High–Risk Coronary Intervention in Severe Left Ventricular Dysfunction

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Severe coronary artery disease in patients with markedly depressed left ventricular function is associated with a poor prognosis. Coronary artery bypass graft surgery has been the mainstay of treatment in such patients in the past but is associated with significant morbidity and mortality. Coronary angioplasty has been offered as an alternative to coronary artery bypass surgery in these patients. The results of PTCA in patients with left ventricular ejection fraction between 35-40% have been reported and show a procedural success of >80% and a mortality of 2.7-5%. These reports also suggest that coronary angioplasty is usually well tolerated in patients with moderately depressed ejection fraction but coronary occlusion caused by balloon inflation or abrupt closure in such patients may result in hemodynamic collapse. Additionally, these patients may not survive the delay required to institute emergency bypass surgery.

Percutaneous cardiopulmonary bypass support (CPS) provides complete systemic hemodynamic support independent of intrinsic cardiac function and has been employed prophylactically in high–risk patients prior to angioplasty or emergently following abrupt closure with hemodynamic collapse or cardiac arrest. A recent report by the National Registry of Elective Supported Angioplasty indicated patients with a left ventricular ejection fraction of 20% or lower had significantly less hospital mortality when prophylactic support was employed compared with standby support. Complications are mostly related to the cannula insertion site and can be minimized by use of current techniques. The discussion that follows details my experience with the technique, the basic principles and management of patients during percutaneously established CPS in patients with poor left ventricular function undergoing coronary intervention. Emergency institution of CPS also remains an option for patients who are in cardiogenic shock or who have sustained cardiac arrest and do not respond promptly to advanced life support techniques.

Technique of Elective Percutaneous Cardiopulmonary Bypass Support. Patients are prepped and draped in the catheterization laboratory in the usual sterile manner, exposing both groins. All items necessary for the percutaneous cannula insertion are available in a compact percutaneous insertion kit (C.R. Bard, Inc. Billerica, MA). Using the Seldinger technique, a 7F pigtail catheter is introduced into the right femoral artery in order to perform iliofemoral angiography, initially visualizing the left side and then if necessary, the right side.

If the left iliofemoral system reveals acceptable anatomy for the insertion of a bypass cannula, the pigtail catheter is exchanged over a standard...
0.038 inch guidewire with a standard 8F angioplasty sheath which is introduced in the right femoral artery. Access to the left femoral artery and vein is obtained using a standard single wall needle and 7F sheaths are left in place. Care is taken to ensure that the actual arterial puncture site is below the inguinal ligament in order to facilitate subsequent external clamp placement for hemostasis. Patients are then heparinized with 225 units of heparin (as a single bolus) per kg body weight to obtain an activated clotting time of 400 sec or greater which is checked after 10 or 15 minutes. The 7F arterial sheath is removed over a 0.038 inch flexible guidewire and an 8F dilator is introduced. The 0.038 inch flexible guidewire is removed and replaced with the stiff 0.038 inch guidewire with a flexible tip. Holding the stiff guidewire in place, the long 8F dilator is removed and the vessel is then dilated with a 12 and then a 14F dilator. The 14F dilator is removed and an 18F bypass cannula is advanced over the stiff guidewire using a rotary motion, taking care to advance both dilator and cannulae assembly as a single unit so that the cannula does not buckle. After the introduction of 18F arterial cannula, the guidewire and the dilator are removed and the tube is closed quickly using the available Robert’s Clamp. Employing a similar approach, an 18F multihole venous cannula is advanced until the tip is positioned just above the junction of the inferior vena cava and right atrium.

Iliofemoral angiography is not performed in patients who present with cardiac arrest. Bypass cannulae are placed in these patients either by using previous arterial and venous access sites or by obtaining de novo access from the right femoral approach. After the patient has been connected to the cardiopulmonary bypass support system, the contralateral femoral vessel may then be cannulated to perform angiography or intervention, if indicated. In patients with cardiogenic shock, particularly those with severe hemodynamic compromise despite intra-aortic balloon pump support, diagnostic angiography is performed after bypass support is initiated.

