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# Trends in Intraaortic Balloon Counterpulsation Complications and Outcomes in Cardiac Surgery

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**Background.** As the proportion of high-risk patients for cardiac surgery increases, use of intraaortic balloon counterpulsation (IABC) has increased, especially in preoperative therapy. Although the efficacy and cost-effectiveness of IABC have been demonstrated, historically higher complication rates have dissuaded some practitioners from using IABC.

**Methods.** This report describes IABC use in cardiac surgery, examines trends in complications over time, and compares outcomes in preoperative versus postoperative use in a single prospective worldwide registry over the past 3 years.

**Results.** The frequency of IABC use appears to be increasing with time as the complication rates have dramatically fallen. The overall IABC-related complication rate was 6.5% (460/7,101), and the rate of major

complications (requiring surgery or transfusion) was 2.1% (148/7,101). Hospital mortality was significantly lower in patients treated preoperatively with IABC compared with patients treated postoperatively (8.8% vs 28.2%,  $p < 0.0001$ ), although this may be due to a selection bias in the postoperative group.

**Conclusions.** Preoperative IABC therapy leads to better patient outcomes in high-risk CABG patients. Improved IABC technology and better surveillance have led to increased use with lower complication rates. Although selection bias is inherent in retrospective studies, the Benchmark Counterpulsation Outcomes Registry outcomes are in close concordance to prospective randomized studies previously reported.

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Intraaortic balloon counterpulsation (IABC) is the most widely used circulatory assist device in cardiac surgery. It provides circulatory support for patients experiencing preoperative and postoperative hemodynamic instability, or for high-risk patients undergoing angioplasty or coronary artery bypass graft (CABG) surgery [1–4]. As the proportion of high-risk patients undergoing cardiac surgery increases [5], use of IABC has also increased, especially for preoperative therapy [1, 6–8]. Although the efficacy and cost-effectiveness of preoperative IABC therapy have been demonstrated [2, 6, 9–14], historically higher IABC-related complication rates have dissuaded some surgeons from IABC use [15–18]. Most reports on IABC complications have been retrospective in nature and cover extensive time periods, during which medical therapy, anesthesia, extracorporeal circulation techniques, and surgical techniques have improved.

This report describes IABC use in cardiac surgery, examines trends in complications over time, and compares outcomes in preoperative versus postoperative

IABC use in a unique voluntary single worldwide registry (Benchmark Counterpulsation Outcomes Registry) [19] over the past 3 years. Registry data were also compared with data from The Society of Thoracic Surgeons (STS) National Database, another large voluntary data base.

## Material and Methods

The Benchmark Counterpulsation Outcomes Registry is an ongoing, large-scale, worldwide prospective registry that was established in June 1996 to track the use of IABC. Datascope Corporation (Fairfield, NJ) provided funding for the database, and the sites included in the registry were institutions that used intraaortic balloons manufactured by Datascope. An independent steering committee designed and implemented this investigator-initiated registry (authors). The registry is a computerized database that incorporates prospectively gathered clinical information on all patients treated with IABC from participating institutions (currently 266 locations worldwide). Database software was custom written and de-

Drs Christenson, Cohen, Ferguson, Miller, Stone, and Urban disclose that they have a financial relationship with Datascope.

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fined. Site data were forwarded by modem to a single registry storage location and handled on a central file server. The registry includes data on patient demographics, indications for IABC use, concomitant medication, in-hospital outcomes, and complications [20]. Accuracy of transmitted data are confirmed by randomized audits, where database case histories are compared with local site records. An external audit (Stat Trade Inc, Morrisville, PA) was performed in 1999. This audit found that the accuracy was more than 95% (lower 95% confidence bound), and that virtually all IABC cases were being reported by each participating hospital. In January 2000, the registry contained 13,945 entries. Of these records, a total of 7,101 patients had cardiac surgery: 5,943 patients (83.7%) underwent myocardial revascularization (CABG), 776 combined CABG and valve surgery (10.9%), and 382 valve surgery (5.4%). Analysis emphasized IABC-related complications, distribution between various types of cardiac surgery, and whether IABC was started preoperatively or intra/postoperatively. Hospital mortality was analyzed as an outcome variable, and the length of IABC therapy was compared with the incidence of complications.

#### *The Society of Thoracic Surgeons National Database*

After receiving written permission from The Society of Thoracic Surgeons (STS) National Database, data sets from the STS Adult Cardiac National Database were harvested from the years 1996 and 1997. The STS National Database had more than 500 participating sites and more than 1.5 million cumulative procedures registered in 1998. The following data were extracted: distribution of IABC use in relation to various cardiac surgery procedures and estimated vascular complications from incidence of complication summary, including vascular/aortic dissection, iliac/femoral dissection, and acute limb ischemia. These data probably represent an overestimation of vascular complications in relation to IABC use, as not all vascular complications that occur in relation to cardiac surgery are related to IABC. Furthermore, data regarding preoperative and intrapostoperative IABC use were analyzed, and mortality was calculated for each subset by univariate analysis using preoperative IABC and intrapostoperative IABC as risk variables.

