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Standard versus *Fiberoptic Pulmonary Artery Catheterization for Cardiac Surgery in the Department of Veterans Affairs*

A Prospective, Observational, Multicenter Analysis

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Background: **Controversy exists regarding the utility of continuous monitoring of mixed venous oxygen saturation ($S\bar{v}O_2$) during cardiac surgery. During a multicenter, prospective, observational study in the Department of Veterans Affairs (Cooperative Study #5), frequency of use of standard pulmonary artery catheterization (PAC) and $S\bar{v}O_2$-PAC was recorded. Here the authors relate these data to clinical outcomes.**

Methods: **Logistic and Cox regression models evaluating the association of PAC type with mortality, one or more postoperative complications, cardiac complications, time to extubation, and intensive care unit length of stay were constructed. The number of thermodilution cardiac outputs and arterial blood gas analyses performed in the first 24 h postoperatively were compared.**

Results: **Data from 3,265 patients undergoing myocardial revascularization (81.7%) or valve replacement–repair (18.3%) were considered. $S\bar{v}O_2$-PAC was used in 49% and PAC in 51% of patients. In the 14 hospitals, $S\bar{v}O_2$-PAC was used in all patients in four, in some patients in four, and never in six. No association of $S\bar{v}O_2$-PAC use with outcome were observed aside from unexplained hospital level effects. A small but statistically significant reduction in the number of arterial blood gas analyses (8 ± 3 *vs.* 10 ± 4, $P < 0.0001$, $S\bar{v}O_2$-PAC *vs.* PAC, respectively) and thermodilution cardiac outputs (14 ± 8 *vs.* 15 ± 9, $P < 0.0001$, $S\bar{v}O_2$-PAC *vs.* PAC, respectively) was observed with use of $S\bar{v}O_2$-PAC.**

Conclusions: **Despite higher cost, $S\bar{v}O_2$-PAC was commonly used in this cohort. Our analysis failed to detect associations with improved outcomes aside from a small reduction in resource utilization. The precise role of $S\bar{v}O_2$-PAC remains uncertain.**

This article is featured in "This Month in Anesthesiology." Please see this issue of ANESTHESIOLOGY, page 5A.

THE need for pulmonary artery catheterization (PAC) in patients undergoing cardiac surgery has been a topic of considerable clinical interest and controversy for nearly two decades. Despite earlier reports from university settings that the majority of elective coronary artery bypass grafting (CABG) could be performed safely with central venous catheterization alone[1–3] and a more recent report of only 58% PAC use in community hospitals for similar cases, PAC use remains popular in many centers and settings.[4]

The first major technological innovation to the PAC was addition of continuous measurement of mixed venous oxygen saturation ($S\bar{v}O_2$) by reflectance spectrophotometry ($S\bar{v}O_2$-PAC).[5,6] In the cardiac surgical setting, the ability to continuously trend $S\bar{v}O_2$, which reflects the balance between whole body oxygen delivery (cardiac output, hemoglobin concentration, arterial oxygen saturation) and utilization (peripheral oxygen consumption) maybe useful as an "early warning system" for impending adverse hemodynamic and clinical events.[7,8] It can also be used to assess adequacy of oxygen delivery during ventilator weaning, potentially decreasing the number of arterial blood gases (ABG) analyses and other laboratory measurements required. Previous studies with differing experimental designs, in either the general medical surgical or cardiac surgical intensive care unit (ICU) settings, reached varying conclusions regarding the clinical utility of $S\bar{v}O_2$-PAC for these purposes.[7–14]

As part of a multicenter, prospective, observational study evaluating the association of perioperative processes and structures of care with risk-adjusted patient outcomes in patients undergoing cardiac surgery with cardiopulmonary bypass in the Department of Veterans Affairs (DVA) medical system, frequency of use of standard PAC and $S\bar{v}O_2$-PAC was collected. Given the large sample size and prospective data capture by trained research nurses during the hospital stay, this database

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affords a unique opportunity to evaluate associations of PAC type with resource consumption and clinical outcome not previously reported.

Methods

Study Protocol

Department of Veterans Affairs Cooperative Study #5, "Processes, Structures and Outcomes of Care in Cardiac Surgery" (PSOCS), was a 4.5-yr prospective, observational study conducted at 14 DVA medical centers. This study investigated the associations of processes (acts of care) and structures (environment of care) on risk-adjusted operative mortality in patients undergoing cardiac surgery requiring cardiopulmonary bypass at 14 participating centers from 1992 to 1996.§§ Details of the data collection methodology have been previously reported.[15] All data, with the exception of a small number of emergent cases, were collected by direct observation by a PSOCS study research nurse. The current analysis represents a substudy from this database. Institutional review board approval for the PSOCS study was obtained from the Hines Veterans Affairs Cooperative Studies Program Coordinating Center Central Human Rights Committee and by the institutional review boards at each participating center; informed consent was obtained as required.

Mixed Venous Oxygen Saturation–Pulmonary Artery Catheterization Data Extraction and Coding

For the period of study (July 1, 1994, to December 31, 1996) with all 14 centers participating, we considered 3,582 patients undergoing CABG or valve replacement–repair with or without concurrent CABG requiring cardiopulmonary bypass enrolled in the operational phase of the PSOCS study.|||| The following subgroups of patients were excluded: 18 intraoperative deaths, 137 monitored with central venous catheters alone (120 of these at one hospital), 151 missing intraoperative catheter data, and 145 missing postoperative catheter data (groups not mutually exclusive). Thus, 3,265 (91%) of enrolled PSOCS patients from the operational phase formed our study cohort.

