Sheathless Versus Sheathed Intra-Aortic Balloon Pump Implantation in Patients Undergoing Cardiac Surgery

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The intra-aortic balloon pump (IABP) is the most widely available mechanical support device, but its use has been disputed in recent decades. Although several efforts have been made to reduce the associated complication rate, contemporary data on this matter is lacking. The present study aims to evaluate the differences in vascular complications between the sheathless and the sheathed IABP implantation technique in cardiac surgery patients. A retrospective multi-center cohort, consisting of patients treated in 8 cardiac surgical centers, was evaluated. Patients who underwent cardiac surgery with peri-operative IABP support were included. Primary outcome was a composite end point of vascular complications. Propensity score matching (PSM) was performed, and a multivariable regression model was applied to evaluate predictors of vascular complications. The unmatched cohort consisted of 2,615 patients (sheathless n = 1,414, 54%, sheathed n = 1,201, 46%). A total of 878 patients were matched (n = 439 for both groups). The composite vascular complication end point occurred in 3% of patients in the sheathless group, compared with 8% in the sheathed group (p <0.001). Vascular complications were significantly associated with mortality (odds ratio [OR] 3.86, 95% confidence interval [CI] 2.01 to 7.40, p <0.001). Peripheral arterial disease was associated with vascular complications (OR 3.10, 95% CI 1.46 to 6.55, p = 0.003), whereas the sheathless implantation technique was found to be protective (OR 0.36, 95% CI 0.18 to 0.73, p = 0.005). In conclusion, the present retrospective multi-center analysis demonstrated the sheathless implantation technique to be associated with a significant reduction in vascular complication rate. Future studies should focus on even less invasive implantation techniques using smaller-sized catheters, sheathless implantation, and imaging guiding. **(Am J Cardiol 2023;189:86−92)**

Historically, the intra-aortic balloon pump (IABP) has been the most widely available and adopted circulatory support device in patients who underwent cardiac surgery.[1] Still, the use of the IABP has been disputed, especially in nonsurgical patients, because of conflicting outcomes, a perceived complication rate, and a lack of beneficial effects in randomized trials.[2,3] However, in cardiac surgery in general, and coronary artery bypass grafting (CABG) in particular, the IABP has the potential to be used as first-line therapy and has been related to improved survival when implanted in high-risk patients in the pre-operative phase.[4,5] The aforementioned associated morbidity comprises bleeding and thrombo-embolic or ischemic complications.[6] Nevertheless, these observations are mainly based on rather outdated studies. Indeed, the complication rate might have been reduced with improvement in detection of ischemic complications and the introduction of modern implantation techniques in the contemporary era.[7,8] Classically, the IABP is introduced over a large-bore sheath, which might subject the patient to these drawbacks. In contrast, the sheathless implantation technique potentially