#### *Definitions*

All-cause hospital mortality was defined as mortality occurring from any cause during IABC or after IABC. Preoperative IABC is preoperative insertion of the intraaortic balloon catheter and the start of IABC before aortic crossclamping in high-risk coronary patients. Intra/postoperative IABC was defined by intraoperative catheter insertion and the start of IABC, due to difficulties weaning the patient from cardiopulmonary bypass once surgery was terminated, or by IABC start during the recovery phase due to postcardiotomy failure.

We defined IABC-related complications as follows: the overall complication rate includes all reported complications—vascular complications (limb ischemia, limb loss, arterial dissection, and vessel perforation), hemorrhage

(balloon insertion site bleeding), infection, and septic complications (verified by positive cultures), balloon entrapment and rupture, and secondary complications related to malpositioning of the balloon catheter itself. Major complications were defined by any complication requiring surgical intervention or blood transfusion, or left permanent sequel. For example, major limb ischemia was defined as a loss of pulse or sensation, or abnormal limb temperature or pallor, requiring surgical intervention. Minor limb ischemia was defined as decreased arterial blood flow as manifested by diminishing pulse that resolves with balloon removal, and not resulting in any impairment of body function. Major bleeding was defined as bleeding that occurred in direct relation to the balloon catheter (perforation of artery or insertion site bleeding), associated with hemodynamic compromise that required blood transfusion or surgical intervention. Minor hemorrhage involved minor hematomas or oozing from puncture site, and did not require blood transfusion or surgical intervention.

High-risk coronary patients were defined as patients who present with at least two of the following preoperative criteria: left ventricular ejection fraction less than 0.30, left main stenosis greater than 70%, unstable angina at the time of surgery despite optimal medical treatment, diffuse coronary artery disease requiring four or more distal anastomosis to achieve complete revascularization, or reoperations or re-reoperations (ie, second, third, or fourth reoperation) [10].

#### *Statistical Analysis*

We employed the  $\chi^2$  test (Fisher's exact test) for nominal measurements, the median or Mann-Whitney tests for ordinal measurements, and an independent group Student's *t* test for metric measurements to assess the differences among groups and subgroups and determine the presence of statistical significance where appropriate. A level of *p* less than 0.05 was required to consider a result statistically significant. Wherever possible, all data were presented as mean  $\pm$  standard deviation.

#### **Results**

In cardiac surgery, both registries revealed that IABC therapy was most frequently used in patients undergoing myocardial revascularization (CABG), 10.4%, or CABG combined with valve surgery, 13.2%, and only occasionally in relation to valve surgery alone, 5.0%.

#### *IABC-Related Complications*

The overall reported IABC-related complication rates from different time intervals, using similar definitions and large study populations showed a trend to diminish, mainly due to fewer major vascular complications (Table 1).

The distribution of IABC-related complications from the Benchmark registry is presented in Table 2.

The IABC-related vascular complications, in relation to the use of this technique in myocardial revascularization (CABG) as reported from the STS National Database and from the Benchmark Counterpulsation Outcomes Regis-

Table 1. Overall IABC-Related Complication Rate at Different Time Intervals as Reported in the Literature<sup>a</sup>

Author [Ref.]	Year	n	Major Vascular Complications	Minor Vascular Complications	Access Site Bleeding	Overall Complication Rate
Makhoul et al [17]	1971–1985	436	8.4%	1.3%	0.7%	10.6%
Arafa et al [15]	1980–1994	509	8.1%	1.6%	1.3%	11.0%
Ferguson et al [19]	1996–2000	9,179	0.9%	2.0%	0.8%	7.0%

<sup>a</sup> Data taken from three literature reports using the same definitions; includes large study populations.

try, respectively, revealed that major vascular complications occurred in 5.4% in the STS National Database (1996 to 1997) and 1.4% in the Benchmark registry (1997 to 1999) (Table 3). Data from the STS National Database include all limb ischemia and therefore represent an overestimation of limb ischemia directly related to IABC use. The close concordance between the two registries should be noticed.

We compared the STS National Database and the Benchmark registry to determine the distribution of preoperative IABC use with intra/postoperative IABC use. In the Benchmark registry, 52.4% of all IABC procedures were initiated preoperatively, which was in close concordance with the STS National Database, where 63.5% of all IABC procedures were initiated in the preoperative period.