Within these patients, PAC was coded in both the intraoperative and postoperative periods in 1,681 patients, whereas $S\bar{v}O_2$-PAC was coded in both periods in 1,383 patients. One hundred forty-eight patients were coded as having $S\bar{v}O_2$-PAC during the intraoperative period but with PAC only in the postoperative period, whereas 53 patients were coded as PAC only in the intraoperative period but with $S\bar{v}O_2$-PAC in the postoperative period. The reasons for these differences are not recorded in the PSOCS database. Potential explanations include clinical factors (*i.e.*, intraoperative PAC changed to $S\bar{v}O_2$-PAC for deteriorating clinical status in the postoperative period or in the reverse situation, the additional equipment necessary to monitor $S\bar{v}O_2$ may not have been available in the ICU and thus the patient would be recoded as PAC only) or data coding errors.## For the purposes of this analysis, these 201 patients were added to the $S\bar{v}O_2$-PAC group to compare patients with some form of the "treatment" under consideration (*i.e.*, $S\bar{v}O_2$-PAC) *versus* those with "no treatment" (*i.e.*, PAC). Thus, the final $S\bar{v}O_2$-PAC group totaled 1,584 patients *versus* 1,681 PAC patients.

Statistical Analysis

Logistic and Cox regression models were constructed to evaluate the association of $S\bar{v}O_2$-PAC with several important clinical outcomes: (1) 30-day mortality; (2) any postoperative complication (appendix A); (3) cardiac complications (appendix A); (4) time to extubation; and (5) ICU length of stay. All deaths were reviewed by the PSOCS Death Review Committee. Complications were coded locally at each site by the research nurses using standardized definitions. A 30-day operative mortality risk estimate derived from population-based logistic regression models developed by the DVA's Continuous Improvement in Cardiac Surgery Program was calculated for each patient and used in each outcome model for risk-adjustment purposes.[16,17] The component risk variables used to calculate the Continuous Improvement in Cardiac Surgery Program estimate (listed in appendices B and C for CABG and Valve/Valve-CABG procedures, respectively) were not used individually in any of the models presented here to minimize colinearity. Given the controversy regarding the relative importance of preoperative risk and perioperative process variables in modulating outcome, we also included the duration of cardiopulmonary bypass in the models as an intraoperative and early postoperative surrogate for risk.[18,19]

We selected preoperative risk factors and perioperative process of care variables with strong clinical bases or evidence-based linkage to outcome. These variables were compared between PAC and $S\bar{v}O_2$-PAC groups using the Wilcoxon rank sum test for continuous variables

§§Six process of care "dimensions," each consisting of multiple variables reduced to weighted scores, were investigated: preoperative evaluation, intraoperative care, postoperative care, supervision by senior physicians, communication between care providers, and communication with patients and families. Similarly, three structures of care dimensions were investigated: organization of professional staff and oversight processes; number, experience, and training of care providers; and physical facilities and equipment.

||||As the pilot and developmental phases of the PSOCS study (before July 1, 1994) used a subset of the final 14 participating centers, we limited our analysis to the operational phase to minimize time-related effects impacting on adoption or expertise with this technology.

##Efforts to maximize data quality in this study included full-time research nurses dedicated only to the PSOCS study, coordination of research nurse activities with a full-time central nurse coordinator (CBB), several multiday training sessions during various phases of the study, weekly conference calls, and an electronic laptop data collection system. Data were screened for completeness by the Hines Coordinating Center with feedback to the local nurse. However, given collection of more than 800 process, structure, and risk variables per patient and expected turnover in nurse positions over the multiple-year time frame of the study, some degree of missing or inaccurate data are unavoidable.

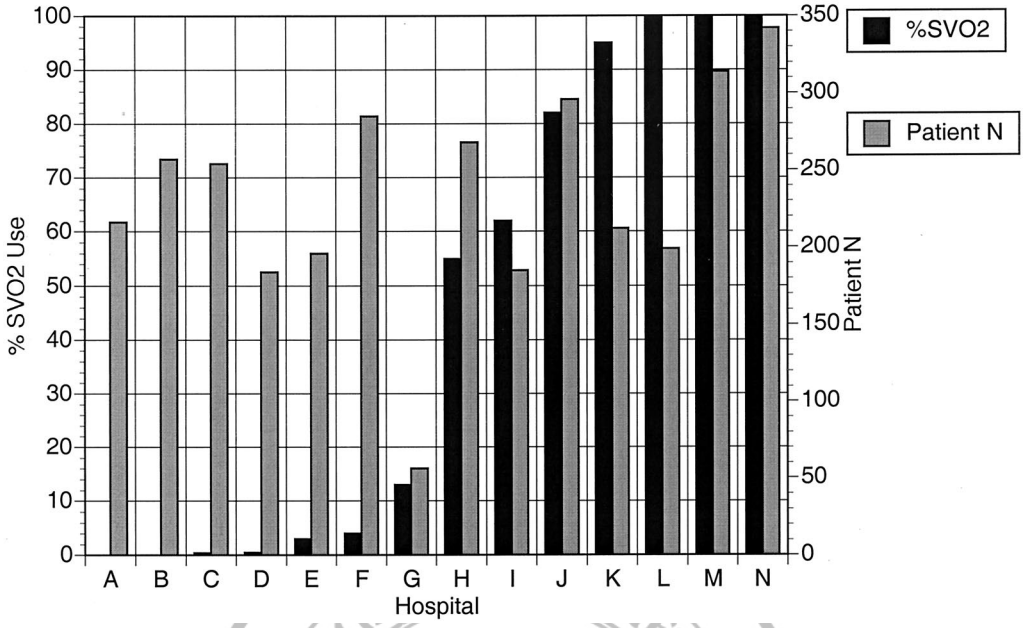

Fig. 1. Distribution of mixed venous oxygen saturation–pulmonary artery catheterization ($S\bar{v}O_2$-PAC) use by hospital as a percentage of patients analyzed.

and chi-square or Kruskall-Wallis test for categorical variables. Significant variables with a P value < 0.1 were entered into the logistic or Cox regression models using backward stepwise selection ($P < 0.05$ for removal).

