------------------------------|-------|
| Age (years), median [IQR]        | 68 [61, 75] |
| Sex (female), n (%)              | 603 (23.1) |
| EuroSCORE (logistic), median [IQR] | 4.0 [2.0, 12.0] |
| NYHA classification, n (%)       |       |
| I                               | 216 (8.3) |
| II                              | 1240 (47.4) |
| III                             | 861 (32.9) |
| IV                              | 298 (11.4) |
| Comorbidities, n (%)             |       |
| Hypertension                     | 1388 (53.1) |
| Diabetes                         | 674 (25.8) |
| Diabetes on insulin              | 407 (15.6) |
| COPD                             | 286 (10.9) |
| Renal insufficiency              | 211 (8.1) |
| Dialysis dependent               | 33 (1.3) |
| History of stroke                | 61 (2.3) |
| History of TIA                   | 55 (2.1) |
| Carotid stenosis >50%            | 166 (6.3) |
| Peripheral vascular disease      | 275 (10.5) |
| Pulmonary hypertension (>55 mmHg)| 341 (13.0) |
| LVEF (%), median [IQR]           | 45 [35, 52] |
| History of PCI                   | 309 (11.8) |
| Extent of CAD, n (%)             |       |
| Left main stenosis               | 453 (17.3) |
| Three-vessel disease             | 1721 (65.8) |
| On inotropics preoperatively, n (%) | 161 (6.2) |
| On levosimendan preoperatively, n (%) | 158 (6.0) |

CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; EuroSCORE: European system for cardiac operative risk evaluation; IQR: interquartile range; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; TIA: transient ischaemic attack.

Baseline characteristics

The median age of the patient cohort was 68 years [25th percentile: 61 years, 75th percentile: 75 years]. The majority of patients was male (n = 2012, 76.9%), with a median LV ejection fraction of 45% [35, 52]. The mean procedural risk as assessed by EuroSCORE (logistic) was 10.0%, median 4.0% [2.0, 12.0, range 1.0-90.0%]. Baseline characteristics are described in more detail in Table 1. Preoperative medication use is presented in Supplementary Material S2.

Procedural characteristics

A detailed description of individual surgical procedures is provided in Supplementary Material S3. The vast majority of procedures comprised isolated CABG (n = 1913, 73.2%), of which 3.5% (n = 66) were performed off-pump. Other procedures (n = 702, 26.8%) were subdivided into procedures with concomitant CABG (n = 227, 32.3% within other procedures) or procedures without bypass surgery (n = 475, 67.7%, Table 2).

Intra-aortic balloon pump parameters

The indication for IABP implantation was LV dysfunction in 15.9% of patients (n = 415), haemodynamic instability in 19.6% of patients (n = 513), ischaemia prevention/diffuse CAD in 61.1% of patients (n = 1597) and other reasons (n = 90, 3.4%). Implantation of IABP was primarily performed in the preoperative phase (n = 1777, 68.0%), and in 32.0% of patients during the operation (n = 838). Implantation technique was distributed equally (sheathed: n = 1201, 45.9%, sheathless: n = 1414, 54.1%, Table 2).

Primary outcome

Early mortality. The primary end point occurred in 12.7% of patients (n = 333). Main causes of death were cardiac (n = 266, 80.0%), neurological (n = 22, 6.6%) and IABP related (n = 5, n = 1.5%). Other causes (n = 40, 13.7%) comprised bowel ischaemia, multi-organ failure, sepsis/infection and withdrawal from support. Table 3 presents the primary end point and its causes. In deceased patients, death occurred after a median of 5 days [2, 13 days].

Secondary outcomes

Vascular complications. In total, a composite secondary vascular complications’ end point occurred in 7.2% of patients (n = 189, with a total of 215 complications). The end point was subdivided in ipsilateral ischaemia (n = 35, 1.3%), IABP-site bleeding (n = 17, 0.7%), non-implantation-site bleeding (n = 76, 2.9%), stroke (n = 49, 1.9%), peripheral emboli (n = 15, 0.6%), vascular laceration (n = 20, 0.8%) and retroperitoneal bleeding (n = 3, 0.1%, Table 3).