Approximately 4 minutes are required to cannulate a patient for CPS using this technique once venous and arterial access have been obtained. While cannulation is being performed a perfusionist primes the disposable perfusion circuit.

**Portable Cardiopulmonary Bypass Support System.** The cardiopulmonary bypass support system (CPS™, C.R. Bard, Inc.) is a battery operated portable system on a hospital cart with a disposable CPS circuit that includes a centrifugal, non-occlusive pump, propylene hollow fiber membrane oxygenator, clamps, connectors, and a heat-exchanger. The perfusion circuit is primed by a perfusionist using 1300 cc of Normosol. It takes less than 10 minutes to set up and prime this system.

**Initiation of Cardiopulmonary Bypass Support.** Baseline hemodynamic measurements, which include arterial, pulmonary artery, and pulmonary capillary wedge pressures are obtained prior to the insertion of bypass cannulae. The patients are kept well hydrated before the initiation of cardiopulmonary bypass support.

During elective supported angioplasty, CPS is started using a flow rate of 2 L/minute with increments of 0.5 L/minute if the pulmonary artery diastolic pressure is > 5 mm Hg or > 50% of the baseline, or chest pain or electrocardiographic changes occur with an increase in the filling pressures after less than 2 minutes, of balloon inflation.

Significant hypotension, defined as a mean pressure of < 60 mm Hg (a lower blood pressure can be tolerated if the patient is awake and
responding to verbal commands), can be corrected in most cases by volume infusion through the pump. In certain circumstances, particularly if the systemic vascular resistance is low, Neosynephrine infusion may be necessary. In patients in cardiogenic shock or cardiac arrest, an estimate of blood flow requirements can be calculated from the patient’s body surface area or body weight (2.2-2.4 liter/m2 or 50-60ml/kg of body weight). Activated clotting time is measured every 15 minutes and is maintained at or about 400 seconds. Arterial blood gas and mixed venous oxygen saturations are determined periodically in all patients.

Patients with cardiac arrest who are in ventricular fibrillation are defibrillated. Patients who are initially asystolic usually return to sinus or junctional rhythm within a few minutes after the institution of bypass flow, and pacemaker insertion rarely is necessary.

Patients who need emergency coronary bypass graft surgery are transported to the operating room on CPS. While the patient is still on CPS, no venous entry should be attempted in order to avoid air embolism. When the surgeon is ready to establish standard bypass support (right atrium to aorta), CPS is interrupted before atrial cannulation to avoid air embolism. The femoral bypass cannulae are removed by the surgeon, and the femoral artery and vein are repaired under direct vision.

**Termination of Cardiopulmonary Bypass Support.** After the completion of coronary intervention, CPS is gradually weaned over a period of 5-30 minutes and cannulae are clamped. During weaning of bypass support, bypass flow is reduced by about 0.5 L/min. Volume is infused as necessary to increase the left ventricle filling pressure estimated by the pulmonary capillary wedge pressure or pulmonary diastolic pressure to at least 8-10 mm Hg or to pre–bypass level whichever is less. In some patients, particularly those with severe left ventricular dysfunction or recent myocardial infarction, inotropic agents (dopamine and dobutrex) may be necessary in order to wean the patient from bypass. Intra-aortic balloon pump may be necessary, which is placed via the contralateral femoral artery. The patient is then transported to the coronary care unit on a stretcher. Weaning and subsequent termination of CPS can be done in the coronary care unit if the patient is not weaned in the catheterization laboratory within about 30 minutes, which happens very rarely in elective cases. A Cell Saver is used to autotransfuse the blood remaining in the bypass perfusion circuit. After autotransfusion is completed, the activated clotting time is checked in the coronary care unit.

In patients with cardiogenic shock or cardiac arrest, who have undergone coronary intervention, termination of bypass support is similar to that in the elective group. In this group of patients, however, weaning may take longer than in the elective group.