To adjust for hospital level effects impacting the choice of catheter, particularly the lack of availability of the $S\bar{v}O_2$-PAC catheter at certain hospitals or protocol-driven effects (*i.e.*, use in every patient at a particular hospital), a three-level indicator variable was also entered into each model. Hospitals in which 95% of patients were coded as having $S\bar{v}O_2$-PAC were considered "always," those with 5% or less were considered "never," and those in between were considered as "some." A 5% threshold was arbitrarily chosen to account for potential data coding errors in this large study in which hundreds of other variables unrelated to this analysis were also collected. In the model results, "never" is the reference category.

Patients with missing data for variables used in a specific regression model were excluded as noted in each of the tables.*** Model discrimination and goodness of fit for dichotomous outcomes were assessed using the C-index and the Hosmer-Lemeshow "goodness of fit" (H-L) statistic, respectively. A C-index of 1.0 represents perfect discrimination, and a value of 0.5 represents chance discrimination only.[20] The H-L statistic tests the null hypothesis of no difference in the average observed and predicted outcome rates across deciles of expected risk.[21] A lower H-L value (with a larger P value) represents better model calibration. Cox proportional hazards regression analysis was used to model time to extubation and ICU length of stay. Patients who died before extubation or in whom no time to extubation was recorded were censored in the time-to-extubation model (n = 58). Deaths during the ICU stay were censored in the ICU length-of-stay model (n = 82). Odds ratios for logistic regression or hazards ratios for Cox regression with 95% confidence intervals are reported.

To evaluate the influence of catheter type on the number of ABG analyses and thermodilution cardiac outputs (TdCOs) performed in the first 24 h postoperatively, we used the mortality risk estimate to stratify patients into three groups (low risk $\leq$ 2.5%, moderate risk 2.6–5.0%, and higher risk $>$ 5.0%) comparing the frequency of each respective measurement using analysis of covariance.

Data are presented as mean ± SD for normally distributed variables or median ± interquartile range for non-normally distributed variables. Statistical significance was considered at $P < 0.05$. All statistical analyses were performed using SAS software (version 6.12; SAS Institute, Cary, NC).

Results

Overall, $S\bar{v}O_2$-PAC was used in 49% and standard PAC in 51% of patients. The distribution of $S\bar{v}O_2$-PAC use by hospital is shown in figure 1. Four hospitals appeared to use $S\bar{v}O_2$-PAC in all patients, four others in some but not all patients (including the one center in which central venous catheterization alone was the predominant clin-

***Although the main PSOCS study used data imputation techniques, they were limited to subscores within the primary "dimensions" and thus were not available on an individual variable level.

Table 1. Preoperative Variables by PAC Type

	$S\bar{v}O_2$-PAC (n = 1584)	PAC (n = 1681)	*P* Value	%Miss
Age (yr)	64 ± 10	64 ± 10	0.47	0
Mortality risk estimate (%) (median-IQR)	3.0 (1.8–5.3)	3.1 (1.8–5.8)	0.45	0
Body mass index (kg/cm^2)	27.8 ± 4.7	27.8 ± 5.0	0.60	0
Male gender (%)	99	99	0.69	0
Cerebrovascular disease (%)	18.2	18.5	0.81	0
Peripheral vascular disease (%)	30.2	24.5	0.001	0
Chronic obstructive lung disease (%)	16.6	14.3	0.07	0
Hypertension (%)	59.3	60.4	0.50	0
Diabetes mellitus (%)	25.3	25.4	0.92	0
Prior cardiac surgery (%)	10.2	11.6	0.32	0
Ejection fraction <0.35 (%)	11.1	11.4	0.80	1.4
Prior myocardial infarction (%)	53.6	50.7	0.10	0
Valve or valve/CABG surgery (%)	18.6	18.2	0.76	0
Elective status* (%)	81.4	77.5	0.006	0
Stable on arrival in operating room† (%)	86.9	83.9	0.018	0

* Elective surgery performed >72 h after cardiac catheterization.

† Absence of unstable angina requiring nitroglycerin infusion or intraaortic balloon pump, pulmonary edema requiring intubation, cardiogenic shock, cardiac arrest requiring cardiopulmonary resuscitation.

PAC = pulmonary artery catheter; %Miss = percent of missing observations for respective variable; IQR = interquartile range; CABG = coronary artery bypass graft.

ical practice), whereas the remaining six centers never used $S\bar{v}O_2$-PAC.

Differences in preoperative risk and intraoperative and postoperative process of care variables between the groups are presented in tables 1–3. The cohort was predominantly male undergoing elective CABG. Because of the large sample size, many variables achieved statistical significance, although most differences were small and of marginal clinical relevance. In the univariate analyses, PAC type had no effect on mortality or morbidity (aggregate cardiac complication variable or any postoperative complications variable), although several individual postoperative complications were significant. There were statistically significant but clinically small differences between PAC type for time to extubation and for ICU and postoperative length of stay.

