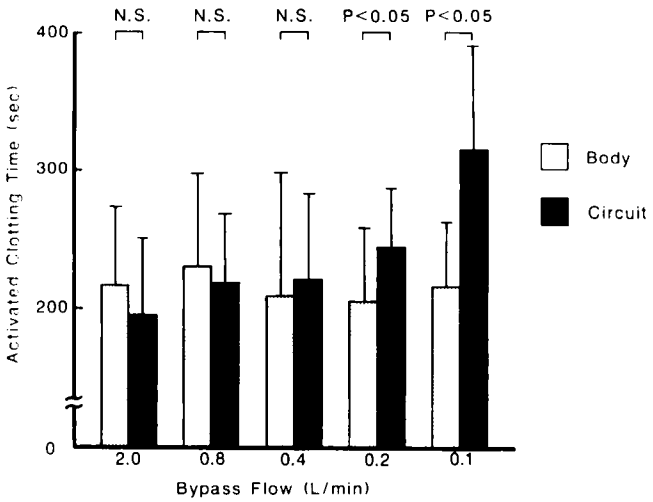

Figure 4. Comparison of ACT values from the systemic circulation, and those from the ECMO circuit at various bypass flow rates. The former values were stable regardless of bypass flow, whereas the later were prolonged with the decrease in flow.

cuit, whereas the blood from the ECMO circuit had almost equivalent ACTs at high bypass flows, but increased ACTs at low flows. Consequently, anticoagulation was enhanced within the circuit relative to the increase in FUT-175 concentration in the circuit with decrease of bypass flow. Given that one of the major problems in conventional ECMO management is the control of coagulation with two reciprocal risks, i.e., a bleeding tendency versus thromboembolism, this method of anticoagulation may provide a great advantage.

Slight to mild pulmonary infarction was found in three animals at autopsy, and was suspected to have originated from thrombus in the oxygenator. Because every clot in the oxygenator was formed at areas of stagnation, it suggests that further sophistication is necessary, from a hydrodynamic point of view, to overcome a hedge of thrombus formation, as well as to provide improved blood compatibility of the material surface.

Conclusions

Use of an RVAD and a newly developed compact oxygenator demonstrated several advantages as an ECMO system, and the proposed method of regional anticoagulation with FUT-175 offered great safety during ECMO. We conclude that our ECMO method may prove useful for long-term respiratory assistance.

Acknowledgments

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ECMO Assisted Angioplasty for Cardiomyopathy Patients with Unstable Angina

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Patients who are otherwise unsuitable candidates for coronary bypass surgery or standard coronary angioplasty (PTCA) may be successfully treated with PTCA during ECMO. Five patients (3 men, 2 women), with a mean age of 57 years, are reported on here. They were not considered good candidates for standard therapy because of poor left ventricular function (mean EF, 24; range, 16 to 28%). Patients were supported by percutaneous femoral bypass using a BARD CPS machine, and underwent successful PTCA of either two vessels (three patients) or three vessels (two patients); in addition, one patient had dilatation of a stenotic aortic valve. Patients were supported with ECMO for 26 to 140 (mean 104) minutes, and required transfusion with 0 to 4 (mean 2) units of blood during or after the procedure. Complications included groin hematoma in two

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patients. All were discharged within 4 days of the procedure. Follow-up of the patients has been completed (4–7 mo) with no further hospitalizations for unstable angina. All patients remain in NYHA Class II or III. These data suggest that ECMO-assisted angioplasty is a safe and effective method of palliation of unstable angina associated with cardiomyopathy. *ASAIO Transactions* 1990; 36: M483–M485.

Advances in percutaneous coronary angioplasty (PTCA) have allowed the application of this technique in patients at high risk secondary to complex coronary artery lesions and ventricular dysfunction.[1,2] Several reports have illustrated the effectiveness of percutaneous coronary angioplasty in high risk patients by providing hemodynamic support with femoral-femoral partial bypass (ECMO).[1–3] This study examined a subset of patients with cardiomyopathy and unstable angina who underwent either isolated coronary angioplasty or coronary angioplasty combined with valvuloplasty using ECMO assistance (CPS).

Materials and Methods

The ECMO system consists of the BARD H-4300 Cardiopulmonary Support System (CPS). The perfusion circuit is a compact, preassembled cardiopulmonary bypass system with a non-occlusive blood pump (BioMedicus 540, Irvine, CA), heat exchanger, oxygenator, and interconnecting tubing. This circuit also includes arterial and venous blood sampling ports, recirculation loop, rapid infusion mechanism, and tubing clamps that facilitate and expedite institution of cardiopulmonary bypass. Set-up and priming can be accomplished within minutes. The prime consists of 1,500 ccs of plasmalite A (Travenol Labs, Inc., Deerfield, IL) and 5,000 units of heparin. Arterial and venous access is obtained percutaneously, using the Seldinger technique and standardized cannulae developed specifically for this system (C. R. Bard Company, Inc., Billerica, MA). Cannulation can be rapidly achieved, provided abdominal arteriograms are performed to assess the suitability of the femoral and iliac vessels before cannulation. Heparin is infused at 300 units per Kg and adjusted to an activating clotting time (ACT) between 400 and 500 sec. Prophylactic antibiotics in the form of 1.5 grams of Cephuroxime, are administered before instituting bypass.

