Preoperative Optimization of Cardiovascular Hemodynamics Improves Outcome in Peripheral Vascular Surgery

A Prospective, Randomized Clinical Trial

JON F. BERLAUK, M.D.,* JEROME H. ABRAMS, M.D.,† IAN J. GILMOUR, M.D.,* S. RHIANNON O’CONNOR, M.D.,* DAVID R. KNIGHTON, M.D.,† and FRANK B. CERRA, M.D.†

The hypothesis that optimizing hemodynamics using pulmonary artery (PA) catheter (preoperative ‘tune-up’) would improve outcome in patients undergoing limb-salvage arterial surgery was tested. Eighty-nine patients were randomized to preoperative tune-up either in the surgical intensive care unit (SICU) (group 1) or the preinduction room (group 2) or to control (group 3). The tune-up consisted of fluid loading, afterload reduction, and/or inotropic support to achieve predetermined endpoints. Patients with a PA catheter had significantly fewer adverse intraoperative events (p < 0.05), less postoperative cardiac morbidity (p < 0.05), and less early graft thrombosis (p < 0.05) than the control group. The overall study mortality rate was 3.4%, with a mortality rate of 9.5% in the control group and 1.5% in the PA catheter groups. There were no differences in ICU length of stay (LOS), hospital LOS, or total hospital costs, although the percentage of cost from complications was higher in group 3 (p > 0.05). In this group of patients, preoperative cardiac assessment and optimization is associated with improved outcome.

Pulmonary Artery (PA) Catheterization for the preoperative evaluation of elective surgical patients remains controversial. Nevertheless, in certain groups of surgical patients, the PA catheter has revealed abnormal cardiovascular hemodynamics, which are not reliably predicted by clinical examination. Patients undergoing surgery for peripheral vascular disease (PVD) tend to be elderly, diabetic, and are known to be at high risk for cardiovascular complications. Although routine PA catheterization of this group of patients has been recommended, preoperative hemodynamic assessment is not standard practice despite a 40% incidence of abnormal left ventricular function (LVF).

While the risks of PA catheterization are well known, reports of benefits from pulmonary artery pressure monitoring, especially in critically ill patients, are also accumulating. However, no controlled, prospective, randomized clinical trial has been performed to show that PA catheterization changes outcome in patients in whom it is used.

We designed our study to answer two questions:
1. In patients with PVD, does the use of a PA catheter to ‘optimize’ LVF and oxygen transport (tune-up) preoperatively influence the clinical outcome?
2. How important is the length of time allowed for the preoperative tune-up?

Materials and Methods

Study Design

A randomized, prospective, clinical trial was approved by the Committee on the Use of Human Subjects in Research at the University of Minnesota. Patients from a single surgical service, scheduled to receive an in situ vein graft bypass for limb salvage, made necessary by peripheral lower-extremity atherosclerotic arterial occlusive disease, were eligible to participate. All operations were performed by a single surgeon (DR Knighton). Patient eligibility was determined by the surgical intensive care unit (SICU) anesthesiologist (JF Berlauk/IF Gilmour). The randomization for all study groups was generated by a random-number generator (Statworks®). Eligible patients were entered consecutively in order of their appearance on the surgical schedule. Patients with the following problems were excluded because these clinical settings have literature documentation that supports the use of the PA catheter during necessary surgical intervention:


Address reprint requests to Frank B. Cerra, M.D., Department of Surgery, University of Minnesota, Box 42 UMC, 406 Harvard St. SE, Minneapolis, MN 55455.

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1. Myocardial infarction (MI) within the previous 3 months.32–36
2. Coronary artery bypass graft (CABG) within the previous six weeks.37
3. Uncompensated congestive heart failure (CHF),7,38–41 identified clinically by pedal edema, jugular venous distention, pulmonary rales, and chest x-ray (CXR) findings of pulmonary edema.
4. Severe valvular heart disease,38,42 defined as symptomatic aortic or mitral valvular disease.
5. ‘Unstable’ angina, defined as angina at rest or a recent change in an angina pattern.