The logistic and Cox regression models for perioperative mortality, one or more postoperative complications, cardiac complications, time to extubation, and ICU length of stay are presented in tables 4–8. With the exception of time to extubation, no independent associations of $S\bar{v}O_2$-PAC with any of these outcomes were observed. In the cardiac-complications model, the hospital indicator for "some" use was significantly associated with a lower frequency of complications, despite the observation that the catheter variable alone was not. This suggests that an unspecified hospital level effect, independent of catheter type, may be responsible.

In the time-to-extubation model, a more complex interaction was observed between catheter type and the hospital indicator. The "always" and "some use" hospital indicators were associated with a shorter time to extubation, but catheter type was associated with a longer time. Inspection of the survival curves for each of the possible six catheter type by hospital indicator combinations (including the null combinations of always used but no $S\bar{v}O_2$-PAC and never used with yes $S\bar{v}O_2$-PAC) revealed that the shortest times to extubation were noted in the some use, no $S\bar{v}O_2$-PAC pair, and the always used, yes $S\bar{v}O_2$-PAC pair relative to the remaining pairs. Overall, PAC patients had shorter times to extubation relative to $S\bar{v}O_2$-PAC, and hospitals in which $S\bar{v}O_2$-PAC was used had shorter times. The presence of a Fast Track protocol was strongly associated with shorter time to extubation (odds ratio, 2.1; 95% confidence interval, 1.9–2.3).

The C-indices and H-L *P* values for the logistic models indicate acceptable model discrimination and calibration.

The mean number of ABG analyses and TdCOs performed in the first 24 h postoperatively at each hospital are presented in figure 2. These data, stratified by terciles of the Continuous Improvement in Cardiac Surgery Program risk estimate, are shown in table 9. An increase in the number of ABG analyses performed with increasing risk was observed ($P = 0.002$). The rate of increase with risk was similar between PAC and $S\bar{v}O_2$-PAC. However, there were fewer ABG analyses performed in the $S\bar{v}O_2$-PAC group ($P = 0.001$). For TdCO measurements, a risk by catheter type interaction was observed. Although the number of TdCO measurements increased in both PAC and $S\bar{v}O_2$-PAC groups with increasing risk, the rate of increase was greater in the PAC group ($P = 0.027$).

Discussion

This analysis reveals that PAC use was nearly universal in the 14 hospitals participating in the PSOCS study between 1994 and 1996, and that $S\bar{v}O_2$-PAC was used in nearly 50% of patients. We cannot be certain if these results were representative of the entire VA system (43

Table 2. Intraoperative Variables by PAC Type

	Svo_2–PAC (n = 1584)	PAC (n = 1681)	*P* Value	%Miss
Units packed red blood cells transfused (median-IQR)	0 (0–2)	0 (0–2)	0.004	.06
% Patients transfused	42.1	37.6	0.008	.06
Duration of CPB (h)	2.1 ± 0.7	2.1 ± 0.9	0.80	0
TEE use (%)	50	48.5	0.38	0.3
Fast track protocol (%)	30.1	33.3	0.10	0
Vasodilator use (%)	81.7	71.6	0.001	0.3
Inotrope use (%)	62.5	53.5	0.001	0.1
IABP use(a) (%)	7.6	9.6	0.05	0

* Any use of IABP (pre-, intra-, or postoperative).

PAC = pulmonary artery catheter; %Miss = percent of missing observations for respective variable; IQR = intraquartile range; CPB = cardiopulmonary bypass; IABP = intra-aortic balloon pump; TEE = transesophageal echocardiography.

Table 3. Postoperative Variables by PAC Type

	Svo_2–PAC (n = 1584)	PAC (n = 1681)	*P* Value	%Miss
Process of care variables				
Units packed red blood cells transfused (median-IQR)	1 (0–2)	0 (0–2)	0.0001	1.4
% Patients transfused	52.5	43.4	0.001	1.4
Number of cardiac outputs (first 24 h)	14 ± 8	15 ± 9	0.0001	2.8
Number of ABGs (first 24 h)	8 ± 3	10 ± 4	0.0001	1.9
Extubation (h from ICU admission) (median-IQR)	17.5 (14–21.7)	18.2 (14.8–23)	0.007	2.2
Extubation within 10 h (%)	15	15.1	0.90	2.2
Vasodilator use (%)	88.8	86.0	0.017	0.8
Inotrope use (%)	69.7	59.6	0.001	0.6
Outcome variables				
Any postoperative complication (%)	59.9	59.3	0.74	0
Any cardiac complication (%)	49.2	48.9	0.86	.03
Low cardiac output	9.0	17.9	0.001	.03
Perioperative myocardial infarction	1.4	6.9	0.001	0.2
Perioperative myocardial injury	2.6	10.0	0.001	0.2
Cardiac arrest	3.2	3.7	0.40	0.1
Ventricular arrhythmias	3.3	3.6	0.58	0.1
Heart block	18.3	3.3	0.001	0.1
Persistent CHF symptoms	3.4	1.9	0.005	0.2
Atrial fibrillation	32.5	30.7	0.26	0.2
ICU LOS (days) (median-IQR)	2.8 (1.9–4.8)	2.7 (1.8–3.9)	0.0001	0.2
Total postoperative LOS (days) (median-IQR)	8 (6–12)	8 (6–12)	0.03	0.2
Death within 30 days (%)	4.6	4.1	0.43	0

PAC = pulmonary artery catheter; %Miss = percent of missing observations for respective variable; IQR = interquartile range; ICU = intensive care unit; CHF = congestive heart failure; AGB = arterial blood gasses; LOS = length of stay.