Other complications. Fifty-five patients (2.1%) required postoperative veno-arterial extracorporeal membrane oxygenation support. Furthermore, 185 patients (7.2%) required postoperative dialysis (in patients not on dialysis preoperatively, Table 3).

Intra-aortic balloon pump balloon-related complications. IABP balloon-related complication occurred infrequently (n = 5, 0.2%). We report 3 IABP balloon ruptures (0.1%) and 2 patients experiencing IABP balloon dysfunction requiring IABP balloon replacement (0.1%, Table 3).

Predictors of early mortality. Baseline and procedural parameters were tested in binary univariable analysis (Supplementary Material S4). The most appropriate model, based on Akaike information criterion was chosen. Multivariable analysis (Table 4) revealed age (OR 1.02, per year), female sex (OR 1.40), COPD (OR 1.62), peripheral vascular disease (OR 1.63), procedures other than isolated CABG (OR 1.71), increased CPB time (OR 1.01, per minute), postoperative thrombocytopenia (OR 1.59), postoperative dialysis requirement (OR 10.40) and vascular complications (OR 2.57) to significantly increase the risk of early mortality. On the other hand, preoperative IABP implantation (compared to intraoperative implantation, OR 0.70) was associated with a protective effect against early mortality. Hosmer and Lemeshow test revealed adequate goodness-of-fit (P = 0.214), while variance inflating factors demonstrated low probability of collinearity. Also, receiver operating characteristic analysis confirmed excellent discrimination, with an area under the curve of 0.847.
Table 2: Procedural and intra-aortic balloon pump characteristics

| Variable                                      | Outcome Number of patients (% | Percentage |
|-----------------------------------------------|-------------------------------|------------|
| Procedures,* n (%)                            |                               |            |
| Isolated CABG                                 | 1913 (73.2)                   |            |
| Of which off-pump                            | 66 (3.5)*                     |            |
| Other than isolated CABG                      | 702 (26.8)                    |            |
| With concomitant CABG                         | 227 (32.3)                    |            |
| Re-operative surgery, n (%)                   | 149 (5.7)                     |            |
| Urgent/emergency surgery, n (%)              | 838 (32.0)                    |            |
| Planned/elective surgery, n (%)              | 1777 (68.0)                   |            |
| Cardiopulmonary bypass time (min)            | 110 (87, 140)                 |            |
| Aortic cross clamping time (min)             | 70 [53, 89]                   |            |
| IABP indications, n (%)                       |                               |            |
| LV dysfunction                                | 415 (15.9)                    |            |
| Haemodynamic instability                      | 513 (19.6)                    |            |
| Ischaemia prevention/diffuse CAD              | 1597 (61.1)                   |            |
| Other                                         | 90 (3.4)                      |            |
| IABP timing, n (%)                            |                               |            |
| Preoperative implantation                     | 1777 (68.0)                   |            |
| Intraoperative implantation                   | 838 (32.0)                    |            |
| IABP implantation technique, n (%)           |                               |            |
| Sheathed                                      | 1201 (45.9)                   |            |
| Sheathless                                     | 1414 (54.1)                   |            |
| IABP implantation site, n (%)                |                               |            |
| Femoral artery                                | 2605 (99.6)                   |            |
| Auxillary artery                              | 10 (0.4)                      |            |

*See Supplementary Material S4 for a detailed description per individual procedure.

Within isolated CABG, within ‘other than isolated CABG’.

CABG: coronary artery bypass grafting; CAD: coronary artery disease; IABP: intra-aortic balloon pump; LV: left ventricle.

DISCUSSION

The current retrospective multicentre study of 2615 patients supported by IABP in the perioperative phase presents contemporary results of IABP use. Although it did not comprise a comparative analysis of patients supported by IABP versus conventional treatment, it does offer numerous important implications for present-day clinical practice.