**Removal of Bypass Cannulae.** Bypass cannulae are removed when the activated clotting time falls below 200 sec. It takes 4-8 hours after the last dose of heparin to achieve this level of activating clotting time. After the cannulae are removed, manual compression for hemostasis is performed for 15-20 minutes. Then mechanical clamp compression system is applied using a new modified disc (Comfort Disc, Instromedix, Hillsboro OR) along with the locked compression clamp (Compressor, Instromedix, Hillsboro OR). Clamp pressure compression is adjusted so that the pedal pulses remain palpable or so that there is good capillary filling. Gradual clamp release 2 mm every 20 minutes is started after 90 minutes of compression if no bleeding is encountered.

Low dose heparin 600-800 units/hour infusion is started after the partial thromboplastin time declines to < 70 seconds or the activating clotting time declines to < 180 seconds and is continued until the patient is fully ambulatory.

**Prophylactic versus Standby by CPS.** In contrast to prophylactic use of CPS which is defined as the implementation of bypass support prior to coronary angioplasty, standby–supported angioplasty refers to a planned situation in which both CPS equipment and personnel are available in the cardiac catheterization laboratory should hemodynamic collapse develop. In fact, even most high–risk PTCA's can be performed safely as long as cardiopulmonary bypass support is immediately available, without advance placement of cannulae or initiation of bypass.

Standby support has been increasingly provided for high–risk patients.10 It requires the same teamwork, perfusion expertise, and bypass system availability but avoids the risk and expense of prophylactic support. If hemodynamic instability or vessel closure occurs, cannula placement and initiation of cardiopulmonary bypass can be accomplished in less than 10 min in at least 90% of instances. Catheterization laboratories performing standby–supported angioplasty have found that only 5 to 10% of standby patients actu-
ally require initiation of circulatory support, although it is very difficult to predict which patients will require it. Emergency initiation of unplanned cardiopulmonary bypass support following unexpected, protracted circulatory collapse or cardiac arrest has been employed in centers with technical expertise.

Clinical Experience

High–Risk PTCA. The 25–center experience in performing elective supported angioplasty has been collected in a national registry since March of 1988.7 Through March 1992, data on 801 procedures are available. Patients were selected for prophylactic or standby support if they had severe or unstable angina, had a dilatable lesion in a target vessel supplying more than one half of the residual viable myocardium, or a left ventricular ejection fraction of less than 25%. Of the 801 patients, 85% had either class III or class IV angina. Multivessel disease was present in 90%, left main coronary artery disease was present in 25%, and dilatation of the only patent coronary vessel, including bypass graft, was noted in 21%. Twenty–one percent of the patients were deemed inoperable. The mean left ventricular ejection fraction was 30%, with 28% of the patients having an ejection fraction of 20% or less. Prophylactic and standby support were undertaken in 72% and 28% of patients, respectively. The clinical characteristics of these two groups of patients were similar except for a higher ejection fraction for the patients undergoing standby support (32.8% versus 28.4%, p < 0.01). Angioplasty was performed in 1.9 vessels per patient with a primary success rate of 93%. Acute myocardial infarction occurred in 0.8% emergency bypass surgery was required in 2.6%, and the hospital mortality for the entire group was 6.9%. Only the presence of age greater than 70 years and left main coronary artery disease were associated with increased mortality. Interestingly, patients with ejection fractions of less than 20%, patients considered inoperable and those undergoing dilatation of their only patent vessel did not experience significantly higher mortality than the group mean. Hospital mortality was least for percutaneous cannulation/prophylactic support and standby support, but was higher for cutdown cannulation prophylactic support.

Of 217 patients scheduled for standby support, however, only 16 (7.4%) required emergency initiation of bypass. In 15 patients, bypass support was initiated successfully in less than 5 min. Twelve of the 16 (75%) requiring circulatory support underwent successful angioplasty without the need of bypass surgery. Of these, 7 survived long–term. Four patients required emergency bypass surgery following initiation of emergency circulatory support of whom 2 survived long–term. These findings suggest that standby support reduces the need for emergency bypass surgery by about two–thirds and reduces the mortality of high–risk angioplasty by about one–half. Despite a significantly higher rate of vascular complications in the prophylactic CPS (12.6% versus 6.1% in the standby group p < 0.05), in patients with ejection fraction of less than or equal to 20% procedural mortality was reduced compared to the standby group (4.8% versus 18.8% p < 0.05). These data suggest that patients with extremely depressed left ventricular function (ejection fraction less than or equal to 20%) may still benefit from prophylactic CPS.