Table 4. Mortality Model

Variable	Odds Ratio	95% CI Low	95% CI High	*P* Value
IABP use	3.63	2.32	5.68	0.0001
Postoperative PRBC transfusion	1.16	1.09	1.24	0.0001
Intraoperative PRBC transfusion	1.19	1.00	1.28	0.0001
Mortality risk estimate	1.24	1.12	1.39	0.0001
Postoperative inotrope use	2.35	1.25	4.43	0.008
Postoperative vasodilator use	0.57	0.36	0.91	0.017
Svo_2–PAC	1.18	0.79	1.76	0.409

Operating room <1.0 = risk factor is protective for higher mortality, >1.0 = risk factor is related to higher mortality.

n = 3189; C-index = 0.839; H-L *P* Value = 0.8843.

CI = confidence interval; IABP = intra-aortic balloon pump; PRBC = packed red blood cells; PAC = pulmonary artery catheter.

Table 5. Any Postoperative Complication Model

Variable	Odds Ratio	95% CI Low	95% CI High	*P* Value
Postoperative inotrope use	2.09	1.78	2.47	0.0001
Postoperative PRBC transfusion	1.26	1.19	1.33	0.0001
Fast track protocol	0.61	0.52	0.73	0.0001
Intraoperative TEE use	1.57	1.33	1.85	0.0001
Mortality risk estimate	1.35	1.20	1.51	0.0001
IABP use	2.45	1.61	3.74	0.0001
Postoperative vasodilator use	0.63	0.47	0.83	0.0011
Intraoperative vasodilator use	0.75	0.61	0.93	0.007
Intraoperative RBC transfusion	1.07	1.01	1.14	0.0281
Duration of CPB	1.13	1.01	1.28	0.0418
$S\bar{v}O_2$–PAC	0.89	0.76	1.04	0.1415

Operating room <1.0 = risk factor is protective for complications; >1.0 = risk factor is related to higher complication rate.

n = 3175; C index = 0.747; H-L *P* Value = 0.138.

CI = confidence interval; PRBC = packed red blood cells; TEE = transesophageal echocardiography; IABP = intra-aortic balloon pump; RBC = red blood cells; CPB = cardiopulmonary bypass; PAC = pulmonary artery catheter.

centers performing cardiac surgery during this time period), although we believe it likely given that the PSOCS study sites were selected based on predefined criteria for geographic location and risk-adjusted mortality, to obtain a representative national mix of sites. The frequent use of $S\bar{v}O_2$-PAC was surprising given the additional cost over standard PAC (approximately $150–200 difference). Our findings contrast with a recent retrospective cohort study of 13,907 patients undergoing elective CABG at community hospitals in 1997, retrieved from a commercial "benchmarking" database, in which PAC (specific type and exact time of insertion not reported) was used in only 58% of patients.[4]

Our data fail to support a statistically significant independent association of $S\bar{v}O_2$-PAC use with the outcomes we selected for modeling. The failure to observe an independent effect on mortality is not unexpected given the multiplicity of factors involved and the complexity of interactions, which is the basic premise of the parent PSOCS study.[22–24] We chose to use a subset of the PSOCS cohort, in which data were collected in a similar time frame at all of the 14 participating centers (operational phase from July 1, 1994, to December 31, 1996) to minimize time-related effects in adoption and use of this technology, lowering our sample size and statistical power relative to the original study's target enrollment of approximately 5,000 patients (which used fewer centers during the earlier pilot and developmental phases).

Our choice of complication models, either all aggregate complications or cardiac complications alone, was based on literature precedent for similar large observational analyses in either cardiac or noncardiac surgery in the DVA[17,25–27] (for the former) and controversies regarding the "early warning" potential for $S\bar{v}O_2$-PAC to alert clinicians to impending (or manifest) hemodynamic abnormalities (for the latter).[7–13] Given the number of complications comprising our aggregate cardiac complication variable, it is possible that analysis of individual complications might have revealed significant results. However, this *a posteriori* approach is likely to yield false-positive associations simply by chance. In addition, several of these complications are subject to variability in interpretation and coding. Because independent validation of complication data by a central study monitoring board was not performed (as was done for mortality), given the high frequency of these events, these

Table 6. Cardiac Complications Model

Variable	Odds Ratio	95% CI Low	95% CI High	*P* Value
Postoperative inotrope use	2.46	2.08	2.92	0.0001
Intraoperative TEE use	2.15	1.82	2.52	0.0001
Fast track protocol	0.64	0.54	0.76	0.0001
Postoperative PRBC transfusion	1.12	1.07	1.17	0.0001
IABP use	2.33	1.66	3.27	0.0001
Postoperative vasodilator use	0.67	0.56	0.81	0.0001
Mortality risk estimate	1.19	1.08	1.30	0.0002
Hospital indicator (some)	0.74	0.61	0.90	0.0025
Intraoperative PRBC transfusion	1.06	1.00	1.12	0.0359
$S\bar{v}O_2$–PAC	0.92	0.78	1.08	0.3009

Operating room <1.0 = risk factor is protective for complications; >1.0 = risk factor is related to a higher complication rate.

n = 3191; C index = 0.737; H-L *P* Value = 0.119.

CI = confidence interval; TEE = transesophageal echocardiography; PRBC = packed red blood cells; IABP = intra-aortic balloon pump; PAC = pulmonary artery catheter.