To our knowledge, the current patient cohort represents the largest series of cardiac surgical IABP patients to date [7, 18, 19]. In our study, patients undergoing preoperative and intraoperative IABP implantation were both eligible for inclusion, as well as the whole spectrum of cardiac surgical procedures, not limited to CABG, differing from earlier published series [7]. Furthermore, cardiac surgical patient risk profile was diverse (as demonstrated by mean logistic EuroSCORE of 10.0%, range 1.0–90.0%), and urgency of surgery and indications for IABP use varied, resulting in a heterogeneous patient population. This heterogeneity enables a real-world evaluation of contemporary IABP use and its associated outcomes, not limited to 1 surgical procedure, time of implantation or specific risk profile.

Early mortality occurred in 12.7% of patients in this diverse patient population. Although previous studies and meta-analyses found a slightly lower in-hospital mortality rate [7], these studies were conducted in patients undergoing specifically CABG, which is generally considered to carry less mortality risk than non-CABG procedures [10]. As the current analysis does not comprise a comparison between IABP and non-IABP treated patients, it remains difficult to put the observed mortality rate in perspective, but it has been suggested that IABP reduces early mortality in this patient group, especially when implanted in the preoperative phase [6, 7]. Of note, the observed protective effect of preoperative implantation in our study only applies when compared to patients undergoing intraoperative implantation (in more unstable circumstances) and should therefore be interpreted with caution.

The current design facilitated an evaluation of risk factors and predictors of mortality in these cardiac surgical patients treated by IABP. In a multivariable model, peripheral arterial disease demonstrated to be the most important categorical baseline predictor of mortality (OR 1.63, P = 0.001), confirming earlier results [20]. Postoperative dialysis dependency (in patients not on dialysis before surgery) was the strongest postoperative predictor of early mortality (OR 10.40, P < 0.001). In post hoc analysis, preoperative renal insufficiency had the most significant association with postoperative dialysis dependency (OR 4.49, 95% CI 3.13–6.45, P < 0.001), but postoperative dialysis was also required in patients without preoperative renal failure (20.0% of postoperative dialysis patients). Inherently, this can be related to extent of surgery and duration of CPB [21], but the IABP balloon itself is also known to compromise renal flow, especially in the case of lengthier IABP balloons [22]. Subsequently, adequate selection of IABP balloon size is imperative and has the potential to reduce renal and mesenteric complication rate and mortality.

Another important postoperative predictor of adverse outcome was a composite end-point of vascular complications, occurring in 7.2% of patients. This composite end point was composed of IABP-related vascular complications and had a strong association with early mortality (OR 2.57, P < 0.001). In another post hoc analysis, peripheral arterial disease, which was also strongly correlated to early mortality, had a significant

Table 3: Early mortality and complication rate

| Outcome                                      | Number of patients (%) | Percentage |
|----------------------------------------------|------------------------|------------|
| Early mortality                              | 333 (12.7)             |            |
| Causes of death                              |                        |            |
| Cardiac                                      | 266 (80.0)             |            |
| Neurological                                 | 22 (6.6)               |            |
| IABP related                                 | 5 (1.5)                |            |
| Other                                        | 40 (13.7)              |            |
| Vascular complications                       | 189 patients (7.2%, 215 vascular complications) | |
| Ipsilateral ischaemia                        | 35 (1.3)               |            |
| IABP-site bleeding                           | 17 (0.7)               |            |
| Non-implantation-site bleeding                | 76 (2.9)               |            |
| Stroke                                       | 49 (1.9)               |            |
| Peripheral emboli                            | 15 (0.6)               |            |
| Vascular laceration                          | 20 (0.8)               |            |
| Retroperitoneal bleeding                     | 3 (0.1)                |            |
| Other complications                          |                        |            |
| Severe thrombocytopenia                      | 293 (11.2)             |            |
| Postoperative V-A ECMO dependency            | 55 (2.1)               |            |
| Postoperative dialysis requirement           | 185 (7.2)              |            |
| IABP-related complications                   | 5 (0.2)                |            |
| IABP balloon rupture                         | 3 (0.1)                |            |
| IABP balloon dysfunction                     | 2 (0.1)                |            |

