Original Article

Vascular Complications With Intra-aortic Balloon Pump (IABP): Experience From a Large Canadian Metropolitan Centre

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ABSTRACT

Background: Intra-aortic balloon pump (IABP) insertion in critically ill patients has been associated with both vascular and nonvascular complications, which have restricted its use. The primary objective for this study was to determine the frequency and predictors of vascular complication in our centre.

Methods: We conducted a retrospective cohort study of consecutive patients treated with an IABP between January 2014 and June 2018. Baseline clinical characteristics, cannulation details, duration of treatment, and complications were recorded.

Results: A total of 216 patients were included in the study. The most common complications were cardiac tamponade (15%), distal embolization (10%), and limb ischemia (9%). The incidence of cardiac tamponade was highest among patients with a history of previous cardiac surgery (22%).

Conclusion: Vascular complications are common in patients treated with an IABP. The incidence and predictors of these complications need to be considered when determining the appropriate use of IABP.

RESUMÉ

Contexte : L’insertion d’un ballon de contrepulsion intra-aortique (BCPIA) chez les patients dont l’état est critique est associée à des complications à la fois vasculaires et non vasculaires, ce qui limite son utilisation. L’objectif principal de cette étude était de déterminer la fréquence des complications vasculaires dans notre centre ainsi que les facteurs prédictifs de ces complications.

Méthodologie : Nous avons mené une étude de cohorte rétrospective auprès de patients traités consécutivement par BCPIA entre janvier 2014 et juin 2018.

Les complications vasculaires les plus fréquentes étaient la tamponnade cardiaque (15%), l’embolie distale (10%) et l’ischémie des membres (9%). L’incidence de la tamponnade cardiaque était la plus élevée chez les patients ayant une histoire de chirurgie cardiaque précédente (22%).

Conclusion : Les complications vasculaires sont courantes chez les patients traités par ballon intra-aortique. L’incidence et les facteurs prédictifs de ces complications doivent être considérés pour déterminer l’appréciation appropriée de l’utilisation du ballon intra-aortique.
Among the many vascular complications, both limb and mesenteric ischemia are the most life-threatening conditions. The aim of our study was to quantify the frequency, and potentially the predictors, of vascular complication following IABP insertion for patients at our centre. To the best of our knowledge, this study is the first to report the prevalence of vascular complications following IABP insertion at a Canadian centre. Ultimately, the goal is to obtain further insight into the risk-benefit balance of IABP treatment, allowing clinicians to make more-informed decisions regarding use of this device.

Materials and Methods

Study design

A retrospective cohort study was conducted. All consecutive adult patients aged 18 years or older who were treated with a peripheral IABP at our centre between January 2014 and June 1, 2018 to determine the presence of vascular complications—specifically limb or bowel ischemia—were eligible for inclusion. Our site is a quaternary care, academic teaching hospital and is unique in accepting patients from other facilities that do not have the expertise for CS management or cardiac surgery. These patients may require even further escalation of treatment, including extracorporeal membrane oxygenation (ECMO).

Demographic data

We collected the following patient demographic data: age, gender, body mass index, presence or absence of preexisting peripheral artery disease, hypertension, hyperlipidemia, diabetes, coronary artery disease (CAD), atrial fibrillation, asthma or chronic obstructive pulmonary disease (COPD), peripheral arterial disease, stroke or transient ischemic attack, and chronic kidney disease (CKD), dialysis and cannulation details (operating room, intensive care unit (ICU), catheterization lab, emergency department, outside hospital, arterial cannula size (> 20 Fr); duration of IABP treatment; and in-hospital, 30-day, and 1-year overall mortality.

Outcomes

Outcomes of interest included incidence of vascular complications, length of hospital stay, and in-hospital and 30-day mortality.

Statistical analysis

Descriptive statistics are reported as mean (± standard deviation) for continuous variables, and median (range) for categorical variables. Normal and nonparametric distributed continuous variables are presented as mean ± standard deviation and median with interquartile range (IQR), respectively. Categorical variables are presented as percentages. Appropriate parametric and nonparametric analysis ($\chi^2$, Fisher’s exact test, Mann-Whitney U test, and t test) was used to identify important univariate predictors of mortality. Following this analysis, backwards logistic regression within variable groups (eg, demographic variables, comorbidities, surgical variables [ICU; length of stay]) was used to identify the significant predictors from within each group. In the last stage of model building, significant variables from the initial backwards
regression were added into a final backwards regression model. Use of this approach allowed us to make the most of our sample by preserving power. All statistical analyses were performed using SPSS version 25.0 (IBM, Armonk, NY). Two-tailed p values of < 0.05 were considered significant.

Ethics approval

Ethics approval was obtained from our institutional research ethics board.

