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Prophylactic Versus Standby Cardiopulmonary Support for High Risk Percutaneous Transluminal Coronary Angioplasty

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Objectives. Data from a national registry of 23 centers using cardiopulmonary support (CPS) were analyzed to compare the risks and benefits of prophylactic CPS versus standby CPS for patients undergoing high risk coronary angioplasty.

Background. Early data from the CPS registry documented a high angioplasty success rate as well as a high procedural morbidity rate. Because of this increased morbidity some high risk patients were placed on standby CPS instead of prophylactic CPS.

Methods. Patients in the prophylactic CPS group had 18F or 20F venous and arterial cannulas inserted and cardiopulmonary bypass initiated. Patients in the standby CPS group were prepared for institution of cardiopulmonary bypass, but bypass was not actually initiated unless the patient sustained irreversible hemodynamic compromise.

Results. There were 389 patients in the prophylactic CPS group and 180 in the standby CPS group. The groups were comparable with respect to most baseline characteristics, except that left ventricular ejection fraction was lower in the prophylactic CPS group. Thirteen of the 180 patients in the standby CPS group sustained irreversible hemodynamic compromise during the angioplasty procedure. Emergency institution of CPS was successfully initiated in 12 of these 13 patients in <5 min. Procedural success was 88.7% for the prophylactic and 84.4% for the standby CPS group ($p = NS$). Major complications did not differ between groups. However, 42% of patients in the prophylactic CPS group sustained femoral access site complications or required blood transfusions, compared with only 11.7% of patients in the standby CPS group ($p < 0.01$). Among patients with an ejection fraction ≤20%, procedural morbidity remained significantly higher in the prophylactic CPS group (41% vs. 9.4%, $p < 0.01$), but procedural mortality was higher in the standby group (4.8% vs. 18.8%, $p < 0.05$).

Conclusions. Patients in the standby and prophylactic CPS groups had comparable success and major complication rates, but procedural morbidity was higher in the prophylactic group. When required, standby CPS established immediate hemodynamic support during most angioplasty complications. For most patients, standby CPS was preferable to prophylactic CPS during high risk coronary angioplasty. However, patients with extremely depressed left ventricular function (ejection fraction <20%) may benefit from institution of prophylactic CPS.

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With increased operator experience and improved technology, the indications for percutaneous transluminal coronary angioplasty have been extended to include some patients at increased procedural risk. Several factors have been associated with high risk coronary angioplasty including dilation of the left main coronary artery, poor left ventricular function, and dilation of the only patent coronary artery (1,2). Several new devices have been used to support the coronary or systemic circulation, or both, during high risk angioplasty procedures. These include autoperfusion catheters (3,4), transcatheter infusion of blood substitutes (5), coronary sinus retroperfusion (6,7) and prophylactic use of the intraaortic balloon pump (8,9). Recently, the technique of partial cardiopulmonary bypass, also known as cardiopulmonary support (CPS) or "supported angioplasty," has been developed (10–19). Cardiopulmonary support is accomplished by using a portable, vortex pump-membrane oxygenator system that provides up to 6 liters/min output with the use of 18F or 20F femoral vein and artery cannulas. After several encouraging reports, the National Registry of Elective Cardiopulmonary Support was formed to evaluate the initial multicenter results with this procedure. Published data from the first year of the Registry's experience (1988) documented a high angioplasty success rate (95%) but also a relatively high procedural morbidity rate, particularly with respect to femoral access site complications and transfusion requirements (20,21). This increased morbidity led many members of the Registry to place some high risk angioplasty patients on so-called "standby CPS" instead of prophylactic

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CPS. Patients undergoing angioplasty with standby CPS were prepared for the emergency use of CPS but cardiopulmonary bypass was initiated only in the setting of irreversible hemodynamic compromise. The objective of this study was to compare the procedural outcome of high risk patients undergoing angioplasty with standby CPS with that of patients in whom prophylactic CPS was instituted.

