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Routine Pulmonary Artery Catheterization Does Not Reduce Morbidity and Mortality of Elective Vascular Surgery

Results of a Prospective, Randomized Trial

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Objective
The authors determined whether the preoperative placement of a pulmonary artery catheter (PAC) with optimization of hemodynamics results in outcome improvement after elective vascular surgery.

Summary Background Data
The PAC commonly is used not only in patients who are critically ill, but also perioperatively in major elective surgery. Few prospective studies exist documenting its usefulness.

Methods
One hundred four consecutive patients were randomized to have a PAC placed the morning of operation (group I) or to have a PAC placed only if clinically indicated (group II). Group I patients were resuscitated to preestablished endpoints before surgery and kept at these points both intraoperatively and postoperatively. Group II patients received standard care.

Results
There was one death in each group. An intraoperative or postoperative complication developed in 13 patients in group I versus 7 patients in group II (p = not significant). Group I patients received more fluid than did group II patients (5137 ± 315 mL vs. 3789 ± 306 mL; $p < 0.003$). There was no significant difference in either overall or surgical intensive care unit length of stay. Only one patient in group II required a postoperative PAC.

Conclusions
Routine PAC use in elective vascular surgery increases the volume of fluid given to patients without demonstrable improvement in morbidity or mortality.

Successful placement of a self-guided, balloon-tipped pulmonary artery catheter (PAC) in canines was first reported in 1953.[1] Another 17 years took place, however, before Swan et al.[2] introduced a reliable PAC that could be placed safely in humans without the routine use of fluoroscopy. In the intervening 27 years, the PAC has become standard in the treatment of critically ill patients. Although studies show that unexpected findings are frequent and significant changes in therapy are therefore made,[3] few prospective, randomized trials exist documenting the PAC's efficacy in these patients. Indeed, a recent large multicenter observational study called into question the whole use of the PAC in the critically ill.[4]

Use of the PAC in major elective surgery remains equally controversial.[5] It is intellectually appealing to use a PAC in patients with a known high incidence of cardiac abnormalities and postoperative complications,[6] but the prospective, randomized trials that do exist have certain methodologic flaws. This includes poor matching of patient groups regarding severity of illness, type of surgery, and additional therapies.[7-9]

We designed a tightly controlled prospective, randomized trial to address the problems of a variety of surgeons performing operations on multiple organ systems with different management strategies.

METHODS

We addressed previous methodologic problems by the following criteria: 1) one vascular surgeon (CEJ) doing the operations in a standard manner; 2) a standard anesthetic regimen while in the operating room; and 3) all patients treated in the surgical intensive care unit (SICU) by one surgical intensivist (JSB). Thus, the only controllable variable in these patients was the presence or absence of a PAC. This protocol was reviewed and approved by the Institutional Review Board. All patients gave written, informed consent. The protocol was submitted in mid-1991 and approved to start in April 1992. After initial submission, a similar study appeared in the literature.[9] Changes were made in the protocol at that time to better conform with this trial's methodology.

Eligibility

All patients of the one vascular surgeon scheduled for elective infrarenal aortic reconstruction or lower limb revascularization (or both) were eligible for enrollment. The patients with the following problems were excluded[10-15]:

1. An anticipated need, before surgery, for supraceliac or suprarenal cross clamp.
2. Myocardial infarction (MI) within the past 3 months or inadequately controlled angina (i.e., unstable angina).
3. Signs and symptoms of poorly compensated congestive heart failure such as presence of an S_3, jugular venous distention, or peripheral edema.
4. Coronary artery bypass grafting within the previous 6 weeks.
5. Symptomatic aortic or mitral valvular disease.

Randomization Procedure

After patients agreed to participate in the study, their written consent was obtained by the vascular surgeon. The patients then were assigned randomly to one of two groups by the surgical intensivist. Group I patients were transferred or admitted to the SICU the morning of their scheduled operation. If cardiovascular physiologic abnormalities were noted, these patients underwent volemic and pharmacologic manipulations to optimize these values as described below. Group II patients received a PAC only if complications arose necessitating its use.