Results

A total of 187 patients required an IABP between January 1, 2014 and June 1, 2018. Baseline patient characteristics are shown in Table 1. A total of 78% of patients were male (n = 146). The most common comorbid conditions included a history of hypertension (49.2%; n = 92), CAD (48.1%; n = 90), hyperlipidemia (42.3%; n = 79), and diabetes (33.2%; n = 62). A summary of the indications for IABP insertion, location of cannulation procedure, site, and duration of insertion is provided in Table 2. The most common indication for insertion was acute decompensated heart failure-CS (58.3%; n = 109) followed by acute MI-CS (26.2%; n = 49). Use for support during percutaneous coronary intervention (non-acute, MI-related), occurred in 15% (n = 28) of our patients. The right groin was cannulated more than 61% of the time (n = 106), and the most frequent hospital location of placement was in the cardiac catheterization room (54.5%; n = 102). Slightly more than one quarter of the patients arrived with their device having been placed at an outside hospital in a cardiac catheterization lab (26.7%; n = 50).

The median length of stay in the ICU was 3 days (IQR: 1-7 days) and hospital length of stay was 10 days (IQR: 4-19 days). In-hospital mortality was 37.4% at 30 days. One year follow-up was available in 1-7 days) and hospital length of stay was 10 days (IQR: 4-19 days). In-hospital mortality was 37.4% at 30 days. One year follow-up was available in 187 patients. Duration is reported as average ± standard deviation.

Table 1. Baseline patient characteristics

| Characteristic         | Value          |
|------------------------|----------------|
| Age, y                 | 65.2 ± 11.5    |
| Sex, male              | 146 (78.1)     |
| Body Mass Index, kg/m² | 26.8 ± 6.2     |
| ICU length of stay, d  | 3 (2-17)       |
| Hospital length of stay, d | 10 (4-19)   |
| Hypertension           | 92 (49.2)      |
| Hyperlipidemia         | 79 (42.3)      |
| Diabetes               | 62 (33.2)      |
| Atrial fibrillation    | 22 (11.8)      |
| Asthma                 | 7 (3.74)       |
| COPD                   | 12 (6.42)      |
| Coronary artery disease| 90 (48.1)      |
| Peripheral arterial disease | 8 (4.3) |
| Stroke or TIA          | 12 (6.4)       |
| Chronic kidney disease | 23 (12.3)      |

Each categorical baseline clinical characteristic is reported as N (%), within the total population of 187 patients. Age is reported as average ± standard deviation. ICU length of stay and hospital length of stay are reported as median with interquartile range.

COPD, chronic obstructive pulmonary disease; ICU, intensive care unit; TIA, transient ischemic attack.

No association was found between increased length of IABP insertion and vascular complications. No association was found between IABP insertion and mortality due to arterial wall damage, or mortality secondary to bleeding. We did not find a significant correlation of duration of IABP insertion or French size with vascular complications.

After running appropriate univariate tests to compare differences between mortality groups, backwards logistic regression was undertaken in stages for variables that were significantly different between groups at the univariate level. One regression analysis included the demographic variables of age, indication, smoking, and hyperlipidemia. A second backwards logistic regression analysis included the medical variables of smoking, hyperlipidemia, CKD, and COPD. From these 2 models, only age and IABP indication remained significant. Therefore, they were entered into the final model.

Using backwards logistic regression modeling, age (B = 0.066; odds ratio [OR] 1.07 [confidence interval: 1.03-1.10]; P < 0.0001) and IABP indication (B = 1.67; OR = 5.31 [confidence interval: 2.36-11.95]; P < 0.0001) remained independent factors that affected overall mortality. With an increase in age, the level of in-hospital mortality increased. A χ² analysis showed that patients with an IABP inserted for CS showed an increased risk of in-hospital mortality, compared to those with acute MI-CS and percutaneous coronary intervention (χ² = 13.24, P < 0.001). No associated increased risk of mortality occurred if the patient had a past medical history of CAD, peripheral arterial disease, diabetes, asthma, COPD, hypertension, CKD, and/or atrial fibrillation (P > 0.05).