Methods

Inclusion criteria. The National Registry of Elective Cardiopulmonary Support consists of 23 medical centers. Participating centers and the names of the corresponding principal investigators are listed in Appendix A. Registry entry criteria for both standby CPS and prophylactic CPS patients were as follows. The patient must have 1) stable or unstable angina pectoris, 2) at least one coronary artery stenosis probably amenable to balloon angioplasty, 3) left ventricular ejection fraction <25% or an angioplasty target vessel supplying >50% of the viable myocardium, or both. In most cases in which the indication was angioplasty of a vessel supplying >50% of the viable myocardium, the target vessel supplied collateral channels to another coronary artery with a proximal chronic total occlusion not amenable to balloon angioplasty. Patients with acute myocardial infarction were excluded from the Registry, as were patients with unstable hemodynamic status (systolic blood pressure <90 mm Hg) before the start of the angioplasty procedure. The assignment of a particular patient to standby or prophylactic CPS was left entirely to the operator's discretion.

Data collection. Data forms were completed at the end of the hospital stay. Data pertinent to this analysis included patient age, gender, angiographic description of coronary artery disease, left ventricular ejection fraction (determined by contrast or radionuclide angiography), and performance of associated interventional procedures. Standby CPS procedural data included the presence or absence of small (5F or 6F) sheaths in the contralateral femoral artery and vein, the presence of a "primed" or "unprimed" CPS system on standby, the prophylactic use of an intraaortic balloon pump, and the need for emergency institution of CPS. Procedural data for patients undergoing prophylactic CPS included method of cannula insertion and method of cannula removal, bypass flow and bypass time. Coronary angioplasty data included: location of coronary artery stenoses undergoing attempted dilation and angiographic appearance of coronary stenoses after dilation. A successful angioplasty procedure was defined as an intervention resulting in >20% decrease in relative diameter vessel narrowing with a residual narrowing of <50% in the absence of major complications, including in-hospital death, emergency bypass surgery or Q-wave myocardial infarction. The presence of any of the following morbid events was also recorded: femoral artery pseudoaneurysm, femoral artery occlusion, deep venous thrombosis, the presence of a femoral hematoma, retroperitoneal bleed, local infection at the femoral cannulation site, femoral nerve weakness and blood transfusion. All data forms were submitted to the coordinating center at the University of Maryland.

Prophylactic CPS procedure. Prophylactic CPS procedures were performed in the catheterization laboratory under local anesthesia and mild sedation. Patients were routinely premedicated with aspirin, nitroglycerin and a calcium channel blocking agent. Iliac angiography was performed before insertion of cannulas to document any iliofemoral disease that would preclude the use of large diameter cannulas. Femoral cannulas were inserted either by local cutdown and direct vessel puncture or by the percutaneous insertion technique described by Shawl et al. (17). For percutaneous insertion, progressive vessel dilation was undertaken before cannula insertion. Under fluoroscopic guidance, the multiple side-hole 18F or 20F venous and arterial cannulas were positioned at the junction of the right atrium and inferior vena cava and distal aorta, respectively. Heparin was administered in a 300 U/kg dose before insertion of cannulas. The activated clotting time was maintained at >400 s during cardiopulmonary bypass. Following cannula placement, CPS was instituted to reduce pulmonary capillary wedge pressure to <5 mm Hg and to maintain adequate systemic pressure and perfusion during angioplasty balloon inflation. Fluid administration was commonly required to achieve adequate systemic pressure. After coronary angioplasty, CPS was tapered over a period of several minutes. Cannula removal was accomplished either by surgical closure or by percutaneously using mechanical groin clamping to achieve hemostasis. The heparin effect was not routinely reversed with protamine after CPS.