After written consent was obtained, eligible patients were randomized into two groups. Group 1 received a PA catheter at least 12 hours before operation. If cardiovascular physiologic abnormalities were discovered by PA catheter measurements, these patients underwent pharmacologic manipulation to ‘optimize’ intravascular volume and cardiac function, as described in ‘Preoperative Treatment Regimens.’ The remaining patients were randomized further into two groups. Group 2 patients received a tune-up within 3 hours of surgery. This group was allowed less time for hemodynamic assessment, but therapeutic goals and endpoints were the same as for group 1. The control patients (group 3) did not receive a PA catheter before operation nor did they undergo a tune-up.

All patients received a radial artery catheter for continuous blood pressure (BP) monitoring if the Allen’s test demonstrated good collateral flow. An automated sphygomanometer (DINAMAP®, Criticon, Tampa, FL) was used on patients with compromised flow.

All patients were given general anesthesia using a standardized technique. A single SICU anesthesiologist directed the intraoperative care. After recovery from anesthesia, all patients were transferred to the SICU. Surgical intensive care unit care was provided to all patients in the study by the same team.

**Preoperative Treatment Regimens**

**Group 1.** Patients were transferred to the SICU approximately 12 hours before surgery. All cardiovascular medications were discontinued except for clonidine, beta-blocking agents, and digoxin. Pulmonary artery and arterial catheters were placed by or under the supervision of SICU attending staff or senior surgical fellows. Most of the PA catheters were inserted via the right internal jugular vein. Mean BP, heart rate (HR), central venous pressure (CVP), pulmonary artery wedge pressure (PAWP), and cardiac output (CO) were measured. All measurements in the SICU were done by trained monitoring technicians. From these measurements derived variables were calculated: stroke volume, systemic vascular resistance (SVR), pulmonary vascular resistance, and cardiac index (CI). We attempted to follow an algorithm for hemodynamic intervention (Fig. 1). Hemodynamic studies were repeated after each intervention and decision making was coordinated with the SICU staff. The endpoints of successful hemodynamic intervention were defined as:

1. \(8 \leq \text{PAWP} < 15 \text{ mmHg,} \quad 33,44 \)
2. \(\text{CI} \geq 2.8 \text{ L/min/m}^2, \quad 45 \)
3. \(\text{SVR} \leq 1100 \text{ dyne·sec cm}^{-5} \quad 43,44 \)

These endpoints were chosen because of their documented correlation with outcome. When these goals were achieved, no further intervention was attempted and intravenous crystalloid was infused at 1 to 2 mL/kg/hr. If these endpoints could not be achieved, the surgeon and SICU staff decided whether the patient would tolerate the anticipated surgical procedure.

**Group 2.** These patients had invasive catheters placed by an SICU anesthesiologist less than 3 hours before surgery in a preinduction room (PIR). Although less time was available, the protocol and endpoints were otherwise identical to those used for group 1.

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**FIG. 1.** Algorithm for preoperative cardiovascular tune-up. CV measurements were repeated after each intervention. Inotropes: dobutamine or dopamine. Vasodilators: nitroglycerin or nitroprusside. CV, cardiovascular; PAWP, pulmonary artery wedge pressure; SVR, systemic vascular resistance; CI, cardiac index. Measurement units are mmHg for pressure, dyne·sec cm\(^{-5}\) for resistance and L/min/m\(^2\) for CI.
**Group 3.** An arterial catheter was placed before anesthesia. Most of these patients received a CVP catheter as well. A PA catheter was not used during operation unless a complication occurred that required its use. Under these circumstances the PA catheter was inserted by the attending anesthesiologist during operation or by the SICU staff after operation.

**Intraoperative Management**

A single anesthetic protocol was followed for all study groups. In the PIR all monitors were applied and necessary vascular access was established. Baseline BP (mean) and HR were measured while the patient was at rest. Pre-medication was midazolam (Versed®, Roche) (0.5 to 4.0 mg administered intravenously) or fentanyl (1.5 to 2.0 μg/kg administered intravenously) as required.

Anesthesia was induced with midazolam (Versed®) (0.15 to 0.30 mg/kg administered intravenously) and intubation was facilitated by vecuronium (Norcuron®, Organon) (0.1 mg/kg administered intravenously). Lidocaine (1 to 1.5 mg/kg administered intravenously) bolus was given 90 seconds before intubation. Anesthesia was maintained with isoflurane (Forane®, Anaquest, Madison, WI), air, and oxygen. Additional fentanyl and vecuronium were given as required.