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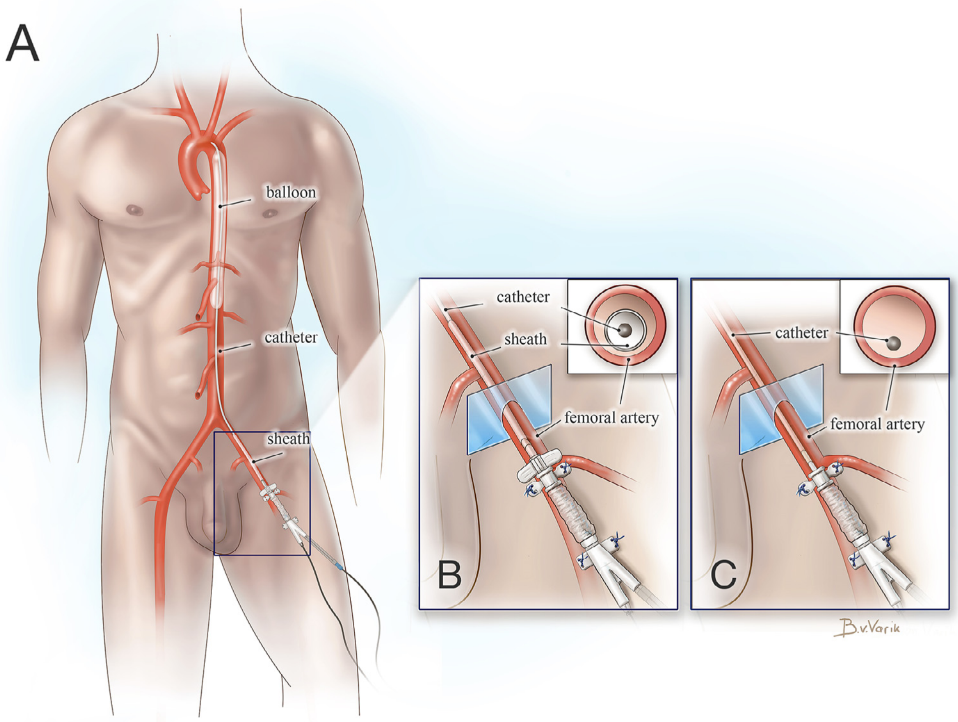

Figure 1. Overview of IABP implantation using the different techniques. *(A)* Full overview of IABP implantation, *(B)* sheathed implantation, *(C)* sheathless implantation. *Illustration by Barry van Varik (Pulse Medical Art).*

circumvents these adverse outcomes, but contemporary data on this technique is lacking. Therefore, the present study aims to compare the occurrence of vascular complications between the sheathless and sheathed IABP implantation technique and evaluate predictors of vascular complications in a large multi-center cohort of patients who underwent cardiac surgery.

Methods

This study was conducted by the *Gruppo Italiano di Ricerca sugli Outcome in Cardiochirurgia (*GIROC)-investigators and comprises a retrospective analysis of prospectively collected data.

The present study was conducted in agreement with the Declaration of Helsinki. The institutional review board of the leading center (Azienda Ospedaliera Spedali Civili di Brescia) approved the present study (Institutional review board approval number: 0020038, date: March 7, 2014), after which this was confirmed and re-approved by all other participating centers. The need for informed consent was waived because of the observational character of the study and the use of anonymized data.

All consecutive adult patients who underwent elective, urgent and emergency cardiac surgery with peri-operative IABP support in 8 cardiac surgery centers were included in this cohort, as described previously.[9] Patients were included between January 2010 and December 2019. Exclusion criteria were non-adult patients and surgery for congenital heart disease. Supplementary Table 1 presents the different participating centers.

The main aim of the present study was to evaluate the outcomes of 2 different implantation techniques, namely the conventional ‘sheathed’ technique and the more contemporary ‘sheathless’ technique. For the classical sheathed technique, an 8.0 Ch sheath was implanted using a Seldinger-derived approach (Figure 1). The sheathless method has been described extensively elsewhere.[8] In short, after a Seldinger-based guidewire insertion, the balloon catheter itself is advanced over the guidewire instead of the sheath system (Figure 1). For both techniques, balloon sizes were dependent on the body measurements of the patient (<152 cm: 25 ml, 152 to 163 cm: 34 ml, 164 to 183 cm: 40 ml, >183 cm: 50).[10] After IABP insertion and balloon inflation, adequate placement was confirmed radiographically in the catheterization lab by locating the radiopaque catheter tip in the aortic notch (Figure 1) or on conventional chest x-ray afterward in the intensive care unit.