Standby CPS procedure. For standby CPS procedures, the CPS equipment and trained personnel were required to be present during the angioplasty procedure. Further preparation was left to the operator's discretion. In most patients, iliac angiography was performed to document the iliofemoral anatomy, thereby identifying the most favorable iliofemoral artery for potential CPS insertion. Small, 5F or 6F, sheaths were placed in the contralateral femoral vein and artery in 94 (52.2%) patients in the standby CPS group. This allowed rapid cannulization under emergency circumstances. In 50 (27.8%) patients in the standby CPS group the CPS apparatus was fully primed. In 11 (6.1%), 18F or 20F femoral cannulas were inserted but cardiopulmonary bypass was not initiated unless urgently needed. Additionally, the intraaortic balloon pump was inserted prophylactically in five patients (2.8%) in the standby CPS group. Heparin was administered to patients in the standby CPS group at the usual dose given to patients undergoing routine angioplasty. This generally is one third to one half of the heparin dose given to patients in the prophylactic CPS group. When emergency cannulation was required, it was performed by the percutaneous insertion technique described above. Once cannulas were inserted, cardiopulmonary bypass was instituted as in patients in the prophylactic CPS group.

Table 1. Baseline Characteristics of 569 Patients With Prophylactic or Standby Cardiopulmonary Support

	Prophylactic CPS (n = 389)	Standby CPS (n = 180)	p Value
Age >75 years	54 (13.9)	32 (17.8)	NS
Female	88 (22.6)	56 (31.1)	NS
Lesions dilated per patient (no.)	1.75	1.65	NS
Unprotected left main dilated	36 (9.3)	10 (5.6)	NS
Only patent vessel dilated	119 (30.6)	37 (20.6)	NS
LVEF (mean)	27.5%	36.7%	< 0.01
LVEF ≤20%	126 (32.4)	32 (17.8)	< 0.05

CPS = cardiopulmonary support; LVEF = left ventricular ejection fraction. Unless otherwise indicated, data are expressed as number (%) of patients.

Statistics. Comparisons were made by using the Student *t* test for continuous variables and the chi-square or Fisher exact test for categoric variables.

Results

Baseline characteristics of our study patients are listed in Table 1. From 1989 through 1990 there were 389 patients in the prophylactic CPS group and 180 in the standby CPS group. The two groups did not differ with respect to age, gender, number of lesions dilated/patient, or dilation of unprotected left main coronary artery stenoses. More patients in the prophylactic CPS group underwent dilation of the only patent vessel (30.6% vs. 20.6%) but this difference was not significant. The mean left ventricular ejection fraction was significantly lower in the prophylactic CPS group (27.5% vs. 36.7%, $p < 0.01$). Additionally, the prophylactic group contained more patients with an ejection fraction ≤20% (32.4% vs. 17.8%, $p < 0.05$). Thus, the two groups were not entirely comparable with respect to this important baseline characteristic.

The procedural outcome is displayed in Table 2. Procedural success for the two groups was similar, 88.7% for patients in the prophylactic group and 84.4% for those in the standby CPS group (p = NS). Major complications were also similar. The mortality rate was 6.4% for the prophylactic group and 6.1% for the standby group (p = NS). This high mortality rate is consistent with the high risk nature of the patients in this study. Emergency bypass surgery was required in 2.8% of prophylactic versus 2.2% of standby CPS groups (p = NS). There was a major difference in procedural morbidity between the two study groups. Forty-two percent of patients in the prophylactic CPS group sustained femoral complications or required blood transfusions compared with only 11.7% of patients in the standby CPS group ($p < 0.01$). Thus, although procedural success and major complication rates did not differ, overall morbidity was significantly increased in the prophylactic CPS group.

Table 2. Procedural Outcome in Total Patient Group

	Prophylactic CPS (n = 389)	Standby CPS (n = 180)	p Value
Procedural success	345 (88.7)	152 (84.4)	NS
Major complications			
Q wave MI	2 (0.5)	1 (1)	NS
Emergency CABG	11 (2.8)	4 (2.2)	NS
Death	25 (6.4)	11 (6.1)	NS
Morbidity			
Femoral complications or transfusion requirement	163 (41.9)	21 (11.7)	< 0.01

CABG = coronary bypass surgery; MI = myocardial infarction; other abbreviation as in Table 1. Data are expressed as number (%) of patients.