Intraoperative monitoring included the V5 lead of the electrocardiogram (EKG), pulse oximetry, and end-tidal CO2. Adverse intraoperative events were defined as:

1. Decrease in mean BP ≥ 30%, \( \frac{32}{46} \) below baseline.
2. Increase in the HR > 30%, \( \frac{41}{46} \) above baseline.
3. Arrhythmia, \( \frac{32}{47} \) defined as any new rhythm disturbance.
4. ST changes, \( \frac{48}{46} \) defined as ST depression > 1 mm or T-wave inversion.

These adverse intraoperative events were chosen because there is documentation in the literature that they correlate with increased perioperative morbidity. Intraoperative events were recorded by the anesthesiologist on the anesthetic record and tabulated later. Those patients with a PA catheter had a hemodynamic profile measured at least every 2 hours during operation. The hemodynamic endpoints previously defined were maintained during anesthesia in groups 1 and 2.

**Postoperative Management**

All patients were continuously monitored in the SICU for at least 18 hours after operation. Major clinical events recorded for the study included:

1. Pulmonary edema by CXR or clinical examination.
2. Acute MI defined by new Q waves more than 0.03 seconds or creatinine phosphokinase MB isoenzyme (CPKMB) more than 5%.
3. Postoperative arrhythmias requiring anti-arrhythmic agents and/or prolonging the SICU stay more than 36 hours.
4. Acute renal failure (ARF), defined as urine output less than 0.5 mL/kg/hr for 5 hours and/or a change in baseline serum creatinine more than 0.5 mg/\%.
5. New wound infection.
7. In situ graft thrombosis.

Criteria for discharge from the SICU were:

1. Hemodynamics stable (mean BP more than 90 mmHg, HR less than 100) for 18 hours.
2. Extubated, PaO2 more than 65 torr on FiO2 ≤ 0.3.
3. Temperature less than 100.5 F measured orally.
4. Urine output ≥ 0.5 mL/kg/hr with a stable creatinine.
5. CPKMB less than 5% of total CPK.
6. EKG unchanged from admission or unchanged for 3 days.
7. Stable EKG rhythm.

**Laboratory Studies**

Baseline studies for all patients included an blood chemistry admission battery, EKG, CXR, 12-hour creatinine clearance, and serum CPKMB. A CPKMB was drawn at the end of the preoperative assessment of group 1. In all groups a CPKMB was drawn at the end of surgery and every 8 hours after operation. After operation an EKG, CXR, and 12-hour creatinine clearance were performed on all patients.

**Data Management**

Data were collected prospectively and entered into a computerized database. Demographic and chemistry data were analyzed by analysis of variance. The clinical outcome variables were analyzed by the chi square (\( \chi^2 \)) technique for nonparametric data. The primary clinical outcome variable was a cardiovascular complication such as congestive heart failure, arrhythmia, or myocardial infarction. Secondary outcome variables were immediate postoperative graft thrombosis and adverse intraoperative events. Significance was defined as \( p < 0.05 \). Data were analyzed periodically for significant differences in the primary clinical outcome variable. When the between-group differences reached \( p < 0.05 \) for this variable, the study was terminated.

**Results**

Eighty-nine patients were enrolled into the study from October 1986 to January 1990. Enrollment continued until the clinical outcome differences between groups were statistically significant. By history 11% of the study patients had angina, 27% had a previous MI, 15% had CHF, 50% had hypertension, 72% had diabetes mellitus, and
23% had a previous cerebrovascular accident. There were 45 patients in group 1, 23 patients in group 2, and 21 patients in group 3 (Table 1). There were no statistically significant differences between groups except that 80% of the patients with a history of angina were randomized to group 1 (p < 0.05). When groups 1 and 2 combined (patients with PA catheters) were compared to group 3 (control patients), there was no statistical difference between the groups except for angina (p < 0.05). No patient randomized to the control group had a history of angina (Fig. 2).

Preoperative Hemodynamic Assessment

While patients with a history of CHF appear to predominate in group 1 compared to group 2 (22.2% versus 4.3%), Table 2 shows that more patients in group 2 had an elevated baseline pulmonary capillary wedge pressure (26.1% versus 17.8%) and demonstrated left ventricular dysfunction (26.1% versus 15.6%) in response to a fluid challenge.