IABP: intra-aortic balloon pump; V-A ECMO: veno-arterial extracorporeal membrane oxygenation.
association with the occurrence of vascular complications (OR 2.69, 95% CI 1.76–3.88, P < 0.001). Unfortunately, based on the available data, it remains unknown whether patients with known peripheral arterial disease underwent computed tomography (CT) preoperatively, to evaluate the presence, extent and location of vascular calcifications. The study period comprised the whole second decade of the 2000s, during which CT emerged as a low-threshold preoperative screening tool. Although only hypothesis-generating, such preoperative screening methods could guide the surgeon in the selection of implantation site (right versus left femoral, femoral versus axillary) and therefore has the potential to reduce vascular complication rate and subsequent mortality.

Based on the observed findings, contemporary IABP-associated complication rate has declined markedly, as compared to results of earlier registries [23] and findings in a recent review regarding IABP-related vascular complications [9]. Especially the devastating complication of limb ischaemia, which can result in amputation and mortality, seems to have decreased (1.3% in the current study) compared to earlier findings, where incidence varied between 1.0% and 27.0% [9, 24, 25]. One potential explanation for this reduction could be the increased use of a smaller sized IABP catheters [27, 28]. However, choosing a smaller balloon just to reduce vascular complications may decrease the efficacy of the counter pulsation principle. Still, with the advent of these less invasive strategies, possibly guided by preoperative screening modalities such as CT, a progressive reduction of complications can be expected, potentially turning the tide for the IABP.

**Limitations**

Inherently, an analysis of retrospective data is subjected to potential bias and missing data. In the current multicentre registry, variable completion was high (99.0%) but was still corrected for using a multiple imputation strategy [17]. Also, logistic EuroSCORE was used to express procedural risk, but some variables warranted for EuroSCORE were missing, such as active endocarditis, recent myocardial infarction and post-infarct septal rupture, potentially leading to an underestimation of surgical risk. The most important missing parameters in the current dataset were the duration of IABP support and the IABP model used. Especially the former might have an important influence on complication rate. Another important missing parameter was the patient’s presentation in terms of quantification of ischaemia with corresponding electrocardiographic findings. This also accounts in terms of protocols for thrombo-embolic prophylaxis, such as duration and dosage of periprocedural heparin administration. Also, we performed an analysis of IABP-related vascular complication rate, but 55 patients were supported by veno-arterial extracorporeal membrane oxygenation in the postoperative phase, and a potential relation of ECMO and vascular complications could not be ruled out based on the current analysis. Finally, the current results do not necessarily support the use of IABP versus conventional treatment in all patient categories, as the study does not comprise a comparative analysis. The same accounts for the timing of implantation.

**CONCLUSION**

Although the IABP has been the most widely adopted temporary mechanical circulatory support device in cardiac surgical patients, its use has declined in the past decades. In the current retrospective multicentre analysis of cardiac surgical patients undergoing a variety of procedures, the use of IABP proved to be safe and demonstrated decreased complication rates compared to previous findings. As such, we believe surgeons should not be held back to use this important device when indicated, and the tide should continue to turn for this first-line key support device.

**SUPPLEMENTARY MATERIAL**

Supplementary material is available at ICVTS online.

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**Data Availability Statement**

Data will be shared upon reasonable request to the corresponding author.
**Author contributions**

Roberto Lorusso: Conceptualization; Data curation; Formal analysis; Writing—review & editing.

Michele De Bonis: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Writing—original draft.

Carlo Antona: Conceptualization; Data curation; Supervision; Writing—review & editing.

Antonio Miceli: Conceptualization; Data curation; Supervision; Writing—review & editing.

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