Table 3. Morbidity in Total Patient Group

	Prophylactic CPS (n = 389)	Standby CPS (n = 180)	p Value
Femoral pseudoaneurysm	3	1	NS
Femoral artery occlusion	10	0	NS
Arterial laceration	1	1	NS
Deep venous thrombosis	3	0	NS
Hematoma	21	5	NS
Retroperitoneal bleed	2	2	NS
Femoral infection	5	0	NS
Femoral nerve weakness	3	0	NS
Arteriovenous fistula	1	0	NS
All above femoral complications	49 (12.6)	11 (6.1)	< 0.05
Transfusion	152 (39.1)	20 (11.4)	< 0.01

Data are expressed as number (%) of patients. Abbreviation as in Table 1.

Procedural morbidity is analyzed further in Table 3. Femoral complications such as pseudoaneurysm, femoral artery occlusion, deep venous thrombosis, hematoma, retroperitoneal bleeding, arteriovenous fistula, femoral infection or femoral nerve weakness were all more frequent in the prophylactic than in the standby CPS group. Transfusion requirements were strikingly different between the two groups. Blood transfusions were required in 39.1% of patients in the prophylactic CPS group but in only 11.4% of those in the standby CPS group ($p < 0.01$).

Emergency institution of CPS in patients with standby CPS. Thirteen (7.2%) of the 180 patients in the standby CPS group sustained irreversible hemodynamic compromise during the angioplasty procedure and required emergency institution of CPS. Bypass was successfully initiated in 12 of the 13 patients within 5 min. One patient required 10 min for initiation of bypass and sustained irreversible brain damage, resulting in death. The indications for emergency CPS in standby patients were as follows: abrupt closure of the vessel treated with angioplasty occurred in two patients, catheter dissection of the left main coronary artery in one patient and irreversible hypotension after coronary instrumentation or balloon inflations, or both, occurred in 10 patients.

Registry entry criteria for the 13 patients requiring emer-

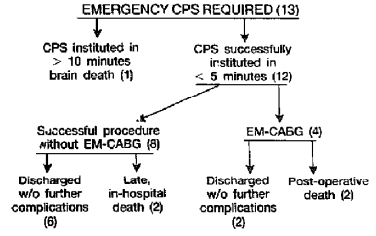

Figure 1. Outcome after emergency institution of cardiopulmonary support (CPS) in patients in the standby CPS group. EM-CABG = emergency coronary artery bypass surgery; w/o = without.

gency institution of CPS were as follows: 7 had >50% of their viable myocardium jeopardized by the target angioplasty vessel, 2 had angioplasty of the only patent vessel; 4 patients had a left ventricular ejection fraction <25%.

The outcome of the 13 patients in the CPS group standby requiring emergency CPS is displayed in Figure 1. One patient requiring 10 min for initiation of CPS died as described earlier. In eight patients the procedure was successfully completed without requiring emergency bypass surgery. Six of these eight patients were discharged from the hospital without further complications and two patients died, one because of abrupt vessel closure 2 days after the procedure and one because of congestive heart failure at 1 week. In four patients in the standby CPS group, emergency bypass surgery was performed after institution of CPS. Two of these four patients had a successful outcome and two died postoperatively.

Hospital mortality. The high procedural mortality in this study underscores the high risk nature of the patients undergoing revascularization. The events surrounding each patient's death are listed in Table 4. There were 36 deaths.

Table 4. Mortality in Total Patient Group

	Prophylactic CPS (n = 389)	Standby CPS (n = 180)
Death during angioplasty	2	1
Death after emergency CABG for failed angioplasty	5	2
Death in the hospital due to late complications after successful angioplasty		
Cardiac arrest	10	4
Congestive heart failure	1	4
Aspiration pneumonia	4	0
Hemorrhage	2	0
Sepsis	1	0

Data are expressed as number of patients. Abbreviations as in Tables 1 and 2.