Preoperative Management

Group I

These patients were transferred or admitted to the SICU the morning of surgery. A PAC was placed supraclavicularly through a previously placed cordis[16] either by or under the direct supervision of the surgical intensivist. Insertion complications were recorded. Blood pressure, heart rate, central venous pressure, pulmonary artery occlusion pressure, and cardiac output were measured. Arterial blood gas was sampled for oxygen content. Systemic vascular resistance, pulmonary vascular resistance, cardiac index, and oxygen delivery index were calculated. An algorithm was followed to optimize hemodynamics (Figs. 1 and 2). The following endpoints were selected as previous studies have shown them to correlate with good outcomes[6,9,17,18]:

1. $8 \leq$ pulmonary artery occlusion pressure ≤ 14 mmHg.
2. Cardiac index ≥ 2.8 L/minute/m^2.
3. Systemic vascular resistance ≤ 1100 dyne-second/cm^5.

Basically, these endpoints were obtained by giving crystalloid until the pulmonary artery occlusion pressure was in the acceptable range. If cardiac index still was too

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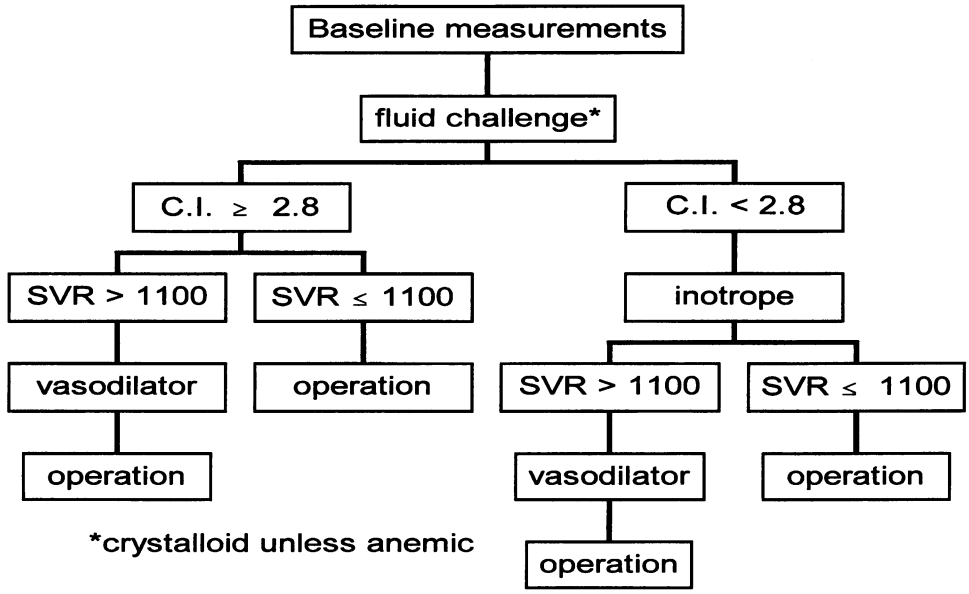

Figure 1. Protocol in patients with initial PAOP < 8 mm Hg.

low, an inotrope (Dopamine; Astra, Westborough, MA) was infused. A vasodilator (nitroprusside) was added if systemic vascular resistance was too high. Patients with anemia were transfused before surgery to an hematocrit of 30 gm%. Finally, those patients whose pulmonary artery occlusion pressure was ≥15 mmHg were given a diuretic to achieve an acceptable number. Surgery was postponed for failure to reach the endpoints.

Group II

These patients received an indwelling radial artery catheter before surgery by the anesthesiologist. Central lines were placed via the percutaneous supraclavicular approach by a dedicated physician's assistant.[16]

Intraoperative Management

Both groups received a standard general anesthesia regimen. This consisted of preoperative sedation with intravenous midazolam. After a bolus of intravenous lidocaine, anesthesia was induced with up to 0.30 mg/kg of intravenous midazolam. General anesthesia then was maintained with a combination of isoflurane, nitrous oxide, fentanyl, and oxygen. Paralysis during both intubation and operation was with vecuronium. Intraoperative monitoring consisting of continuous Holter monitoring, electrocardiogram, pulse oximetry, and end-tidal carbon dioxide was done in all patients. Liberal-use beta blockers were allowed in both groups.[19]

Patients in both groups received 5000 units of intravenous heparin just before proximal clamping. This was followed by 1000-unit boluses every 1 hour until the anastomoses were complete. Aortic patients were reversed with protamine before abdominal closure, whereas nonaortic patients were not reversed. Routine completion angiography was not performed. Strict attempts were made to avoid hypotension by slow release of the proximal clamp.