In 25 of 68 patients (36.8%) who received a PA catheter, baseline cardiovascular (CV) measurements met our endpoints so nothing further was done (intervention A). Of these 25 patients, 1 (group 1) subsequently developed ARF, 1 (group 1) developed CHF, and 1 (group 2) had a postoperative graft thrombosis (Table 4). Eighteen of sixty-eight patients (26.4%) required fluids alone (intervention B) to achieve the endpoints. The remaining 25 of 68 patients (36.8%) with a PA catheter required inotropic and/or vasodilator agents along with intravenous fluid to achieve "optimal" hemodynamic status (interventions C, D, and E). Only one patient from group 1 did not achieve the endpoints after all of the above interventions. In this patient the planned surgery was canceled and a less complicated procedure was performed under local anesthesia without complications.

We found no correlation between either the baseline hemodynamic profile or the hemodynamic response to therapy and subsequent complications in groups 1 and 2.

Intraoperative Events

Sixty-six of eighty-nine patients (74%) received anesthetic care from a single SICU anesthesiologist; 81 of 89 patients (91%) received anesthetic care from either of two SICU anesthesiologists.

After entry into the study, no patient was excluded but surgery was canceled for two patients in group 1, leaving 43 patients who completed the study (Table 3). One of these patients had a preoperative MI (see Complications section) and the other could not achieve the hemodynamic

TABLE 1. Patient Characteristics

<table>
<thead>
<tr>
<th>No. of PA Catheter</th>
<th>PA Catheter</th>
<th>No PA Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

* Mean ± SD.
† p < 0.05 compared to group 3.

MI, myocardial infarction; CHF, congestive heart failure; HTN, hypertension; DM, diabetes mellitus; CVA, cerebrovascular accident.

TABLE 2. Results of Hemodynamic Assessment and Intervention

<table>
<thead>
<tr>
<th>Initial Assessment</th>
<th>Treatment Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>1      2</td>
</tr>
<tr>
<td>SVR &gt; 1100 dynes-sec cm⁻¹</td>
<td>45 23</td>
</tr>
<tr>
<td>CI &lt; 2.8 L/min/M²</td>
<td>30 11</td>
</tr>
<tr>
<td>PAWP ≥ 15 mmHg</td>
<td>8 6</td>
</tr>
<tr>
<td>PAWP ≥ 15 mmHg after IV</td>
<td>7 6</td>
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</table>

Intervention

<table>
<thead>
<tr>
<th>No. of patients achieving all hemodynamic endpoints</th>
<th>1</th>
<th>2</th>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>B</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>C</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>D</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>E</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

A: Baseline hemodynamics meet endpoints.
B: IV fluids alone (colloid plus crystalloid).
C: IV fluids plus an inotrope OR vasodilator.
D: Inotrope AND vasodilator required.
E: Cannot achieve endpoints despite therapy.

Fig. 2. Patient characteristics.
endpoints (see Preoperative Hemodynamic Assessment section). In addition one patient from each group had the vein graft bypass aborted during operation for technical reasons because of poor vessels. However their data are included in Table 3.

The control group (group 3) experienced a significantly higher incidence of intraoperative events (tachycardia, hypotension, and arrhythmias) as compared to either group 1 (p < 0.05), group 2 (p < 0.05), or combined groups 1 and 2 (p < 0.05). In addition these adverse intraoperative events correlated with major perioperative complications in the control patients (p < 0.05) (Table 3). Overall patients who received a PA catheter before operation were more stable during operation. All adverse events were less than 10 minutes in duration. Because permanent real-time recordings of intraoperative events were not obtained, observations of ST-T changes were considered unreliable and eliminated from analysis.

**Complications**

The overall complication rates were 17.8% (8 of 45 patients) in group 1, 13% (3 of 23 patients) in group 2, and 42.9% (9 of 21 patients) in group 3 (Table 4). The mortality rate was 2.2% (1 of 45 patients) in group 1, 0% in group 2, and 9.5% (2 of 21) in group 3. The morbidity rate associated with the preoperative tune-up, including placement of the PA catheter, was 4.4% (3 of 68). Morbid events included two preoperative MIs (see below) and one pneumothorax.