Balloon catheter implantation was performed either in the intensive care unit, catheterization lab, or operating room. In general, IABP indications were stratified in left ventricular

Table 1
Baseline characteristics of the prematching and postmatching groups

Patient characteristics	Sheathless (n=1,414)	Sheathed (n=1,201)	p-Value	Sheathless (n=439)	Sheathed (n=439)	p-Value
		prematching			*postmatching*	
Age (years)	67 [60, 73]	70 [62, 76]	**<0.001**	68 [60, 75]	68 [60, 76]	**0.99**
Gender (female)	284 (20%)	319 (27%)	**<0.001**	100 (23%)	105 (24%)	**0.75**
EuroSCORE (log)	3 [1, 5]	10 [4, 21]	**<0.001**	5 [2, 13]	5 [3, 12]	**0.944**
History						
Hypertension	586 (41%)	802 (67%)	**<0.001**	278 (63%)	261 (60%)	**0.267**
Diabetes	369 (26%)	305 (25%)	**0.687**	133 (30%)	95 (22%)	**0.004**
COPD	118 (8%)	168 (14%)	**<0.001**	47 (11%)	67 (15%)	**0.056**
Renal insufficiency	110 (8%)	101 (8%)	**0.565**	32 (7%)	35 (8%)	**0.8**
Dialysis dependent	18 (1%)	15 (1%)	**1**	4 (1%)	4 (1%)	**1**
History of stroke	28 (2%)	33 (3%)	**0.197**	21 (5%)	13 (3%)	**0.22**
History of TIA	24 (2%)	31 (3%)	**0.133**	13 (3%)	12 (3%)	**1**
Peripheral arterial disease	74 (5%)	201 (17%)	**<0.001**	48 (11%)	50 (11%)	**0.915**
LVEF (%)	48 [40, 53]	40 [30, 50]	**<0.001**	45 [35, 55]	45 [35, 55]	**0.795**

COPD: = chronic obstructive pulmonary disease; EuroSCORE = European system for cardiac operative risk evaluation; LVEF = left ventricular ejection fraction; TIA = transient ischemic attack.

(LV) dysfunction, hemodynamic instability, prevention of ischemia/diffuse coronary disease, and other reasons.

In case of hemodynamic instability, IABP was implanted immediately, and the patients were operated on within 24 hours. In less urgent and planned cases with diffuse coronary artery disease, critical stenoses, or severely diminished LV function, the IABP was implanted in the catheterization lab an hour before surgery. In other cases, IABP could be implanted intra-operatively.

To determine the surgical risk profile of a patient, the European system for cardiac operative risk evaluation (logistic EuroSCORE[11]) was computed manually. All IABP-related and procedure-related characteristics were collected to present the procedural characteristics. Type and extent of surgery were presented individually (Supplementary Table 2) and in a binary form (isolated CABG or other cardiac surgical procedures).

Primary outcome was a composite outcome of vascular complications. A composite outcome was selected, as vascular complication rate seemed to decrease over recent decades.[6] Furthermore, a composite outcome has the capacity to cover ischemic/thrombo-embolic and bleeding and balloon-related complications. The composite outcome consisted of the following individual vascular complications: ipsilateral ischemia, IABP-site bleeding, stroke, vascular laceration, retroperitoneal bleeding, balloon rupture, and balloon dysfunction warranting replacement. Secondary outcomes were the individual vascular and balloon-related end points, early mortality, and predictors of the composite outcome.

Definitions of complications and parameters are provided in Supplementary Table 3.

Several methods have been proposed to deal with missing data, but multiple imputations has proved to serve as the most appropriate technique, providing least biased results.[12] Multiple imputation was performed before PSM in the present dataset. Ten multiple imputation datasets were realized, and a pooled dataset was used for further analyses.

For transparency reasons, Supplementary Table 4 presents the amount and distribution of missing data for the overall cohort.

Categorical variables were presented as numbers and corresponding percentages (%). Continuous variables were presented as mean $\pm$ SD or median (25th and 75th percentile). Continuous variables were assessed for normality using the Kolmogorov−Smirnoff test.

For categorical data, the chi-square test was used (when cell count $\leq$5, Fisher's exact test was applied). In the presence of a normal distribution, *t* test was performed to compare continuous data; in all other cases, the Mann−Whitney *U* test was applied. Statistical significance was defined as $p < 0.05$.