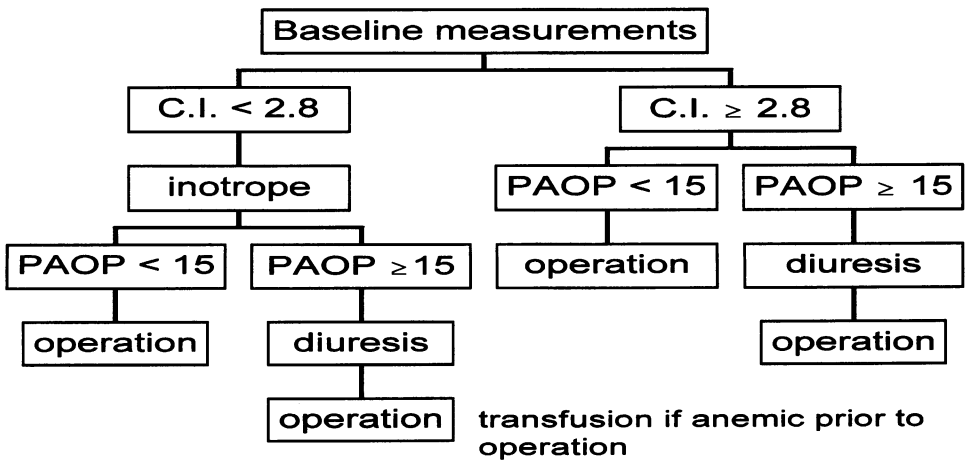

Figure 2. Protocol in patients with initial PAOP ≥8 mm Hg.

Table 1. PATIENT DEMOGRAPHICS

	Group I (n = 51)	Group II (n = 53)
Age (yr)	65.3 ± 1.2	65.5 ± 1.1
Male/female	32/19	37/16
Aortic/nonaortic	27/24	20/33

Adverse intraoperative events were recorded and defined as:

1. Decrease in mean blood pressure ≥ 30% below baseline.
2. Increase in heart rate ≥ 30% above baseline.
3. Any new arrhythmia (rhythm disturbance).
4. ST depression or elevation > 1 mm or T-wave inversion.

Patients with a PAC had hemodynamics measured hourly. The hemodynamic endpoints were maintained throughout the operation. Although these measurements and manipulations were done primarily by the anesthesiologists, the surgical intensivist was present at some point of the operation in all cases to ensure compliance.

Postoperative Management

All patients were monitored in the SICU for at least 16 hours after operation. Group I patients had hemodynamics checked every 4 hours and appropriate adjustments made to keep within the endpoints. Patients in both groups received precordial nitropaste (1 inch every 4 hours, blood pressure permitting). All patients were treated jointly by the vascular surgeon and the surgical intensivist. Extubation, if not performed in the operating room, was done after standard criteria. The PAC was kept in place until the decision was made to transfer the patient out of the SICU. Criteria in both groups for discharge from the SICU were as follows:

1. Hemodynamic stability.
2. Extubated with $pO_2 \geq 65$ on $F_IO_2 \leq 0.40$.
3. Temperature ≤ 38.1 C.
4. Urine output ≥ 0.5 mL/kg/hour.
5. Creatine phosphokinase isoenzymes < 5% of total.
6. Unchanged electrocardiogram from admission or unchanged for 3 days.
7. Stable rhythm.