Table 7. Time to Extubation Model

Variable	Odds Ratio	95% CI Low	95% CI High	*P* Value
Fast track protocol	2.07	1.90	2.26	0.0001
Postoperative PRBC transfusion	0.88	0.86	0.90	0.0001
Hospital indicator (always)	1.83	1.56	2.15	0.0001
IABP use	0.58	0.50	0.67	0.0001
Postoperative inotrope use	0.73	0.66	0.81	0.0001
Hospital indicator (some)	1.43	1.26	1.62	0.0001
Mortality risk estimate	0.89	0.86	0.93	0.0001
Intraoperative PRBC transfusion	0.94	0.92	0.96	0.0001
Duration of CPB	0.90	0.85	0.95	0.0001
$S\bar{v}O_2$–PAC	0.76	0.66	0.87	0.0001
Intraoperative TEE use	0.87	0.80	0.94	0.0004
Intraoperative inotrope use	0.88	0.80	0.96	0.0068

Operating room <1.0 = risk factor is related to longer time to extubation; >1.0 = risk factor is related to shorter time to extubation.

n = 3130.

CI = confidence interval; PRBC = packed red blood cells; IABP = intra-aortic balloon pump; CPB = cardiopulmonary bypass; PAC = pulmonary artery catheter; TEE = transesophageal echocardiography.

results must be considered tentative. Our finding of a hospital level effect of $S\bar{v}O_2$-PAC for cardiac complications, in the absence of a patient level association with catheter type, is interesting and is likely a result of either a higher-order hospital effect (*i.e.*, different processes of care at an individual hospital within the three-level hospital group indicator we used that might impact on cardiac complication rates) or variability in coding of complications at different centers, issues beyond the scope of this analysis.

Evaluating resource utilization parameters (time to extubation, ICU length of stay, number of ABG and TdCO measurements performed), we noted several interesting findings. With regard to time to extubation, a complex interaction between the hospital indicator and catheter type was noted. The overriding effect of hospitals with a Fast Track protocol was the predominant factor, as would be expected. As noted in a previous DVA study from this time period, a bimodal distribution of patients is usually present in time to extubation.[19] Although the exact role of preoperative risk *versus* perioperative processes in modulating postoperative outcome remains controversial, it is likely that healthier patients undergoing "successful" procedures are extubated earliest, followed by "sicker" patients undergoing "successful" procedures, followed by patients undergoing complicated or "stormy" procedures. Given the physiologic basis for $S\bar{v}O_2$-PAC in evaluating the stability of weaning from mechanical ventilation,[14] it is likely that its true clinical utility may be in the latter "sicker" groups of patients. Thus, an association with a longer time to extubation may occur.

Modeling of hospital length of stay is a complex process, and it is unlikely that an isolated process variable such as $S\bar{v}O_2$-PAC would have a measurable impact on it (as we have noted). As noted previously, reduction in time to extubation is unlikely to significantly reduce postoperative length of stay, except in hospitals with "aggressive" fast-tracking protocols.[28,29]

Finally, we noted a highly significant but clinically modest reduction in the number of ABG and TdCO measurements performed in hospitals with $S\bar{v}O_2$-PAC. As expected, higher-risk patients were subjected to more measurements, but at all levels fewer measurements

Table 8. Intensive Care Unit Duration of Stay Model

Variable	Odds Ratio	95% CI Low	95% CI High	*P* Value
Intraoperative PRBC transfusion	0.89	0.87	0.90	0.0001
Fast track protocol	1.51	1.40	1.63	0.0001
Intraoperative TEE use	0.71	0.66	0.76	0.0001
Postoperative inotrope use	0.70	0.64	0.78	0.0001
Intraoperative PRBC transfusion	0.93	0.91	0.95	0.0001
Mortality risk estimate	0.90	0.87	0.94	0.0001
IABP use	0.67	0.57	0.78	0.0001
Postoperative vasodilator use	1.15	1.03	1.29	0.0105
Intraoperative inotrope use	0.89	0.81	0.98	0.0187
$S\bar{v}O_2$–PAC	0.97	0.90	1.04	0.4161

Operating room <1.0 = risk factor is related to longer intensive care unit stay; LOS >1.0 = risk factor is related to shorter intensive care unit stay.

n = 3092.

CI = confidence interval; PRBC = packed red blood cells; TEE = transesophageal echocardiography; IABP = intra-aortic balloon pump; PAC = pulmonary artery catheter.

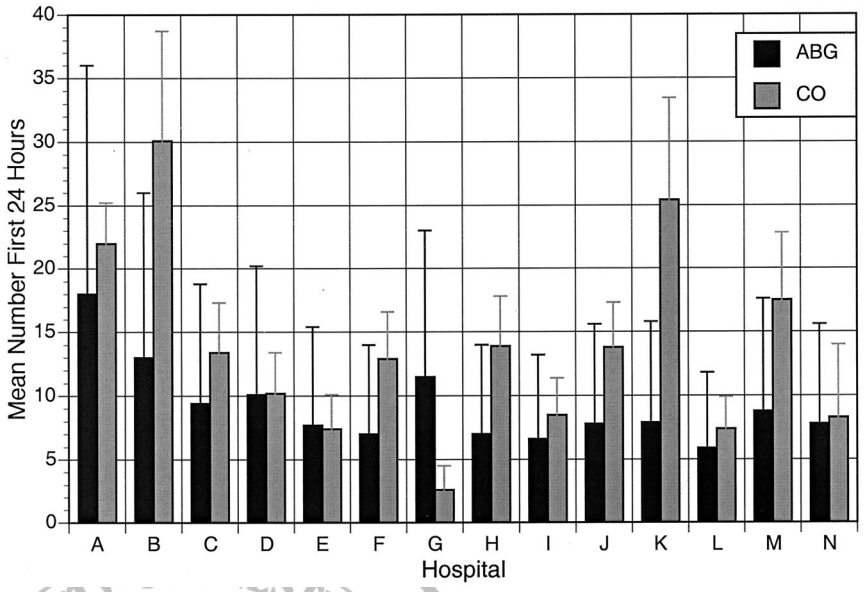

Fig. 2. Mean number (± SD) of arterial blood gas (ABG) and thermodilution cardiac output (CO) measurements performed in the first 24 h postoperatively. Hospital codes are same as those used in figure 1.

were made in the $S\bar{v}O_2$-PAC group. Although we have not and are unable to perform a cost analysis, it is unlikely that the small difference (based on the entire cohort data) would offset the cost of the more expensive catheter. However, we cannot completely discount the possibility that, at a particular center, such an offset might have occurred.