Table 5. Outcome in the Subgroup of 158 Patients With a Left Ventricular Ejection Fraction ≤20

	Prophylactic CPS (n = 126)	Standby CPS (n = 32)	p Value
Procedural success	112 (90.5)	26 (81.2)	NS
Major complications			
Q wave MI	2 (1.6)	0	NS
Emergency CABG	2 (1.6)	0	NS
Death	6 (4.8)	6 (18.8)	< 0.05
Morbidity			
Femoral complications or transfusion requirement	52 (41.3)	3 (9.4)	< 0.01

Data are expressed as number (%) of patients. Abbreviations as in Tables 1 and 2.

Only 10 (27.8%) of the 36 occurred as an immediate complication of the angioplasty procedure (either death in the catheterization laboratory or death after emergency bypass surgery). The remaining 26 deaths (72.2%) occurred later in the hospitalization after an initially successful angioplasty procedure. Fourteen of these deaths were due to cardiac arrest, probably caused by late closure of the recently dilated vessel. Twelve deaths were due to aspiration pneumonia, hemorrhage, congestive heart failure or sepsis.

Patients with an ejection fraction ≤20%. More patients in the prophylactic CPS group had severely reduced left ventricular function. Therefore, the outcome of patients with a left ventricular ejection fraction ≤20% in the prophylactic and standby CPS groups was compared (Table 5). There were 158 patients in this subgroup, 126 from the prophylactic and 32 from the standby CPS subgroup. Procedural morbidity was significantly higher in the prophylactic CPS group (41% vs. 9.4%, $p < 0.01$), but procedural mortality was higher in the standby group (4.8% vs. 18.8%, $p < 0.05$).

Discussion

Femoral vein to artery cardiopulmonary bypass has been used to provide hemodynamic support in diverse clinical settings. After its initial use in cardiac surgery (10,13,19), this technique has recently been applied outside the operating room to patients undergoing percutaneous aortic valvuloplasty or elective but high risk coronary angioplasty, patients with in-hospital cardiac arrest and patients in cardiogenic shock due to acute myocardial infarction (15,18,22). The technology of CPS differs from that of traditional cardiopulmonary bypass systems in that a centrifugal pump is used to aspirate blood from the central venous pool instead of a gravity-fill system. Systemic flow rates of 4 to 6 liters/min can be obtained by using 18F to 20F cannulas. These large diameter cannulas can be inserted percutaneously by using the sequential dilating technique of Shawl et al. (17,23). In 1988 the National Registry of Elective Cardiopulmonary Support was established to evaluate the initial experience with this technology (20,21). In the first

year of the Registry's experience, 14 centers enrolled 105 high risk angioplasty patients with use of the inclusion criteria described in this study. Although the angioplasty success rate was high (95%), complications were frequent. The in-hospital mortality rate was 7.6% and was particularly high in patients >75 years old with left main coronary artery disease. Overall, 39% of patients experienced complications. Most complications were related to the femoral cannulation site and 43% of patients required blood transfusion.

Present study. With increased experience, Registry members found the time required for percutaneous insertion of cannulas and initiation of cardiopulmonary bypass decreased to <5 min, particularly if femoral access was previously obtained with small diameter sheaths. In light of the complications associated with CPS, it seemed reasonable to place some high risk angioplasty patients on "standby CPS" (24). The level of standby readiness varied among institutions. In general, the physician matched his or her skill at urgently initiating CPS with the level of patient risk. Many patients (52.2%) had instrumentation of the contralateral femoral access site, and some patients (27.8%) had the CPS apparatus primed. Priming the CPS apparatus incurs a cost of approximately $1,000. Therefore, most physicians primed the system only for those patients whose condition was considered most tenuous.

Patient selection for standby CPS versus prophylactic CPS also varied among institutions. Generally, as physician experience with standby CPS increased, more patients were treated with this technique. Patients in the standby and prophylactic CPS groups were similar with respect to most baseline clinical and anatomic factors except that left ventricular function was worse in the prophylactic CPS group (see Study limitations section). This difference reflected the feeling of many operators that the highest risk patients should be placed on CPS prophylactically. Therefore, because of these patient selection differences, standby and prophylactic CPS patients were not at precisely equivalent risk. However, the requirement for emergency institution of CPS in 13 patients (7.2%) in the standby CPS group is evidence that the standby group clearly represented a high risk group.