Adverse outcomes in the SICU (or after transfer out of the SICU) were recorded and defined as:

1. Pulmonary edema confirmed by chest x-ray.
2. Acute MI defined as new Q waves on electrocardiogram and/or creatinine phosphokinase isoenzyme level greater than 5%. Confirmation by an independent cardiologist also was required.
3. New arrhythmia requiring treatment.
4. Acute renal failure defined as an increase in the baseline serum creatinine by more than 1 gm%.
5. Postoperative wound infection.
6. Postoperative hemorrhage.
7. Sepsis.
8. Early graft thrombosis or infection.
9. Death from any cause either during the same hospitalization or within 30 days of operation.

Data

Data (except for charges) were collected prospectively. A computerized data management program was used. Statistics were done using chi square (with Yates' correction for small numbers), Fisher's exact test, or Student's t test. Significance was assumed for $p < 0.05$. As originally designed, the study was expected to show a significant decrease in complications after 200 patients were enrolled.

RESULTS

Over the 3-year period of the study, 121 patients were considered. Seventeen were excluded because of high-risk criteria (suprarenal or supraceliac clamping, n = 5; recent MI, n = 4; uncompensated congestive heart failure, n = 4; recent coronary artery bypass grafting, n = 3; symptomatic valvular disease, n = 1). Of the remaining 104 patients, 51 were randomized to group I and 53 to group II. Table 1 lists the patient demographics that were similar in both groups. Tables 2 and 3 list patient comorbidities and indications for operation, respectively. The only statistically significant difference in either of the latter tables is the presence of hypertension in 27 of 51 patients in group I versus 16 of 53 patients in group II (p = 0.019; chi square).

Table 2. PATIENT COMORBIDITIES

	Group I (n = 51)	Group II (n = 53)
Hypertension	27*	16
Heart disease	18	16
Diabetes	15	20
Prior vascular surgery	21	19
Other	34	28

* p = 0.019.

Table 3. INDICATIONS FOR SURGERY

	Group I (n = 51)	Group II (n = 53)
Rest pain	18	20
Ulcer	16	17
Claudication	5	8
Gangrene	2	2
Aneurysm	10	6

Preoperative Events

There were no complications associated with PAC insertion except for transient premature ventricular contractions in three patients. No patient failed to meet the hemodynamic endpoints in group I. Of the 51 patients in group I, 33 met the criteria after the initial measurements after insertion of the PAC. Eight patients required crystalloid infusion and seven required addition of an inotrope. One patient each required both fluid and an inotrope, a vasodilator, and blood (which was given in lieu of crystalloid). Two patients had preoperative transfusions in group II.

Intraoperative Events

All patients underwent successful general anesthesia without significant induction difficulties. Table 4 lists the adverse intraoperative events. There were more overall complications in group I, but none of the individual groups of events were statistically different. Interestingly, there was no significant hypotension in either group. All group I patients were kept within protocol limits.

Postoperative Events

There was one death in each group. Each of these patients underwent a relatively prolonged aortic procedure. Both of their early postoperative courses were complicated by pneumonia and sepsis. This progressed to multisystem organ failure and eventually death.

Table 4. ADVERSE INTRAOPERATIVE EVENTS

	Group I (n = 51)	Group II (n = 53)
ST changes	5	1
Arrhythmia*	5	2
Decrease BP ≥30%	0	0
Increase HR ≥30%	0	1

BP = blood pressure; HR = heart rate.
* All atrial fibrillation.

Table 5. POSTOPERATIVE COMPLICATIONS IN SEVEN PATIENTS IN EACH GROUP

	Group I	Group II
Myocardial infarction	3	5
Pulmonary edema	2	1
Sepsis	2	2
Graft thrombosis	1	1
Arrhythmia	1	1
Intraabdominal hemorrhage	1	0
Groin hematoma	0	1

Seven patients in each group had a nonfatal postoperative complication (Table 5). All of the patients in whom postoperative MIs developed had intraoperative ST changes. Both episodes of graft thrombosis were thought to be due to technical problems. No technical problem could be found in either of the patients who had postoperative bleeding. Three of the four episodes of sepsis were pulmonary in origin, whereas the other was due to urosepsis. The development of one postoperative complication in a patient made the development of a second one in that patient more likely.