**Group 1.** Eight hemodynamic complications occurred in group 1 (Table 4). Two patients in group 1 had non-Q-wave MIs during the tune-up. In one patient clinical symptoms, hypotension, and EKG changes called attention to the problem and surgery was canceled. A CPK<sub>MB</sub> fraction of 22% of total CPK later confirmed the clinical

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### Table 3. Intraoperative Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Treatment Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PA Catheter</td>
</tr>
<tr>
<td>Tachycardia*†</td>
<td>n = 43</td>
</tr>
<tr>
<td>Hypotension*†</td>
<td>n = 21</td>
</tr>
<tr>
<td>Arrhythmia*†</td>
<td>n = 8</td>
</tr>
</tbody>
</table>

- * p < 0.05 for group 1 vs. 3.
- † p < 0.05 for groups 1 and 2 vs. 3.

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### Table 4. Hemodynamic Profile of Patients with Complications

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Complication</th>
<th>Initial Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>CI &lt; 2.8</td>
</tr>
<tr>
<td>Group 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>ARF</td>
<td>(-)</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>CHF</td>
<td>(-)</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>Death</td>
<td>(-)</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>Graft thrombosis</td>
<td>(-)</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>Postop MI</td>
<td>(-)</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>CHF</td>
<td>(-)</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>Preop MI</td>
<td>(+)</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>Preop MI</td>
<td>(-)</td>
</tr>
<tr>
<td>Group 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>M</td>
<td>CHF</td>
<td>(-)</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>CHF</td>
<td>(-)</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>Graft thrombosis</td>
<td>(-)</td>
</tr>
<tr>
<td>Group 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>F</td>
<td>Arrhythmia</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>Graft thrombosis</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>Graft thrombosis</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>Graft thrombosis</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>Death (cardiac arrest)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>Death (cardiac arrest)</td>
<td></td>
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<tr>
<td>7</td>
<td>M</td>
<td>Postop MI</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>ARF, CHR</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>Graft thrombosis</td>
<td></td>
</tr>
</tbody>
</table>

See Table 1 for abbreviations.
diagnosis of subendocardial MI. A second patient had no signs or symptoms of MI and underwent surgery with no complications. Only later was the MI appreciated when the preoperative CPK_Mb returned at 15% of total CPK. The data was analyzed both with and without these two patients. The results were unaffected by their inclusion or exclusion from the data analysis.

Six other patients had other perioperative CV complications. One patient developed ARF after operation. This was attributed to a large intravenous contrast medium load. The renal failure resolved before the patient was discharged from the hospital. A second patient died on postoperative day (POD) 7 during emergency surgery to repair a ruptured common iliac artery. Percutaneous angioplasty had been performed on the vessel earlier that day. One patient suffered vein graft thrombosis about 36 hours after operation. Thrombectomy failed to restore blood flow and a below-knee amputation was performed on POD 3. Another patient had a non-Q-wave MI on POD 1 with CPK_Mb enzyme elevation to 12.4% of total CPK. His recovery was not affected by complications. The last two patients developed mild CHF after operation; they were treated with fluid restriction, diuresis, and supplemental O2. No evidence of MI was found in either patient.

Group 2. Three patients had postoperative hemodynamic complications in group 2 (Table 4). Two patients had CHF without evidence of MI. Both responded rapidly to fluid restriction, diuresis, and supplemental O2. One patient developed an early postoperative graft thrombosis and underwent a successful thrombectomy about 2 hours after the initial operation.

Group 3. There were two postoperative deaths from cardiac arrest in group 3. One patient died on POD 6 after several days of refractory ventricular arrhythmias. Myocardial infarction could not be confirmed as the cause of her arrhythmias. No PA catheter was used in this patient. The second patient suffered cardiac arrest on POD 5 and could not be resuscitated.

There were eight other postoperative hemodynamic complications in seven patients in group 3 (Table 4). One patient had an acute MI on POD 2 and underwent an emergency five-vessel CABG on POD 3. A second patient had serious atrial and ventricular arrhythmias for 2 days after operation. These arrhythmias were successfully treated pharmacologically. No PA catheter was used in this patient. A third patient developed ARF and CHF during operation necessitating PA catheter insertion during operation. After operation the patient responded to dialysis and inotropic support. The ARF resolved; no MI was found. Four patients had graft thromboses within 36 hours of operation. Re-exploration of the surgical anastomosis and repeat angiograms revealed no technical problems. All patients had successful thrombectomy with restoration of blood flow and were placed on heparin. The grafts remained patent. None of these patients received a PA catheter.