We do not know the current prevalence of $S\bar{v}O_2$-PAC use in this population and to what extent the wider institution of "fast tracking" in the DVA system has impacted on it.[19,28] It is likely that fast tracking, with its emphasis on efficiency and curtailing excessive resource consumption, may have significantly decreased $S\bar{v}O_2$-PAC use. However, shortly after this study concluded, a "continuous" cardiac output PAC was introduced clinically and has been found to have acceptable accuracy and correlation with bolus TdCO in this setting.[30,31] This catheter is marketed with or without continuous $S\bar{v}O_2$ capability, and the price of a "dual" catheter is only marginally greater than continuous cardiac output PAC alone. Thus, it is possible that some centers continue to use these catheters over standard PAC, given the additional information provided at a similar cost to $S\bar{v}O_2$-PAC alone.

An additional factor likely to influence the use of $S\bar{v}O_2$-PAC is the increasing use of off-pump and minimally invasive coronary artery bypass procedures. Avoidance of cardiopulmonary bypass in the vast majority of these cases is likely to lead the clinician to curtail use of the more costly $S\bar{v}O_2$-PAC. However, there is still controversy regarding reduction of adverse outcomes after off-pump or minimally invasive coronary artery bypass and the extent of perioperative resource utilization relative to cardiopulmonary bypass procedures.[32] The risk profile of patients undergoing off-pump coronary artery bypass may vary significantly between centers, with some reserving them for the sickest patients and others performing them routinely on the healthiest patients, a factor that could influence choice of monitoring in either direction.[33]

The continuing clinical controversy regarding the value of "goal-oriented hemodynamic therapy," in which oxygen delivery is maintained at a supranormal level (as manifested by increased cardiac output and $S\bar{v}O_2$), may also influence choice of PAC.[34–36] Although predominantly studied in medical ICU patients (with conflicting results), a recent randomized study of 403 cardiac surgical patients reported a significant reduction in the frequency of organ dysfunction at the time of discharge in the protocol group (1.0 *vs.* 5.6% control, $P < 0.01$).[37] Thus, the capability to continually monitor $S\bar{v}O_2$ may be advantageous, although further confirmatory studies are required.

Table 9. Number of Arterial Blood Gases (ABG) and Thermodilution Cardiac Outputs (TdCO) Performed in the First 24 h Postoperatively

Risk Strata	% in Each Risk Strata		Mean No. ABGs			Mean No. TdCOs		
	PAC	SvO_2–PAC	PAC	SvO_2–PAC	*P* Value	PAC	SvO_2–PAC	*P* Value
≤2.5	41.0	40.0	9.6 ± 4.4	7.4 ± 2.7	.0001	14.0 ± 7.7	13.0 ± 7.7	.03
2.6–5.0	28.8	32.7	10.2 ± 4.2	7.6 ± 2.9	.0001	15.4 ± 8.7	13.8 ± 8.0	.005
>5.0	30.3	27.3	10.8 ± 4.5	8.1 ± 2.9	.0001	17.3 ± 10.0	14.4 ± 7.9	.0001

N = 3265.
PAC = pulmonary artery catheter.

Given the observational nature of our study, the statistical methodology to assess the impact of $S\bar{v}O_2$-PAC is considerably more controversial than what would be used in a randomized controlled trial.[38] Our models must be considered exploratory as they were constructed solely to evaluate associations of $S\bar{v}O_2$-PAC with a small group of variables (especially relative to the much larger parent PSOCS study). We considered risk and process covariates modulating outcome and decision-making related to choice of catheter, entering into the regression models a core set of risk variables and other risk–process variables with statistically significant differences between catheter groups, allowing us to adjust for these imbalances. Those that appear significant in the output of the models may or may not be clinically relevant if the analysis was performed with a variable other than PAC–$S\bar{v}O_2$-PAC as the "primary" variable because it is likely that different covariates would be considered in the regression model. Thus, interesting and controversial findings (*i.e.*, transesophageal echocardiography use, differences in blood transfusion, *etc.*) may suggest other analyses but are not necessarily relevant findings of this analysis. It must be emphasized that, with such a large sample size, highly statistically significance differences in the absence of clinical significance is a common finding. The clinician must carefully inspect actual percentage differences and not rely on small *P* values. Although we present basic model calibration and discrimination statistics (C-index and H-L test), we have not performed additional diagnostics (*i.e.*, bootstrapping, *etc.*) required for validation of prediction models. In addition, the PSOCS study analysis makes extensive use of complex data reduction and variable weighting techniques to deal with hundreds of clinical variables collected, before entry into the primary outcome mortality logistic model, which we have not performed. Thus, our limited modeling approach should be interpreted cautiously.

Other statistical techniques such as subclassification on propensity scores can be used along with logistic regression and case-matching to evaluate treatment bias related to treatment choice (in this case catheter type).[39] However, each has different exclusion criteria and might yield different results. With propensity scoring, patients in the PAC-only hospitals would be excluded from consideration because of the absence of $S\bar{v}O_2$-PAC at those hospitals. Inclusion of a catheter-related hospital indicator variable (never, some, always) serves a somewhat similar role, allowing inclusion of a substantially larger number of patients.