PSM analysis was performed. Covariates included in the propensity score were determined using logistic regression analysis for the primary outcome in the overall cohort, consisting of baseline and procedural characteristics. For sensitivity analytical purposes, additional matching procedures were performed for IABP indications to evaluate the robustness of the observed results. Remaining covariates were added for balancing purposes and based on available literature. Propensity scores were matched in a 1:1 ratio with a caliper distance of 0.1, not allowing replacement.

A multivariable binary regression model was composed of all covariates with a p value of <0.20 in univariable binary logistic regression analysis. As a rule of thumb, 1 covariate per 10 events was allowed in the multivariable model.[13] Results of binary regression analyses were presented in odds ratios (ORs) and corresponding 95% confidence intervals (CIs). Model discrimination was tested in a receiver operating characteristic (ROC) analysis. Finally, different compositions of the model were tested, and the model with lowest Akaike information criterion was chosen. A sensitivity analysis, presenting the multivariable model with inclusion of all covariates, was performed for evaluation of the robustness of these results as well. All statistical analyses, including multiple imputations, were performed using commercially available

Table 2
Procedural aspects and IABP characteristics in the matched population

	Sheathless (n=439)	Sheathed (n=439)	p-Value
Procedures (n, %)*			
Isolated CABG	341 (78%)	323 (74%)	0.181
Of which off-pump	16 (5%)†	8 (3%)†	0.148
Other than isolated CABG	98 (22%)	116 (26%)	0.181
Re-operative surgery (n, %)	19 (4%)	24 (6%)	0.532
Urgent/emergency surgery (n, %)	174 (40%)	151 (34%)	0.124
Planned surgery	265 (60%)	288 (66%)	0.124
Cardiopulmonary bypass time (mins)	104 [87, 127]	118 [81, 168]	<0.001
Aortic cross-clamping time (mins)	68 [54, 82]	71 [49, 94]	0.138
IABP indications (n, %)			<0.001
LV dysfunction	54 (12%)	98 (22%)	
Hemodynamic instability	47 (11%)	140 (32%)	
Ischemia prevention/diffuse CAD	332 (76%)	174 (40%)	
Other	6 (1%)	27 (6%)	
IABP timing (n, %)			
Pre-operative implantation	360 (82%)	191 (44%)	<0.001
Intra-operative implantation	79 (18%)	248 (57%)	<0.001
IABP implantation site (n, %)			
Femoral artery	438 (99%)	438 (99%)	1
Subclavian artery	1 (0.2%)	1 (0.2%)	1

CABG = coronary artery bypass grafting; IABP = intra-aortic balloon pump.
* See Supplementary Table 2 for a detailed description per individual procedure.
† Within isolated CABG.

software (IBM SPSS Statistics for Windows, Version 27.0. Armonk, New York),

Results

A total of 2,615 consecutive patients who underwent cardiac surgery with peri-operative IABP support were included (distribution of patients per center in Supplementary Table 1). The cohort was divided into 2 groups: the sheathless (study) group (n = 1,414, 54% of the overall cohort) and the sheathed (control) group (n = 1,201, 46%).

Median age of the entire patient cohort was 68 years (25th percentile: 61 years, 75th percentile: 75 years) but differed significantly between the sheathless and sheathed group (67 years [60, 73] vs 70 years [62, 76], p <0.001). Furthermore, gender, surgical risk as determined by logistic EuroSCORE, hypertension, chronic obstructive pulmonary disease, presence of peripheral arterial disease (PAD), and LV ejection fraction (LVEF) differed significantly at baseline (Table 1, prematching section).

The variables for PSM included hypertension, procedural urgency, isolated CABG, age, gender, LVEF, EuroSCORE (log), and presence of PAD. A total of 878 patients were matched (439 pairs, Table 1, postmatching section).