Complications are summarized in Table 5. Both groups of patients with a PA catheter had significantly fewer adverse intraoperative events (p < 0.05), less postoperative cardiac morbidity (p < 0.05), and less early graft thrombosis (p < 0.05) compared to the control group. The mortality rate was 9.5% in the control group and 1.5% in the combined groups of patients with a PA catheter.

Other Analysis

There were no significant differences between groups in baseline blood urea nitrogen (BUN), serum creatinine (Cr), blood lactate, or serum potassium (K+). There were no differences between groups in length of hospital stay (LOS) before surgery, LOS in the ICU, total hospital LOS, or total hospital charges (Table 6). Furthermore no differences were found between patients with a complication versus no complication, except control patients with complications spent 3.6 ± 2.9 days in the ICU compared to 1.9 ± 0.6 days if no complication occurred (p < 0.05). In addition the increased total hospital charges ($29,928 ± 14,078) for a complication in the control group offset any costs associated with PA catheter insertion in the SICU ($29,102 ± 13,207) or in the PIR ($23,770 ± 12,418) (Table 6).

Discussion

Does ‘optimizing’ cardiovascular hemodynamics using a PA catheter improve outcome? To test this hypothesis, we chose to study surgical patients with PVD, a group known to be at high risk for perioperative cardiovascular complications.8 Because aortic and intraperitoneal surgery are associated with increased postoperative cardiac complications,32,33,38,39 only patients with peripheral vascular surgery for limb salvage were included. To help decrease the number of confounding clinical variables, the study used a single vascular surgeon, a single anesthetic technique, and a single SICU service.

Using the PA catheter to optimize a patient’s preop-

<table>
<thead>
<tr>
<th>Table 5. Complication Summary</th>
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</thead>
<tbody>
<tr>
<td>Characteristic</td>
</tr>
<tr>
<td>Intraoperative event (arrhythmia, tachycardia or hypotension)</td>
</tr>
<tr>
<td>Postop cardiac morbidity</td>
</tr>
<tr>
<td>Early graft thrombosis (&lt;36 hr)</td>
</tr>
<tr>
<td>Death†</td>
</tr>
</tbody>
</table>

* p < 0.05 compared to group 3.
† 1.5% for groups (1 and 2 versus group 3 (p = 0.08).
operative cardiovascular status is not new. The catheter has been used in the preoperative assessment of patients undergoing hip pinning, aortic aneurysm repair, peripheral vascular surgery, and other ‘major’ surgical procedures. Therapeutic endpoints of the cardiovascular tune-up vary with the different studies. The endpoints for our therapeutic interventions were directed at (1) preoperative hypovolemia and (2) improving myocardial performance to meet the increased respiratory, circulatory, and metabolic demands imposed on the postoperative patient. Distal vascular surgery is not a high-risk procedure so we chose normal values as therapeutic endpoints.

The demographics of our study group corroborate their high-risk status. Seventy-two per cent of the patients had DM, 33% had hypertension, 32% had a previous MI, 15% had compensated CHF, and 11% had angina. These risk factors were evenly distributed between groups except that no patient with angina was randomized to the control group. Although the randomization sequence was performed at the beginning of the study, actual patient entry into the study was finalized the evening before surgery. Bias of the chief surgical resident, who determined the operating room schedule, may account for the lack of patients with angina in the control group. While stable angina is controversial as a predictor of cardiac morbidity in the noncardiac surgical patient, its presence in the patient groups receiving a PA catheter imply that they may have had more CV disease than the control group.

In this study we found that patients ‘tuned up’ before operation with a PA catheter had fewer adverse intraoperative events (<0.05), less postoperative cardiac morbidity (<0.05) and early graft thrombosis (<0.05), and fewer deaths (p = 0.08) than the control group (Table 6). The overall complication rate was 16.2% in the PA catheter groups and 42.9% in the control group. We could find no difference in outcome between the SICU tune-up (group 1) compared to the PIR tune-up (group 2), i.e., the duration of the tune-up was not a significant factor.

More than 36% (36.8%) of our patients with a PA catheter (groups 1 and 2) had normal hemodynamics and LVF without intervention, 26.4% needed fluids alone, and 36.8% needed pharmacologic intervention. Our findings coincide with those of other authors. In a group of 75 patients with PVD, Babu et al. found that 33.3% had normal LVF, 26.7% needed only fluids to improve myocardial function, and 40% needed additional pharmacologic intervention. In 100 high-risk surgical patients, Del Guerico et al. found no patients with normal hemodynamics, 55% needed fluid alone, and 45% needed additional intervention. Interestingly, while Del Guerico et al. found that most of the complications occurred in the last group of patients, we could not confirm this finding. However an implication of this finding is that if the PA catheter is placed immediately before operation, up to 40% of surgical patients may need to have their surgical procedure delayed until optimal hemodynamic status is achieved.