In this study, standby CPS provided excellent support for most high risk angioplasty patients. Patients in the prophylactic and standby CPS groups had similar success and major complication rates. However, those in the prophylactic CPS group had more femoral access site complications and a very significant increase in blood transfusion requirement (39.1% vs. 11.4%, $p < 0.01$). Therefore, for the study group as a whole, prophylactic initiation of CPS resulted in increased morbidity and no improvement in outcome compared with that of standby CPS.

Review of the study data suggests several explanations for the lack of benefit from prophylactic CPS. 1) The success rate in the standby CPS group was high (84.4%) and similar to that reported in the National Heart, Lung, and Blood Institute and several other large angioplasty series (25–28). Thus, standby CPS is a highly effective technique providing results in high risk angioplasty patients similar to those reported for more routine angioplasty patients. It would be difficult for prophylactic CPS to improve on this high success rate. 2) The results of this study demonstrate that standby CPS can reliably establish immediate hemodynamic support for patients experiencing angioplasty complications. The immediate availability of CPS in the standby group clearly improved the angioplasty success rate and decreased complications. Thirteen of the 180 patients in the standby CPS group had irreversible hemodynamic deterioration during angioplasty. In 12 of the 13 patients, CPS was successfully initiated and 6 of the 12 went on to have a successful procedure without requiring bypass surgery. Of the four patients in the standby CPS group taken to emergency bypass surgery, two survived and two died. Thus, the availability of CPS almost certainly prevented eight deaths in the standby CPS group. Therefore, without CPS the mortality rate in the standby group would probably have been 10.6%, underscoring the effectiveness of the standby technique. 3) Our standby and prophylactic CPS groups had similar outcomes because the majority of deaths occurred after the angioplasty procedure when prophylactic CPS could no longer benefit the patient. Fully 72.2% of the study deaths occurred late in the hospital stay after an initially successful procedure. Most of the deaths were probably due to closure of the angioplasty target vessel; the remaining deaths were due to multiple medical complications. Obviously, prophylactic CPS can provide hemodynamic support only during the procedure and cannot reduce complications occurring outside of the catheterization laboratory.

In a subgroup analysis (Table 5), patients with a left ventricular ejection fraction ≤20% receiving prophylactic CPS had a significantly lower procedural mortality rate than that of patients in the standby group. Thus, this subgroup with extremely depressed left ventricular function appears to be at highest risk. Prophylactic institution of CPS may be indicated in this subgroup.

Requirement for CPS institution in patients in the standby CPS group. Only 13 of the 180 patients in the standby CPS group required emergency institution of cardiopulmonary bypass. This small number precludes rigorous analysis of factors in the standby group predictive of the need for CPS institution. The majority of these patients did not have an ejection fraction <25%. Thus, at present it should be emphasized that the need for CPS institution in patients in the standby group is unpredictable, and all patients meeting our entry criteria should be considered potential candidates for its emergency use. However, only 2.8% of patients in the standby group had prophylactic insertion of an intraaortic balloon pump and only 1 of the 13 patients in the standby group requiring CPS institution had prophylactic balloon pump insertion. In a recent report (29), prophylactic insertion of an intraaortic balloon pump was used successfully as a support mechanism for patients with poor left ventricular function undergoing coronary angioplasty. It is possible that

initiation of CPS would have been required less frequently if more patients in our standby CPS group had been supported prophylactically with an intraaortic balloon pump.

Study limitations. There are several limitations to this study. Patients were not randomized and more patients in the prophylactic than in the standby CPS group had severely depressed left ventricular function. When a subgroup of patients with an ejection fraction ≤20% was compared (Table 5) there was a mortality benefit for patients in the prophylactic CPS group. However, the number of patients in this subgroup was small, possibly resulting in statistical artifact or inadequate baseline comparability of the two groups (30). Additionally, because most deaths in this study occurred well after the angioplasty procedure and, when needed, CPS could be quickly initiated in almost all patients, one cannot conclude that prophylactic initiation of CPS would have reduced mortality in this subgroup.