Shawl13 reported 103 consecutive patients with left ventricular ejection fraction less than or equal to 25% who underwent CPS supported angioplasty between 1988 and 1991. Fifty–seven percent of patients were in functional class IV, and 43% were in class III; 70% had unstable angina; 46% were declared inoperable. Seventeen percent had previous coronary artery bypass graft surgery, and 55% had only one remaining patent vessel, including 7 with only one bypass graft patent. Mean left ventricular ejection fraction was 19.5% ± 3.5% (range 11 to 25%). A total of 224 lesions in 195 vessels were attempted with procedural success in 97 (94%). Mean bypass time was 47 ± 20 minutes (range 13 to 120 minutes). Six patients died prior to discharge. Survival at 36 months was 61% and the majority of those patients (97%) showed clinical and functional improvement. The post–procedure ejection fraction increased to 29% (p < 0.05). In the multicenter registry, including 527 prophylactic and standby support patients, 90% had class II angina during follow–up, and the ejection fraction had risen from 27.3% to 35.7% (p < 0.05). The survival including in–hospital mortality at 1, 2, and 3 years was 82%, and 77%, respectively.

In another series, Shawl14 reported 30 patients who underwent CPS–supported intervention for treatment of their unprotected left main coronary artery disease. All these patients were deemed inoperable due to low ejection fraction and/or systemic noncardiac disease. A total of 61 vessels were dilated with a success rate 97%. Overall survival was 80% at a mean follow–up of 19 ± 11 months, and the mean ejection fraction...
rose from 25 ± 12% pre-PTCA to 42 ± 12% post-procedure (p < 0.05).

Emergency CPS in Severe Cardiogenic Shock or Cardiac Arrest. Overlie and coworkers have collected the National Registry experience of the last 7 years, which now totals 210 patients. The most frequent clinical situation requiring emergency support has been PTCA complicated by vessel closure, acute myocardial infarction associated with cardiogenic shock, and post-cardiac surgery hemodynamic collapse. Shawl and coworkers reported a series of eight patients suffering acute myocardial infarction complicated by cardiogenic shock. Emergency CPS was instituted between 30 and 180 min after onset of shock with mean flow rates of 3.2 to 5.2 liters per minute. Seven of the eight patients who underwent successful coronary angioplasty of 15 of 16 attempted lesions survived. All seven patients were alive at a mean follow-up of 8.2 months.

Coronary angioplasty of only the infarct-related vessel in patients with multivessel disease in cardiogenic shock has been associated with a poor prognosis. Eleven consecutive patients with multivessel coronary artery disease in acute myocardial infarction had CPS instituted at 32 to 240 min after the onset of cardiogenic shock. Eight had prior myocardial infarctions, four were on intra-aortic balloon pump, and four had recent cardiac arrest. Ejection fraction ranged from 11 to 40% (mean 24.3%), and TIMI flow was diminished to grade I or grade II in 12 of the 17 non-infarct-related vessels. Coronary angioplasty, was attempted in 28 vessels (2.5 vessels per patient), with angiographic success in 27. All infarct-related vessels were successfully dilated. Four patients died post-coronary angioplasty, two due to acute closure of the infarct-related vessel, one due to cerebral vascular accident, and one from sepsis. Seven patients were alive at a mean follow-up of 24 ± 6 months, with ejection fraction increased to 38 ± 5% (p < 0.05). These data suggest that CPS can stabilize patients in cardiogenic shock and facilitate multivessel coronary angioplasty which may result in improved survival.