Tables 6 and 7 list the overall outcome in both groups. The only statistically significant difference was more crystalloid given to group I patients. This was measured from entrance into the study to the end of the first 24 hours or until transfer out of the SICU, whichever came first.

Tables 8 and 9 list the results in the aortic and nonaortic patients, respectively. The only statistical difference was in the amount of crystalloid given to patients in the nonaortic group I. Although the amount also was greater in aortic patients, this value did not reach statistical difference ($p = 0.23$, Student's t test). Although not shown, there also was no difference between the subgroups regarding indication for operation, comorbidities, operative length, estimated blood loss, blood transfused, or plasma

Table 6. OVERALL OUTCOME

	Group I (n = 51)	Group II (n = 53)
Operative length (min)	320 ± 13	322 ± 13
Blood loss (mL)	716 ± 84	675 ± 156
Crystalloid (mL)	5137 ± 315*	3789 ± 306
Blood transfused (units)	1.3 ± 0.1	1.8 ± 0.2
FFP transfused (units)	2.3 ± 0.9	2.5 ± 1.5

FFP = fresh frozen plasma.
* $p < 0.003$.

Table 7. OVERALL OUTCOME

	Group I (n = 51)	Group II (n = 53)
SICU LOS (days)	27 ± 0.2	2.6 ± 0.5
Hospital LOS (days)	12.5 ± 1.4	12.0 ± 1.3
Death	1	1
Postoperative complications	7	7
Hospital charges ($)	25,945 ± 2156	23,202 ± 2050

SICU = surgical intensive care unit; LOS = length of stay.

transfused. Only one patient in group II required a postoperative PAC.

DISCUSSION

Whether routine use of a PAC can improve outcome in either already critically ill individuals or prevent complications in high-risk surgical patients remains controversial. It is somewhat surprising, then, that more prospective, randomized trials have not been performed. The lack of such trials has led others to propose a moratorium, or at least a restriction on PAC's use, until data from such studies would support its effectiveness.[20] Our study would seem to confirm this proposal as no benefit could be shown by PAC's routine use.

There have been three previous prospective, randomized trials published regarding the preoperative use of PAC. All three concluded that the use of PAC made a positive difference. Closer analysis of these trials, however, shows that they have methodologic flaws or variables other than the PAC that may bias the results. In the first published study, Schultz et al.[7] randomized 70 patients with fractured hips either to receive a preoperative PAC with optimization of "cardiac, pulmonary, and metabolic parameters before surgery" versus standard care.

Table 8. RESULTS IN PATIENTS UNDERGOING AORTIC SURGERY

	Group I (n = 27)	Group 2 (n = 20)
Age (yr)	66.9 ± 1.6	65.7 ± 1.4
Crystalloid (mL)	6350 ± 384	5458 ± 614
SICU LOS (days)	3.6 ± 0.4	4.2 ± 1.1
Hospital LOS (days)	11.0 ± 1.3	10.2 ± 0.9
Deaths	1	1
Complications	4	4
Hospital charges ($)	28,135 ± 3330	28,214 ± 3613

SICU = surgical intensive care unit; LOS = length of stay.

Table 9. RESULTS IN PATIENTS UNDERGOING NONAORTIC SURGERY

	Group I (n = 24)	Group II (n = 33)
Age (yr)	63.6 ± 1.7	65.5 ± 1.6
Crystalloid (mL)	3772 ± 343*	2777 ± 154
SICU LOS (days)	1.7 ± 0.1	1.6 ± 0.2
Hospital LOS (days)	14.2 ± 2.5	13.1 ± 2.1
Deaths	0	0
Complications	3	2
Hospital charges ($)	23,481 ± 2623	20,165 ± 2347

SICU = surgical intensive care unit; LOS = length of stay.
* $p < 0.012$.

Mortality was 2.9% in the monitored group as opposed to 29% in the control group. There was no difference in morbidity or length of stay. The cause of the higher mortality in the control group was not examined. Although the two groups were reported to be demographically the same, control patients were not operated on until an average of 6.7 days after admission versus 3.7 days in the monitored group. The reason for this difference was not explained, although the implication in the article was that this extra time was required to get the patients ready for surgery. Last, the protocol actually followed was not clearly explained nor was any explanation given as to how pulmonary and metabolic problems were corrected differently in the two groups.