Very few patients in the standby group in this study underwent prophylactic support with an intraaortic balloon pump. If patients in this group had been routinely supported with the intraaortic balloon pump, the need to institute CPS might have been reduced. In particular, the very high mortality rate for patients in the standby group with an ejection fraction ≤20% might have been favorably influenced by prophylactic balloon pump insertion.

Clinical implications. The most clinically significant finding of this study was that standby CPS provided effective support in the setting of sudden, otherwise irreversible, hemodynamic deterioration in all but one patient in the standby group. The similar success and major complication rates for patients in the prophylactic and standby CPS groups were due to the ability of CPS to stabilize the condition of 12 of the 13 patients in the standby group who required immediate hemodynamic support. Eight of these patients ultimately survived. Without the immediate availability of CPS, these patients would probably have died. The standby technique was superior to the prophylactic technique in the majority of our study group because CPS was directed only to those relatively few patients who definitely required it. Most patients were spared the morbidity of femoral cannulation and cardiopulmonary bypass. In addition, patients in the standby CPS group were usually spared the significant cost (approximately $1,000) of the equipment required for femoral cannulation. This savings, added to savings from reduced morbidity (less transfusion, femoral artery injury, and so forth) underscores important economic advantages of standby CPS.

As the CPS procedure evolves, morbidity, particularly blood transfusion requirements, will likely decrease. However, no benefit was derived from prophylactic CPS in our patients with an ejection fraction >20%. Even if morbidity rates were as low as those of standby CPS, the increase in procedure time, patient discomfort and expense would prohibit use of prophylactic CPS unless a clear benefit is demonstrated.

A subgroup of patients with an ejection fraction ≤20% demonstrated improved survival with prophylactic CPS. Thus, this technique may be indicated in patients with extreme left ventricular dysfunction. This subgroup warrants further study, ideally a randomized trial using intraaortic balloon support for patients in the standby CPS arm.

Initiation of CPS is a relatively complex procedure requiring specific technical skills and a high degree of coordination among physicians, nurses, cardiovascular technologists and perfusionists in the catheterization laboratory. To urgently initiate CPS in a patient in the standby CPS group, it is essential that the patient be well prepared (preferably the contralateral femoral vessels instrumented and the iliofemoral anatomy defined) and the catheterization laboratory team well practiced in the technique. Before a cardiac center uses standby CPS, experience with prophylactic CPS is mandatory. Furthermore, the catheterization laboratory policy and procedures must require periodic dry run-throughs to maintain proficiency.

Finally, the high frequency of late mortality in this study deserves special emphasis. Most deaths (72.2%) occurred outside of the catheterization laboratory when CPS was not immediately available. Mortality was due either to closure of an angioplasty target vessel or associated medical problems. This finding underscores the fact that patients requiring prophylactic or standby CPS are often relatively ill and tolerate late complications poorly. Vigilant and meticulous medical care is essential after the angioplasty procedure. Furthermore, the overall high mortality rate in this study underscores the importance of case selection. The relative risks and benefits of coronary bypass surgery versus angioplasty using either CPS or standby CPS must be carefully considered.

Conclusions. In this study, standby CPS provided excellent support for patients undergoing high risk angioplasty procedures. The CPS was urgently required in 7.2% of standby patients. When needed, standby CPS reliably established immediate hemodynamic support in almost all patients. Patients in the standby and prophylactic CPS groups had comparable success and major complication rates but procedural morbidity was more frequent in patients in the prophylactic CPS group. For most patients studied here, standby CPS was preferable to prophylactic CPS during high risk coronary angioplasty. However, patients with extremely depressed left ventricular function (ejection fraction <20%) may benefit from institution of prophylactic CPS.

Appendix

National Registry of Elective Cardiopulmonary Support

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