Discussion

This retrospective analysis highlights the contemporary evidence of IABPs and vascular complications (2014-2018). To the best of our knowledge, this study is the first in Canada...
Table 3. Intra-aortic balloon pump complications

| Complication            | N (%) |
|-------------------------|-------|
| Overall mortality       |       |
| In-hospital             | 70 (37.4) |
| 30-day                  | 6 (5.1) |
| 1-year                  | 2 (1.8) |
| Amputation              | 0 (0.0) |
| Limb ischemia           | 6 (3.2) |
| Aortoiliac dissection   | 0 (0.0) |
| Compartment syndrome    | 1 (0.5) |
| Return to operating room| 1 (0.5) |
| Bleeding                | 3 (1.6) |
| Infection at insertion  | 0 (0.0) |
| Mesenteric ischemia     | 1 (0.5) |
| Fasciotomy              | 1 (0.5) |
| Thrombectomy            | 0 (0.0) |
| Bypass                  | 0 (0.0) |

Each categorical baseline clinical characteristic is reported as n (%) within the total population of 187 patients. 30-day mortality is calculated from the number that died from the remaining total population (N = 117). 1-year mortality is calculated from the number that died from the remaining total population since 30-day mortality (N = 111).

to investigate this topic, at a large quaternary centre. Since 2014, globally, no further studies have been published on this issue. A review published in 2018 by de Jong et al. reviewed a total of 21 papers published between 1990 and 2014. However, due to the heterogeneity of the studies and differences in outcomes, a meta-analysis could not be performed.

We conducted a retrospective cohort study reviewing our 4-year experience with IABP insertion with vascular complications. A total of 11 vascular complications in 7 patients were noted in our cohort. The overall combined prevalence was 3.74%. A review looking at vascular complications following IABP insertion over a 26-year period found that the incidence of IABP-related vascular complications varied from 0.94% to 31.1%, with the most frequently reported vascular complication being limb ischemia (range: 0.9%-26.7%). In comparison, our study demonstrates concordance with these prior reports. In our cohort, we saw that the most common vascular complications were limb ischemia (2.7%; n = 5), bleeding (1.6%; n = 3), mesenteric ischemia (0.5%; n = 1), and fasciotomy (0.5%; n = 1). Furthermore, we did not see any amputations, aortoiliac dissections, compartment syndrome, infection at the insertion site, need for thrombectomy, or bypass surgery. The incidence of these complications at our centre are lower than those previously reported in several papers. This difference could be secondary to improvements of insertion methods over the years; however, further studies of differences in techniques are warranted.

This study was a comprehensive evaluation of all vascular outcomes related to IABP insertion. No association was found between increased length of IABP insertion and vascular complications. No association was found between IABP insertion and mortality due to arterial wall damage, age, body mass index, or sex of the patient. Furthermore, no associated mortality secondary to bleeding was found. We also did not find any correlation between duration of IABP insertion or French size and vascular complications, despite prior reports.

Patients who received an IABP for CS had an increased risk of in-hospital mortality, as compared to any other indication, including hemodynamic support (OR = 5.31, P < 0.001). This increase could be secondary to the underlying nature of their disease. CS is the leading cause of death after acute MI. Our results demonstrate that 51 patients (46.8%) with CS died in-hospital, which is similar to the previously reported prevalence of 40%-60%. We hypothesize that the higher transfer rate of patients from other facilities and the severity of disease can explain the higher rate (10%) of CS noted in our cohort. The distance to the treating facility for patients with an IABP inserted, in connection with risk of mortality, can be explored in future studies.

Our data identified that almost one third of the patients in our cohort were transferred to our centre. Referring centres tend to be smaller institutions that do not have access to an IABP, thus leading to transfer of these patients to our institution for cardiac care. Overall, only 26.7% of the IABPs for the patients in this study (N = 50) were placed at an outside centre, and none of these patients presented to the hospital with a vascular injury. A review of the data indicated that only 2 patients who had IABPs placed at another institution developed ischemia, after IABP pump insertion while at our centre, after their index procedure.

This study has associated limitations. One is that the study is a single-centre experience. Our centre is one of the largest quaternary care centres in Ontario and receives patients with IABPs from different regions of the province. Patients are transferred if the home centre does not have the resources necessary to aid patient survival. The patients received by our centre therefore have a more severe progression of their primary diagnosis, compared to that of patients at other centres. Due to this difference, great caution should be used in generalizing the results of our study to the remainder of the country’s population. Second, this study uses retrospective cohort data. Therefore, the results are at risk of being affected by recall bias or misclassification bias. Furthermore, retrospective cohort studies require a large cohort to demonstrate a statistically significant result for rare outcomes. Although our cohort includes more than 180 participants, a lack of significant difference could be secondary to a lack of power. Studies investigating these outcomes in a multicentre, large cohort can mitigate these shortcomings.

Conclusions

We demonstrated a low rate of vascular complications or mortality associated with IABP insertion. The site of insertion—peripheral hospital vs tertiary hospital—did not affect the prevalence of vascular complications. We identified a greater prevalence of in-hospital mortality among patients with CS, and although this prevalence is greater than that previously reported, our overall in-hospital mortality, at 30-days and 1-year, was comparable to that reported in the literature.

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Disclosures

The authors have no conflicts of interest to disclose.
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