CPS is currently the only practical circulatory support system for the cardiac catheterization laboratory that can provide complete hemodynamic support in the absence of an intrinsic cardiac rhythm. The key to improved survival is the early initiation of cardiopulmonary bypass support. In the report from the National Registry experience of 173 patients in whom emergency cardiopulmonary bypass support was initiated in less than 20 min, 38% survived long-term, compared to an 18% long-term survival of patients in whom support was initiated greater than 20 min after hemodynamic collapse.

In another series, Shawl and coworkers reported on 43 patients in cardiac arrest who had emergency institution of CPS in the catheterization laboratory. Patients were divided into three groups: Group I (n = 11) had CPS initiated in less than 10 minutes; Group II (n = 19) had CPS initiated within 25 min of cardiopulmonary arrest; and Group III (n = 13) had CPS initiated after 25 minutes of cardiopulmonary arrest. The survival in Group I was 100%, 60% in Group II and only 4% in Group III. These data suggest that early institution of CPS is the most important factor determining survival. These data certainly suggest that CPS should be available in a busy catheterization laboratory. It is of interest that two of group I patients who were stabilized with CPS had suffered severe hemodynamic collapse secondary to contrast media induced anaphylactic shock.

Complications. The most common complications of CPS occur at the cannula insertion site. These complications usually arise after removal of the bypass cannulae. In the initial series, bypass cannulae were removed in the catheterization laboratory after the patient was hemodynamically stabilized. Because patients had received a large bolus of heparin before the initiation of CPS, a large amount of circulating heparin remained at the time of cannula removal. In this anticoagulated state, the patients in this series were decannulated early and required long clamp compression to achieve hemostasis. Because of this prolonged clamping, more blood transfusions were needed and frequent local complications occurred.

The rate of local complications in the elective series has been reduced to less than 2% (Figure 2) with the current cannula removal technique that entails lower circulating heparin levels at the time of cannula removal.12 Thus, rapid hemostasis (less than 3 hours) can occur, and external clamp compression time is shortened. Also the need for blood transfusion has been reduced to less than 4% in the elective series using a cell saver to isolate and reinfuse red cell volume from the bypass circuit. The current technique of cannula removal also allows reinstitution of cardiopulmonary bypass in the coronary care unit in the event of hemodynamic compromise due to abrupt closure. The National Registry data reported by Vogel and colleagues also found a lower complication rate in
the prophylactic CPS group with cannulation by percutaneous technique rather than by surgical cutdown.

**Limitations.** The primary limitations of CPS are that (a) the iliofemoral anatomy of some patients is unsuitable for cannulation and (b) support with the device is limited to about 8 hours. In addition, CPS does not eliminate ischemia distal to an occlusion. For this reason abrupt coronary closure not quickly correctable in the catheterization laboratory should be treated surgically. Finally, ventricular unloading in patients with prolonged cardiac arrest or severe ischemia may not be complete with CPS alone. In such cases left ventricular venting may be necessary.

**Conclusions.** A safe and easily applied technique of CPS has been developed for use in the cardiac catheterization laboratory. This technique maintains hemodynamic stability during high-risk interventional procedures regardless of heart function. The ease of initiation by sequential vascular dilatation and placement of venous and arterial cannulae permits rapid initiation of bypass flow rates up to 5 liters per minute. This technique can be applied to support patients with cardiac arrest, those with hemodynamic collapse following abrupt closure during catheter intervention, and those with cardiogenic shock, as well as those undergoing high-risk elective angioplasty.

Femoro–femoral cardiopulmonary bypass support instituted percutaneously in the catheterization laboratory makes interventional procedures feasible in patients who previously were not candidates. CPS reduces the need for operator haste and allows achievement of an optimal result. This form of support also permits transport of patients to the operating room in a stable condition following failed angioplasty. Complications are related for the most part to cannula removal and can be minimized by use of the described techniques. Although the ultimate role of CPS remains to be defined, I believe this technique makes a significant contribution to the interventionalist’s armamentarium and extends the availability of PTCA to the very high–risk patient.

**References**

11. Shawl FA, Domanski MJ, Wish MH, Davis M.