*Complications: Preoperative Versus Postoperative IABC in High-Risk Coronary Patients*

A more detailed analysis of the Benchmark registry data showed that any kind of limb ischemia related to IABC use (minor as well as major) was significantly higher in the intrapostoperative IABC group compared with the preoperative IABC therapy group (4.5% and 2.6% respectively,  $p = 0.028$ ). Also, major limb ischemia (ie, requiring surgical intervention) had a significantly higher incidence for intrapostoperative IABC treatment (1.8%) than for preoperative IABC therapy (0.8%;  $p = 0.012$ ).

Table 2. Distribution of IABC-Related Complications From the Benchmark Counterpulsation Registry (1997–1999)

Complication	Percent
IABC-related mortality <sup>a</sup>	0.0%
Major limb ischemia	1.3%
Minor limb ischemia	1.2%
Limb amputation as consequence of major limb ischemia	0.1%
Major access site bleeding	0.7%
Minor access site bleeding	1.0%
Neurologic events <sup>b</sup>	0.0%
Unsuccessful IABC <sup>c</sup>	2.2%
Major IABC-related complications	2.1%
Overall IABC-related complications	6.5%

<sup>a</sup> Death as direct consequence of IABC therapy. <sup>b</sup> Any neurologic event that was not present preoperatively. <sup>c</sup> Includes balloon leak, poor inflation, poor augmentation, and insertion difficulties.  
IABC = intraaortic balloon counterpulsation.

However, there was no evidence that the overall complication rate was lower or higher in the preoperative IABC group.

Preoperative IABC took a median of 4 hours less of IABC treatment time compared with postoperative IABC. This was not a statistically significant difference at the 0.05 level, but showed a clear trend. However, least-square sums statistics showed  $p = 0.0089$  on the hypothesis that mean 1 was equal to mean 2. In high-risk patients, on the other hand, there was a significantly shorter IABC therapy time for preoperative IABC ( $n = 1,247$ ) compared to postoperative IABC ( $n = 1,370$ ;  $41.0 \pm 32.0$  hours and  $50.1 \pm 48.5$  hours, respectively;  $p = 0.0293$ ).

*Hospital Mortality*

Table 4 presents hospital mortality rates, used as the outcome variable, for patients undergoing various types of cardiac surgical procedures and who either received preoperative IABC therapy or intrapostoperative IABC treatment. In the Benchmark Registry and the STS National Database, hospital mortality was significantly lower when preoperative IABC therapy was initiated (8.8% and 9.5%, respectively) compared with when IABC was introduced as intrapostoperative treatment (28.2% and 23.6%,  $p < 0.0001$ ). Still, mortality rates were clearly higher in the preoperative IABC therapy patients than in patients where the variable IABC was not present (2.5 to 2.9%; STS National Database) (Table 4).

Table 3. Comparison of Major Vascular Complications (Requiring Surgical Intervention and/or Blood Transfusions Due to Severe Access Bleeding or Vessel Perforation) in Relation to Intraaortic Counterpulsation

Complications	STS Database 1996	STS Database 1997	Benchmark Registry 1997–1999
IABC	19,715	21,335	7,101
Major vascular complications (n)	1,058	1,161	148
Major vascular complications (%)	5.4%	5.4%	1.4%

Data taken from two major registries (the STS National Database 1996–1997 and the Benchmark Registry 1997–1999).

IABC = intraaortic balloon counterpulsation; Major vascular complications = major limb ischemia (loss of pulse sensation, abnormal limb temperature, or pallor), arterial vessel perforation and arterial dissection due to the balloon catheter.

**Table 4. Hospital Mortality (Outcome Parameter) For Patients Undergoing Cardiac Surgery (CABG or Valve Surgery), Who Either Received Preoperative IABC Therapy or Required Intra/Postoperative IABC Treatment Due to Postoperative Low Cardiac Output**

Type of Therapy	Benchmark Registry 1997–1999 Mortality/Total Operations With IABC, n (%)	STS National Database 1996–1997 Mortality/Total Operations With IABC, n (%)	STS National Database 1996–1997 Mortality/Total Operations Without IABC, n (%)
Preoperative IABC	8.8 (329/3,721)	9.5 (2,487/26,077)	2.9 (10,919/378,810)
Intra/postoperative IABC	28.2 (954/3,380)	23.6 (3,528/14,933)	2.5 (9,878/389,954)

Based on data from the STS National Database 1996–1997 and the Benchmark Counterpulsation Registry 1997–1999 compared to hospital mortality for patients who had neither preoperative nor intra/postoperative intraaortic counterpulsation.

CABG = coronary artery bypass grafting; IABC = intraaortic balloon counterpulsation.

## Comment

The main purpose of this study was to explore the complication rates of current IABC use. The overall complication rate in the Benchmark Counterpulsation Outcome registry was 6.5% (460 of 7,101) and the rate of major complications (ie, requiring surgery or blood transfusion) was only 2.1% (148 of 7,101). By far, vascular complications and bleeding from the access site are the most frequently encountered complications, representing more than 90% of all complications, whereas the incidence of limb loss is only about 0.5% [20]. Therefore, we concentrated our analysis on vascular complications and access site bleeding.