In the most widely quoted study, Shoemaker and associates[8] randomized 88 patients to 3 groups. The first received central venous pressure monitoring, the second received PAC monitoring, and the third received a PAC and was resuscitated to supranormal values. These values were obtained from a prior retrospective review of critically ill survivors versus nonsurvivors.[21] Mortality, morbidity, length of stay, and costs were reduced significantly in the last group. Unfortunately, no data were presented to show that the groups were equivalent regarding age, diagnosis, underlying disease, or type of operation. Multiple surgeons and anesthesia regimens also were used. There was a very high incidence of renal failure in the control group as well.

Berlauk et al.[9] attempted to answer some of the above criticisms by limiting the number of variables. The patients of only one surgeon doing in situ vein bypass were studied. Eighty-nine patients were randomized to 3 groups: the first received a PAC and optimization in the SICU the night before operation, the second received a PAC and optimization in the preinduction room, whereas the third was the control group. Groups were similar regarding age, underlying disease, length of operation, and blood loss. There was a significant decrease in mortality

and complications in the first two groups as opposed to the control group. Unfortunately, less than a quarter of the patients were randomized as control subjects. The exact indications for operation (e.g., gangrene, claudication) also were not specified. More important, protocol patients also received precordial nitropaste in the perioperative period, whereas control subjects did not.[22] Because most of the complications were cardiac, it is possible that this simple maneuver resulted in much of their noted improvement.

This trial appeared in the literature as our study was undergoing review by our Institutional Review Board. Several changes were made in our protocol at that time to more closely mimic the Berlauk trial.[9] Specifically, the optimization endpoints (we lowered them) and the criteria for adverse intraoperative events were changed somewhat. We also altered the protocol to place precordial nitropaste in both protocol and control patients.

As more aortic patients were randomized to group I, if anything this would have biased results in favor of the PAC. No difference was seen in our patients regarding mortality, postoperative complications, and length of stay in either the SICU or the hospital. Our patients were statistically similar in all categories except for hypertension. Adverse intraoperative events were more frequent in protocol patients. This was not statistically significant, but the increased number of arrhythmias may have been a function of having the PAC in place. Hospital charges also tended to be higher in the protocol group, although the reason for this is unclear as the additional fluid and interventions that were done do not account for this difference.

Our study also has some weaknesses. For one, we mixed both aortic and nonaortic patients together. This was done to increase the number of patients available for the study. Even though breakdown into subgroups of aortic versus nonaortic patients also showed no difference in results, the smaller numbers in these subgroups increase the chance that a type II error exists.

The second weakness is whether our patients were representative of vascular patients everywhere. Whereas all operations exclusive of aneurysm were done for limb salvage, and the degree of underlying disease was similar to that seen in previous work, only 35.3% of patients required optimization after the insertion of the PAC. Although this number is not much different from that of studies showing a 40% incidence of abnormal left ventricular function in vascular patients,[23] it is lower than we expected and certainly is lower than the 63.2% of patients who needed preoperative interventions as reported by Berlauk.[9] All the protocol patients, however, required some sort of intervention during the study based only on their hemodynamic monitoring numbers, so perhaps this is an unfair criticism.

The third weakness is that this study does not address the supranormal values issue. Resuscitation to this extreme would likely prevent only septic and graft thrombosis problems as opposed to cardiac. Because our problems with these were so low, we think that such a study would be unlikely to show a difference. Indeed, our initial protocol was designed to test supranormal values. A cardiologist on the Institutional Review Board objected to these numbers, and it was while we were discussing this that the Berlauk study was published that showed lower numbers were likely to be just as effective.

Finally, the fourth weakness is that this study does not address the use of the PAC in very high-risk patients. Because the absolute numbers of these patients are relatively small in any one institution, however, a multicenter trial would be necessary to study this issue.