Age, gender, EuroSCORE (log), and presence of PAD, previously marked as important covariates, were equally balanced. The only residual imbalance comprised an increased presence of diabetes mellitus in the sheathless group; all other baseline characteristics were distributed equally.

Most procedures were isolated CABG (n = 341 [78%] vs n = 323 [74%], p = 0.181). A significant difference in cardiopulmonary bypass time was noted (104 minutes [87, 127] vs 118 minutes [81, 168], p <0.001), without a difference in aortic cross-clamping time (p = 0.138). Significantly more patients underwent pre-operative implantation in the sheathless group than in the sheathed group (n = 360 [82%] vs n = 191 [44%], p <0.001). Furthermore, distribution of indication for IABP implantation differed (p <0.001) between both groups (Table 2). A detailed description of individual surgical procedures is provided in Supplementary Table 2.

The primary composite vascular complication end point occurred in 3% of patients in the sheathless group (n = 12), compared with 8% in the sheathed group (n = 35, p <0.001, Table 3). This finding was confirmed in a sensitivity analysis, where matching for IABP indication was performed as well (281 pairs, vascular complication rate 4% [sheathless] vs 9% [sheathed], p = 0.035, Supplementary Table 5).

A significant difference in postoperative stroke was observed in the sheathed group (n = 4 [1%] vs n = 14 [3%], p = 0.029). Differences in other complications did not reach statistical significance (Table 3).

Table 3 lists 2 balloon ruptures (1%) in the sheathed group versus none in the sheathless group (p = 0.499). In both groups, 1 patient required balloon replacement because of balloon dysfunction (p = 1.000).

Severe thrombocytopenia, defined as platelet count $<50 \times 10^9$/L, postoperative dialysis requirement in patients not on dialysis pre-operatively, and postoperative volt-amperes extracorporeal membrane oxygenation dependency, occurred more in the sheathed group (5% vs 22%, p <0.001, 5% vs 11%, p <0.001, 2% vs 5%, p = 0.033, respectively, Table 3).

Early mortality differed significantly between both groups (5% vs 19%, p <0.001). Again, this was confirmed in the IABP indication-matched sensitivity analysis (6% vs 16%, p <0.001, Supplementary Table 5). Within the deceased population, causes of death comprised cardiac,

Table 3
Complication rate in the matched population

Outcome	Sheathless (n=439)	Sheathed (n=439)	p-Value
*Vascular complications - composite endpoint**	12 (3%)	35 (8%)	<0.001
Vascular complications - individual endpoints			
Ipsilateral ischemia	4 (1%)	9 (2%)	0.263
IABP-site bleeding	4 (1%)	5 (1%)	1
Stroke	4 (1%)	14 (3%)	0.029
Vascular laceration	3 (1%)	6 (1%)	0.506
Retroperitoneal bleeding	0	1 (0.2%)	1
Other complications			
Severe thrombocytopenia	23 (5%)	96 (22%)	<0.001
Postoperative	8 (2%)	20 (5%)	0.033
V-A ECMO dependency	21 (5%)	49 (11%)	<0.001
Postoperative dialysis requirement			
Balloon-related complications			
Balloon rupture	0	2 (1%)	0.499
Balloon dysfunction warranting replacement	1 (0.2%)	1 (0.2%)	1
Early mortality	21 (5%)	84 (19%)	<0.001
Causes of death			
Cardiac	16 (77%)	70 (83%)	0.527
Neurological	2 (10%)	6 (7%)	0.659
IABP-related	0	2 (2%)	1
Other	3 (14%)	6 (7%)	0.69

IABP = intra-aortic balloon pump; V-A ECMO = veno-arterial extracorporeal membrane oxygenation.
* Composite end point consisting of ipsilateral ischemia, IABP-site bleeding, stroke, vascular laceration, retroperitoneal bleeding, balloon rupture, and balloon dysfunction warranting replacement.

neurologic, and IABP-related death, without significant differences between both groups regarding these causes. Other causes (14% vs 7%, p = 0.690) comprised bowel ischemia, multi-organ failure, sepsis/infection, and withdrawal from support (Table 3).