Using data from a large prospective cohort of patients undergoing cardiac surgery with cardiopulmonary bypass, we failed to note any independent association of $S\bar{v}O_2$-PAC use with a variety of important clinical outcomes. A small reduction in resource utilization as measured by ABG and TdCO measurements was observed. Given development of new technology (continuous cardiac output) and changes in surgical practice (off-pump and minimally invasive coronary artery bypass), the clinical implications of these findings are uncertain. Further study of the effectiveness of sophisticated PACs using a variety of data sources and experimental designs, especially in light of ongoing controversy regarding PAC use,[40] appears worthy of further research.

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Appendix A: Complication Variables Definitions

Low cardiac output: cardiac index $< 2.0\ l \cdot min^{-1} \cdot m^{-2}$ or peripheral manifestations (*e.g.*, oliguria, hypotension, obtundation), or both for 6 h or longer postoperatively requiring inotropic or intraaortic balloon pump support.

Perioperative myocardial infarction: new Q waves or widening of Q waves by 0.02 s on the electrocardiogram within 30 days postoperatively.

Perioperative myocardial injury: (1) electrocardiogram changes consistent with a non-Q myocardial infarction (new ST segment depression $\geq$ 2 mm in two or more adjacent leads, deep [$\geq$ 5 mm] inverted T waves, or new left bundle branch block (LBBB); (2) CK-MB (creatine kinase MB isoenzyme) isoenzyme changes $\geq$ twice the upper limit of normal; or (3) a technetium pyrophosphate scan showing myocardial damage.

Cardiac arrest: external or open cardiopulmonary resuscitation occurring in the ICU, ward, or out of hospital after the chest has been completely closed and within 30 days of surgery.

Ventricular arrhythmias: ventricular tachycardia or ventricular fibrillation requiring cardioversion or defibrillation (with or without cardiopulmonary resuscitation).

Heart block: second- or third-degree heart block documented by electrocardiogram requiring the insertion or activation of a temporary or permanent pacemaker.

CHF symptoms: New York Heart Association functional class III or class IV congestive heart failure throughout the postoperative hospital stay.

Atrial fibrillation: one or more episodes of atrial fibrillation (documented by electrocardiogram) postoperatively.

Coma: Decreased level of consciousness (exclude transient disorientation or psychosis) for $\geq$ 24 h during postoperative hospitalization as evidence by lack of response to deep, painful stimuli.

Stroke: new objective neurologic deficit lasting $\geq$ 30 min with onset intraoperatively or during the postoperative hospital stay.

Respiratory failure: total duration of ventilator-assisted respiration during postoperative hospitalization $\geq$ 48 h.

Reintubation: reintubation for postoperative respiratory failure.

Pulmonary embolus: a ventilation–perfusion scan interpreted as a high probability of pulmonary embolism or positive pulmonary arteriogram.

Mediastinitis: a bacterial infection below the sternum requiring drainage and antimicrobial therapy diagnosed during the postoperative hospitalization or within 30 days after surgery.

Endocarditis: two or more positive blood cultures with the same organism, or development of vegetations and valve destruction seen by echo or repeat surgery, or histologic evidence of infection at repeat surgery or autopsy, or any combination.

Pneumonia: clinical signs and symptoms and infiltrate on chest radiograph.

Vein harvest infection: a vein harvest site (usually saphenous) infection manifested by draining pus with positive cultures that may require or be relieved by antibiotic therapy.

Chest wound infection: a bacterial infection of the sternotomy incision not involving the sternum but requiring antibiotic therapy and prolonging the hospital stay.

Renal failure: new renal failure requiring dialysis or an exacerbation of renal failure requiring the initiation of dialysis (not on dialysis preoperatively).

GI bleed: gastrointestinal bleed that requires a transfusion of more than three units of erythrocytes, that results in hematocrit decreasing more than 20%, or that requires an operative procedure during postoperative hospitalization.

Hepatic failure: severe liver dysfunction manifested by visible jaundice, serum total bilirubin greater than 5.0 mg/dl, serum albumin less than 3.0 g/dl, or INR (prothrombin time) greater than 3.0 (not on warfarin).

Coagulopathy: a diagnosis of disseminated intravascular coagulation manifested by diffuse bleeding with a serum fibrinogen less than 100 mg/dl and a platelet count less than 100,000/μl.

Appendix B: Variables Included in the Continuous Improvement in Cardiac Surgery Program Coronary Artery Bypass Grafting Mortality Risk Estimate

Definitions of the following variables are available at www.va.gov/HEALTH/CSCC/maincscc.htm:

Serum creatinine
Ejection fraction
Prior myocardial infarction
Surgical priority
CHF functional class
Preoperative PTCA
Age
Prior heart surgery
Hx cerebrovascular disease
Hx COPD
Preoperative ST segment depression on 12-lead electrocardiogram
ASA class
Hx peripheral vascular disease
Preoperative IABP

Appendix C: Variables Included in the Continuous Improvement in Cardiac Surgery Program Valve Surgery Mortality Risk Estimate

Definitions of the following variables are available at www.va.gov/HEALTH/CSCC/maincscc.htm:
Serum creatinine
Ejection fraction
Prior myocardial infarction
Surgical priority
Angina functional class
Procedure type
Age
Prior heart surgery
Current smoker
Functional status
Gender
Endocarditis
Rales on physical examination
ASA class