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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

RÉSUMÉ

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

The intra-aortic balloon pump (IABP) is one of the most commonly used circulatory assist devices in critically ill patients with compromised cardiac function.[1] This technique has been used during numerous cardiac surgical procedures, including after acute myocardial infarction (MI) and during cardiogenic shock (CS), to both increase coronary blood flow and decrease left ventricular afterload.[2]

The concept behind the IABP is that the counterpulsation caused by the pumping of the balloon causes "volume displacement" of blood within the aorta at both proximal and distal locations. This action leads to a potential increase in coronary blood flow, and in addition, it can lead to improvements in systemic perfusion by augmentation of the intrinsic "Windkessel effect."[3] IABP treatment, therefore, enhances the ventricular performance of the failing heart by facilitating an increase in myocardial oxygen supply, in addition to decreasing the myocardial oxygen demand.[3]

Despite the evidence in favour of IABP treatment, recent guidelines both nationally and internationally have downgraded the use of an IABP for CS from class I to class IIa in American guidelines, whereas in Europe, the IABP is now a class III treatment.[4,5] Furthermore, the recent Intraaortic Balloon Pump in Cardiogenic Shock II (IABP SHOCK-II) trial demonstrated that IABP treatment did not significantly reduce 12-month mortality in patients with CS complicating MI undergoing early revascularization, although the self-reported quality of life was moderate to good in survivors.[6] A number of recent studies have challenged the outcomes of the IABP SHOCK II trial, illustrating the fact that further work is still required to determine the benefit of this modality in the clinical setting.[7,8] In addition to the IABP SHOCK II trial data, data from available from widespread clinical use of the IABP previously were restricted due to complications relating to the insertion of the balloon pump. Despite improvement in IABP technology, such complications remain an important issue.[9]

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Ethics Statement: Ethics approval was obtained from our institutional research ethics board.

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treatment and management, overall mortality, and complications were extracted from electronic and paper medical records.
Results: A total of 187 patients required an IABP; of these, 146 were male (78.1%), the average age was 65.2 ± 11.5 years, and body mass index was 26.8 ± 6.2 kg/m^2. A majority of the patients had an IABP inserted in either the cardiac catheterization laboratory (54.5%) or an outside hospital (26.7%). The main indications for insertion were acute decompensated heart failure-cardiogenic shock (58.3%), followed by acute myocardial infarction and cardiogenic shock (26.2%). From the documented cannulation site, the right femoral artery was cannulated in 61.6% of patients, with a median size of 7.5 Fr (range: 5 -12 Fr). Mortality for in-hospital, 30-day, and 1-year mortality was calculated at 37.4%, 40.6%, and 41.7%, respectively. Limb ischemia (3.2%), bleeding (1.6%), mesenteric ischemia (0.5%), compartment syndrome (0.5%), and fasciotomy (0.5%), were rare occurrences. No records indicated amputation, aortoiliac dissection, thrombectomy, or infection at the site of insertion.
Conclusions: This single-centre retrospective study demonstrated that more than one third of this patient population died secondary to their primary diagnosis. The incidence of vascular complications secondary to IABP insertion remained low, with less than 3% developing an ischemic limb.

2014 et juin 2018. Les caractéristiques cliniques initiales, les détails sur la canulation, la durée du traitement et de la prise en charge, la mortalité globale et les complications ont été extraits des dossiers médicaux électroniques et en format papier.
Résultats : Au total, un BCPIA a été nécessaire chez 187 patients; 146 d'entre eux étaient des hommes (78,1 %), l'âge moyen était de 65,2 ± 11,5 ans, et l'indice de masse corporelle moyen était de 26,8 ± 6,2 kg/m^2. La majorité des insertions de BCPIA s'étaient déroulées soit dans le laboratoire de cathétérisme (54,5 %) ou dans un hôpital externe (26,7 %). Les principales indications pour lesquelles ces insertions ont été effectuées étaient l'insuffisance cardiaque aiguë décompensée avec choc cardiogénique (58,3 %), suivie de l'infarctus du myocarde aigu avec choc cardiogénique (26,2 %). Selon les sites de canulation documentés, l'artère fémorale droite avait été canulée chez 61,6 % des patients, avec un calibre médian de 7,5 Fr (de 5 à 12 Fr). Les valeurs de mortalité à l'hôpital, à 30 jours et à un an, ont été établies à 37,4 %, 40,6 % et 41,7 %, respectivement. L'ischémie d'un membre (3,2 %), l'hémorragie (1,6 %), l'ischémie mésentérique (0,5 %), le syndrome des loges (0,5 %) et la fasciotomie (0,5 %) ont été constatés dans quelques rares cas. Aucun dossier n'indiquait d'amputation, de dissection aorto-iliaque, de thrombectomie ou d'infection au point d'insertion.
Conclusions : Cette étude de cohorte rétrospective unicentrique a permis de démontrer que plus d'un tiers des patients de la population à l'étude sont décédés des suites de leur diagnostic primaire. L'incidence de complications vasculaires secondaires à l'insertion d'un BCPIA est demeurée faible, avec moins de 3 % des patients présentant une ischémie d'un membre.

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 (χ^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

Table 1. Baseline patient characteristics

Characteristic	Value
Age, y	65.2 ± 11.5
Sex, male	146 (78.1)
Body Mass Index, kg/m^{2†}	26.8 ± 6.2
ICU length of stay, d	3 (3−17)
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.

Table 2. IABP insertion characteristics

Duration, d	2.5 ± 3.3
IABP indication for insertion	
ADHF-CS	109 (58.3)
Acute MI-CS	49 (26.2)
PCI (use for support during PCI)	28 (15.0)
IABP cannulation site	
Left femoral	66 (38.4)
Right femoral	106 (61.6)
Unknown	15 (8.0)
Location for cannulation procedure	
Intensive care unit	34 (18.2)
Cardiac catheterization laboratory	102 (54.5)
Emergency department	1 (0.5)
Outside hospital	50 (26.7)
Operating room	0 (0)

Each categorical baseline clinical characteristic is reported as a percentage within the total population (187 patients). Duration is reported as average ± standard deviation.

ADHF, acute decompensated heart failure; CS, cardiogenic shock; IABP, intra-aortic balloon pump; MI, myocardial infarction; PCI, percutaneous coronary intervention.

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 catherization 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 and overall mortality reached 40.6% and 41.7%, respectively. The most common vascular complications were as follows: limb ischemia (3.2%), with 0.5% of patients developing compartment syndrome and requiring a fasciotomy; bleeding (1.6%); and mesenteric ischemia (0.5%). This cohort did not have any patients who needed an amputation, thrombectomy, or bypass surgery, nor did any patients in the cohort develop an aortoiliac dissection or infection at the insertion site (Table 3).

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 univarite 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 χ^2 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 ($\chi^2 = 13.24$, $P < 0.001$). 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.[10] However, due to the heterogeneity of the studies and differences in outcomes, a meta-analysis could not be performed.[10]

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%).[10] 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.[11,12] 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.[10,12]

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.[13] Our results demonstrate that 51 patients (46.8%) with CS died in-hospital, which is similar to the previously reported prevalence of 40%-60%.[13,14] 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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