Potentially important baseline and procedural parameters were tested in binary univariable analysis for occurrence of the composite end point of vascular complications (Supplementary Table 6). The most appropriate multivariable model, based on Akaike information criterion, was determined. Multivariable analysis revealed PAD to significantly increase the risk of vascular complications (OR 3.10, 95% CI 1.46 to 6.55, p = 0.003). The sheathless implantation technique demonstrated a protective effect against vascular complications (OR 0.36, 95% CI 0.18 to 0.73, p = 0.005, Table 4). ROC analysis confirmed acceptable discrimination, with an area under the curve of 0.71 (p <0.001). Of note, these findings were confirmed in a sensitivity analysis containing a multivariable model with inclusion of all univariably evaluated covariates (sheathless implantation persisted in having an independently protective association: OR 0.36, 95% CI 0.17 to 0.74, Supplementary Table 7).

Table 4
Predictors of vascular complications in binary logistic multivariable analyses of the matched population

Variable	Odds ratio	95% CI	p-Value
Diabetes	0.445	0.191−1.037	0.061
Peripheral arterial disease	3.095	1.463−6.548	0.003
Pre-operative IABP implantation	0.858	0.494−1.799	0.858
Re-operative surgery	2.547	0.964−6.728	0.059
Implantation technique (sheathless)	0.359	0.175−0.738	0.005

CI = confidence intervals; IABP = intra-aortic balloon pump.

Finally, the occurrence of vascular complications was significantly associated with mortality (OR 3.86, 95% CI 2.01 to 7.40, p <0.001).

Discussion

To our knowledge, the present multi-center study represents the largest cohort of patients supported by IABP in the peri-operative phase.[5,14,15] Our main findings are that vascular complication rate is significantly decreased by the sheathless implantation technique in this patient population, and implantation technique is protective of vascular complications, whereas PAD is significantly associated with the occurrence of these complications.

The study initially consisted of 2,615 patients. However, important baseline characteristics, such as PAD, age, and gender, differed significantly between the unmatched population. To balance the groups for these important covariates, PSM was performed, which resulted in the matching of 439 pairs, creating equal groups, also in terms of surgical risk as defined by logistic EuroSCORE. Only diabetes mellitus, which is also related to the occurrence post-IABP vascular complications,[16] persisted as a difference between the groups, but its incidence was increased in the sheathless group.

Sheathless implantation was associated with a significant reduction in vascular complications (3% vs 8%, OR 0.36, p <0.001). When implanted without a sheath, the effective lumen of the femoral artery is markedly increased, therefore, lowering the risk of ipsilateral ischemia. Additionally, the size of the puncture site in the artery is evidently smaller, potentially reducing bleeding events. These findings are in line with previous non-matched cohorts, which might be considered outdated.[7] Other modifiable factors in reducing vascular complications comprise the use of smaller-sized balloon catheters, which have been increasingly applied in recent years.[17,18]

Compared with recent findings from the National Inpatient Sample database, evaluating vascular complications in over 200,000 patients who underwent any form of mechanical circulatory support, the vascular complications rate is comparable or even slightly decreased in our sheathless implantation group.[19] However, in this referenced study, the implantation techniques were not reported, and it must be noted that this vascular complication end point is definition-dependent and, therefore, not always comparable between separate studies.