Compiled data regarding IABC-related complications may be skewed and may not show the true picture. However, by comparing data from two major large registries, we demonstrate that recently published data correspond well with registry data, both from the most important cardiac surgery registry (the STS National Database) and a more specific global registry (the Benchmark Counterpulsation Outcomes Registry). The concordance between these two registries is striking.

Importantly, major complications (requiring surgical intervention or blood transfusion for access site bleeding) continued to decrease over time. Improved balloon catheters, smaller catheters, better education and surveillance of patients treated with IABC, increased use, and more experience may be factors to explain this trend. Early detection and adequate reaction to limb ischemia in IABC treatment ultimately results in fewer severe complications and lowered risk of limb loss.

The Benchmark registry demonstrated that both preoperative and intra/postoperative IABC therapy were associated with low complication rates. In fact, major limb ischemia was significantly lower for preoperative IABC therapy, most likely due to the shorter treatment times. This was an important finding because it helps to alleviate concerns about high complication rates previously suggested in relation to prophylactic IABC use. Moreover, preoperative IABC therapy was associated with low mortality rates, despite the high-risk status of most of these patients, which corresponds with findings from earlier studies [6, 11, 19].

Holman and coworkers [7] recently reported that preoperative IABC was beneficial, but they did not show survival advantage over intra/postoperative IABC use.

Fasseas and colleagues [14], on the other hand, reported on Benchmark registry patients with left main coronary disease and found decreased mortality with prophylactic IABC use. Data from the Benchmark registry and the STS National Database also clearly demonstrate survival benefits for the preoperative IABC group; however, this may be due to a selection bias in the intra/post operative group. These results also find support in numerous retrospective and prospective studies [1, 6, 9, 11, 21].

As the number of high-risk coronary patients admitted for cardiac surgery has increased, IABC use has also increased at many cardiac centers, particularly for preoperative IABC therapy [6–8, 21, 22]. For example, Creswell and coworkers [1] reported an increase in IABC use from 6.4% in 1986 to 12.7% in 1990. However, as reported by Ghali and associates [22], great variations in IABC use between centers in the United States exists, with rates varying from 7.8% to 20.8% (on average 13.4%). Regional and global variations in the use of IABC are also described, such as the comparison of the IABC use in the United States with Europe [23].

There are many reasons for the large variations in IABC use. These include the fact that controversy persists about indications for IABC use, and that the use of IABC is regarded and registered as a complication rather than a therapy. Certainly, economic factors may also play an important role in the decision-making process of using IABC, although recent studies have clearly demonstrated that IABC therapy is cost-effective [6, 10]. In addition, prospective users have been deterred from initiating IABC by numerous reports in the literature of a high incidence of balloon-related complications. Various complications have been reported in relation to the use of IABC, such as vascular complications (limb ischemia and limb loss, acute vascular dissection, embolization), bleeding complications from the insertion site, infection and septic complications, and neurologic complications [20].

In the present study, better patient outcomes along with improved IABC technology led to increased use and lower complication rates. Recent registry data demonstrates that preoperative IABC therapy is associated with increases in survival. Although selection bias is inherent in retrospective studies, the Benchmark Registry outcomes are in close accordance with prospective randomized studies previously reported.

### Study Limitations

The information presented in this study is observational only. In addition, data from the Benchmark Registry and the STS database are not necessarily comparable because of slightly varying patient demographics and indications. There may also be a selection bias for patients treated intra/postoperatively.

The present study has, based on data from a large patient population over a short time span, clearly demonstrated a low complication rate related to IABC usage in cardiac surgery. Particularly encouraging is the seemingly lower complication rate in patients when IABC was used as prophylactic therapy.

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### INVITED COMMENTARY

In the current era of ventricular assistance and artificial hearts, the treatment of patients with end-stage heart failure is evolving. The venerable intraaortic balloon pump (IABP), in its fourth decade of use, remains the mainstay of therapy in patients with acute coronary syndromes or post cardiotomy heart failure. This multicenter paper uses a data registry to review contemporary complication rates of intraaortic balloon pump therapy. The study is flawed by the voluntary nature of the registry and may not be representative of the entire spectrum of clinical practice, but nonetheless has the following features of interest:

- (1) Preoperative balloon placement in the catheterization laboratory is associated with fewer complications and possibly with better cardiac outcomes. There are several good reasons for this. Insertion is technically easier with fluoroscopic guidance, and the institution of balloon pumping before surgery, as opposed to after a problem develops, is probably beneficial in a high risk subset of patients.
- (2) Significant vascular complications of intraaortic balloon pumping have become relatively rare, with

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