Our study also allowed liberal use of beta blockers during the operation. This was done in both groups at the insistence of our anesthesia colleagues who thought that such a regimen would improve outcome. A recent publication seems to support this.[19] Undoubtedly, this is what led to the paucity of tachycardia that would have been recorded as an adverse intraoperative event.

Pulmonary artery catheter use in elective vascular surgery, although increasing the amount of fluid given, did not reduce morbidity, mortality, cost, or length of stay. Its routine use should be limited to specific clinical situations unless a clinical trial is being conducted.

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Discussion

DR. DONALD D. TRUNKEY (Portland, Oregon): I think this is a good paper. It confirms a recent article and accompanying editorial in *JAMA* by Conners and his colleagues. I also believe it fulfills Class 1 criteria as defined by Eddy, and that we could use this in evidence-based practice guidelines. The bottom line is that pulmonary catheters are not needed in routine vascular surgery cases.

I personally am more interested in the patients that you excluded in this study. There were 17 patients. Five required suprarenal or supraceliac clamping, four had recent myocardial infarctions, four had uncompensated congestive heart failure, three had recent coronary artery bypass grafts, and one had symptomatic valve disease. Did these exclusion patients all have pulmonary artery catheters? If so, were the same end-points used? Did you achieve these end-points in the exclusion patients? Were the results the same in this group of patients? Could you compare those with your controls?

Another question relates to the use of nitropaste and propranolol. Did this confuse your results because you use them liberally in both groups?

In closing, I would congratulate the authors on their paper, and particularly on the very short, succinct discussion and excellent critique of their own perceived shortcomings and weaknesses in their study design.

DR. BASIL A. PRUITT (San Antonio, Texas): I rise to compliment Dr. Bender and his colleagues on helping us place one aspect of invasive monitoring, specifically the use of pulmonary artery catheters, in clinical perspective. Just because pulmonary artery catheters can help in monitoring critically ill patients does not mean that every intensive care unit patient should have one, and the data presented indicate that not every elective major vascular surgical patient needs or benefits from a pulmonary artery catheter.

In this study, the pulmonary artery catheter patients received more fluid overall, and it seems as if there might be some hidden benefit if that represented replacement of a preoperative fluid deficit, which then lessened postoperative fluid needs. To identify such, I ask the authors whether they can partition the fluid into preoperative and postoperative fluids?

I do have concerns about whether the patient groupings were too inclusive. Because there are almost twice as many pulmonary artery catheter patients with hypertension as a comorbidity, I wonder whether you can segregate out those patients and identify a pulmonary artery catheter benefit in that group?

Lastly, we need to know whether this study has refined your indications for preoperative insertion of pulmonary artery catheters and what those indications presently are?

DR. PALMER Q. BESSEY (Rochester, New York): I too am pleased to discuss the paper. I think it has been well designed and well conducted and clearly shows that in this group of patients who have fairly low acute cardiac risk who are operated on in the standardized way, the results are very good and the pulmonary artery catheter adds little to the arterial line, the central venous line, and the Foley catheter in achieving those results. But the strengths of this study also limit it a little bit because they make it so very specific. When trying to figure out how we should translate this into our own practice, some of those factors have to be considered.

For example, what was the secret of success if it was not the pulmonary artery catheter? Was it the fact that the surgical team was fairly stable, including the anesthesiologist, and the overall routine care was very standardized? Did the role of beta blockers of the nitropaste have a major effect on the outcome of the patients? Is the central venous pressure catheter and the way they used it in this particular group of patients an equally good measure of preload as the pulmonary artery catheter might be in the larger group of patients?

Another area that is particularly interesting to me reflects back on some of the previous work of members of this Association. Dr. George Clowes, Dr. Louis DelGuercio, and others have shown us for years that patients who have normal or a little higher than normal cardiac performance following major abdominal and thoracic procedures do better. They have a better outcome, they have better survival, and better results. The question is, is that still true today? Is a normal or low normal cardiac index satisfactory for patients undergoing elective procedures?

I too would specifically like to ask Dr. Bender what indeed these patients look like. What are the physiologic parameters