Although not the primary outcome of the present analysis, early mortality also differed significantly, with an evidently better outcome in the sheathless group (5% vs 19%), despite a balance in 30-day mortality risk as defined by EuroSCORE. Several factors, which were unexplored in the present study, could contribute to this finding, including differences in indications for and timing of IABP implantation. Indeed, in the sheathed population, IABP was more frequently implanted for LV dysfunction and hemodynamic instability. In contrast, in the sheathless group, IABP was implanted for diffuse coronary artery disease in most patients in the pre-operative phase, also known as prophylactic IABP. Such a planned prophylactic strategy itself has been associated with a reduction in early mortality in high-risk cardiac surgical patients.[4] Still, as the incidence of vascular complications was associated with mortality in the present analysis and previous studies,[4] the mere decrease in complications in the sheathless group itself could have partly contributed to the mortality reduction. This relation between vascular complications and mortality was confirmed in a previous study,[16] whereas an elegant follow-up study by the same research group evaluating 2 eras with different protocols found a reduced vascular complication rate and mortality rate after implementation of a specific IABP-protocol using smaller-sized catheters, percutaneous implantation, and sheathless insertion.[18] Also, in other studies evaluating related procedures, such as trans-catheter aortic valve implantation, the vascular complication rate was an important driver of mortality,[20] which might also influence other long-term outcomes such as quality-of-life, unexplored in the present cohort.

In multivariable analysis, besides the sheathless implantation technique, the presence of PAD significantly influenced the incidence of vascular complications (OR 3.10), confirming the observations of previous studies, both in surgical and nonsurgical patients.[16,21] Although PAD causes arterial wall calcification and narrowing of the vascular lumen, especially PAD patients who underwent sheathed IABP implantation could be exposed to an increased risk of ipsilateral ischemia. Although sheathless implantation has the hypothetical potential to reduce this risk in this specific patient group, the question arises whether femoral implantation is appropriate in these cases. Of note, in the present matched analysis, only 1 patient in both groups underwent nonfemoral (i.e., subclavian) implantation. Still, PAD occurs significantly less in the upper extremities (in a ratio of 1:5[22]), making the subclavian or axillary arterial approach specifically amenable in patients affected by PAD. With the advent of routine computed tomography angiography (CTA) in the pre-operative phase, the location and extent of PAD in the peripheral vessels can be adequately assessed, facilitating a more appropriate vessel selection (i.e., right vs left, femoral vs subclavian). In extreme cases, based on imaging evaluation, even a transthoracic approach can be considered.[23] The advantages of pre-operative CTA evaluation would especially apply to patients who underwent planned procedures with prophylactic IABP implantation.

The present study was subjected to missing data, but variable completion was high (99%) and was still corrected for using a multiple imputation strategy, providing the least biased method for dealing with missing data.[12] Still, the most important parameters missing in the present cohort were the exact duration of IABP support and the type and model of IABP applied, which might influence outcome. Before matching, important predictive baseline characteristics differed between both study groups. PSM was applied to resolve these important imbalances. Important covariates were determined by use of regression analyses; however, it cannot be ruled out that PSM could not correct for unknown confounders. Only randomization could resolve such issues. Baseline characteristics were eventually evenly balanced between groups, but procedural aspects were not. Most importantly, the timing and indication of IABP implantation differed between groups. Still, the present analysis primarily aimed to evaluate differences in vascular complications between both groups, which are not perceived to be affected by timing and indication of implantation. This was confirmed in the multivariable analysis, as timing of implantation was not associated with the occurrence of vascular complications, which is reassuring in terms of potential bias. Then, whereas CTA has the potential to determine the ideal access site for IABP implantation, its use in the present cohort was not reported, and definite statements regarding its use cannot be derived from the presented data.

Finally, we hypothesize vascular complications are not only associated with long-term outcomes such as mortality, but also quality-of-life. Therefore, future studies evaluating different implantation techniques and protocols should incorporate this important patient-specific parameter in their analysis.

In the present retrospective multi-center analysis of cardiac surgical patients supported by IABP in peri-operative phase, the sheathless implantation technique was associated with a significant reduction in vascular complications. By focusing on less invasive implantation techniques using smaller-sized catheters, sheathless implantation, and imaging guiding, complications could be even further reduced, potentially leading to a more appropriate use of this indispensable first-line circulatory support device in patients who underwent cardiac surgery.

Disclosures

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Supplementary materials

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