Mangano reviewed studies from the past 35 years of intraoperative predictors of perioperative cardiac morbidity (PCM). He concluded that while both hypotension and tachycardia predict PCM, there are conflicting data about hypertension and insufficient data on arrhythmias. In our study we found more intraoperative episodes of hypotension (p < 0.05), tachycardia (p < 0.05), and arrhythmias (p < 0.05) in the control group (Table 3). While we cannot confirm a causal relationship, many control patients with intraoperative problems did develop postoperative complications.

One of these complications was early (less than 36 hours after operation) graft thrombosis. A high incidence of graft thrombosis in the control group was found on re-exploitation not to result from technical errors. We postulate that inadequate blood flow (i.e., CO) may have contributed to this problem and that patients with a PA catheter
had less graft thrombosis because of increased peripera-
tive cardiac output.

We found a mortality rate of 1.5% in the patients with
a PA catheter compared to 9.5% in the control group,
with an overall study mortality rate of 3.4%. It is note-
worthy that the only death in the study group followed
unexpected exsanguination, an event not influenced by
PA catheter monitoring. The two deaths in the control
group followed cardiopulmonary arrest. Babu et al.3 had
a 1.3% mortality rate in their study of monitored patients
undergoing diverse peripheral vascular procedures. Ja-
emieson et al.6 found a 1.4% mortality rate in a small subset
of unmonitored patients who had femoropopliteal pro-
cedures. However only 4.3% of Jamieson's entire study
group had diabetes; Babu3 did not delineate the clinical
characteristics of their study group. Diabetes is a signifi-
cant, independent risk factor for PCM.4,5 Seventy-two per
cent of the patients in our study had DM, which may
account for the higher mortality rate in our control group.

In our study only one patient had a significant com-
pliation from insertion of the PA catheter. A small pneu-
mothorax was discovered on CXR after operation in a
patient from group 1. The PA catheter had been inserted
through the subclavian approach in this patient. Two other
patients had non-Q-wave Mls associated with the tune-
up. We think this is the first report of morbidity associated
with the preoperative tune-up. One patient had no clinical
signs or symptoms of MI; had we not drawn cardiac en-
zymes before and after tune-up we would have assumed
it to be an intraoperative complication. We think
preoperative MI may be underreported in other clinical
studies.

The cost of technology should be included in any benefit
analysis. Schoemaker et al.62 reported that the use of the
PA catheter reduced complications, duration of hospital-
ization, ICU stay, duration of mechanical ventilation, and
total cost when used to augment rather than simply nor-
malize circulatory responses in a group of high-risk sur-
gical patients. We found the use of the PA catheter to be
cost neutral, i.e., the increased cost of PA monitoring and
tune-up in the study groups was offset by the increased
cost of treating the complications in the control group.
We believe that we failed to find a significant cost differ-
bence between groups because of the severity of the un-
derlying vascular disease. These patients commonly re-
quire lengthy hospitalization because of the end-organ in-
jury incurred from their disease before the operative
intervention.

The insertion of a PA catheter is not therapeutic. While
intervention on the basis of catheter-derived information
is thought to be beneficial,63 at least one study refutes this
presumption.64 Why did we find a benefit? It is known
that early resuscitation and restoration of oxygen transport
improves outcome in trauma patients.65 Shoemaker et
al.62 have shown that preoperative resuscitation to supra-
normal cardiovascular indices may be necessary when the
postoperative oxygen demands imposed by major surgery
are also supranormal. A patient's ability to respond im-
mEDIATELY to the oxygen demands imposed by the stress
of surgery appears to be one key to reducing postoperative
moribundity. In addition we used a highly integrated team
approach to the postoperative management of these high-
risk patients. A recent study supports the position that a
knowledgeable, experienced physician is an essential
component of this technology.66

The PA catheter, when used by knowledgeable physi-
cians to evaluate and optimize cardiac performance before
operation, is cost neutral and improves outcome in pa-
ents undergoing peripheral revascularization procedures.

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