The patient population consisted of three men and two women with a mean age of 57 years, and left ventricular ejection fractions ranging from 16 to 28% (mean 24%). These patients were selected for ECMO support during PTCA because of their poor left ventricular function and associated unstable angina **(Table 1).** Bypass times in this group ranged from 26 to 140 minutes, with a mean of 104 minutes at a mean flow of 2.7 liters per minute **(Table 2).**

Table 1. Patient Characteristics

Patient Number	Gender	Age	Ejection Fraction (%)	Cardiac Function
1	M	48	23	Ischemic cardiomyopathy and poor LV function
2	M	41	25	Ischemic cardiomyopathy and poor LV function
3	F	52	16	Ischemic cardiomyopathy and poor LV function
4	M	52	28	Ischemic cardiomyopathy and poor LV function
5	M	91	28	Aortic stenosis with unstable angina and poor LV function
Mean		57	24	

Table 2. ECMO Data

Patient Number	Cannulation	Bypass Time (min)	Flow (H/min)	Transfusions
1	Percutaneous	116	2.0–3.0	2 units PRBC
2	Percutaneous	26	2.0–3.0	—
3	Percutaneous	120	2.0–3.5	2 units PRBC
4	Percutaneous	119	2.0–4.0	4 units PRBC
5	Percutaneous	140	2.0–3.0	2 units PRBC
Mean		104	2.7	2

PRBC = packed red blood cells.

Results

All patients had one or more coronary vessels with >50% luminal stenosis **(Table 3),** and one patient had severe aortic stenosis with a gradient of 125 mmHg, in addition to three-vessel coronary artery disease. All five patients were supported with ECMO, remained hemodynamically stable during balloon inflation, and were weaned from cardiopulmonary bypass without the aid of inotropic support. In this group, there were no episodes of chest pain during angioplasty with ECMO, and no alterations in hemodynamic sta-

Table 3. Angioplasty Data

Patient Number	Vessels Dilated	Stenosis Predilation and Postdilation	Maximum Inflation Time (sec)
1	CIRC	95/30	100
	PDA	80/30	60
2	RCA	60/30	90
	CIRC	95/30	60
3	Distal CIRC	100/NA	NA
	LAD	95/10	110
	OM	80/10	90
	RCA	80/10	90
4	OM	80/30	60
	CIRC	80/20	60
5	LAD	80/20	105
	CIRC	80/20	60
	RCA	70/20	60
	Aortic valve	125 mmHg/125 mmHg	—

RCA = right coronary artery; OM = obtuse marginal; LAD = left anterior descending; CIRC = circumflex coronary artery.

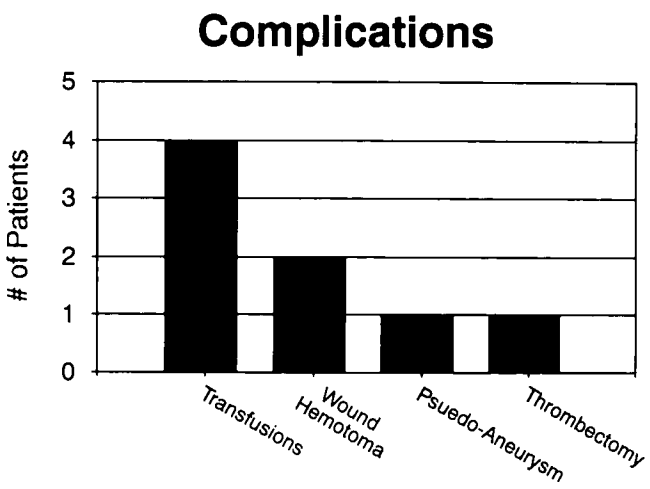

Figure 1. Complications found with use of CPS system.

bility. Postoperatively, all patients remained hemodynamically stable throughout the first 24 hour period. Perioperative complications included the need for blood transfusions, with a mean of two units packed red blood cells transfused per patient **(Table 3).** The most consistent and serious complication associated with this technique was encountered at the cannulation site **(Figure 1).** Two patients developed significant wound hematomas, despite the application of the pressure clamp. One patient developed a pseudoaneurysm that required open repair, and one patient developed distal lower extremity ischemia that required thrombectomy. One additional patient had the cannulae removed surgically as the primary procedure.

All patients were discharged from the hospital after a mean stay of 4 days. Follow-up from 6 to 10 months was available, with no further hospitalization of these patients for unstable angina. All patients remain in New York Heart Association Class II or III.

Discussion

Our initial experience with ECMO assisted PTCA supports the belief that partial bypass decreases the risks during PTCA in patients with severe left ventricular dysfunction. The reduction of physiologic work provided by ECMO allows for complex PTCA, as well as mixed procedures in patients whose conditions would otherwise prohibit intervention. The complications associated with ECMO assisted PTCA are principally bleeding and vascular complications at the cannulation site. Although nonsurgical removal of the cannulae is desirable, our experience suggests that this technique is associated with significant bleeding and hematoma formation, and may be avoided, as we found no increased risk with surgical removal using local anesthetic agents.

Use of the BARD CPS system as an extracorporeal membrane oxygenation system during PTCA offers a unique method for safe intervention in a subset of patients that is at high risk from unstable angina and cardiomyopathy. This modality may also be effective for patients who are cardiac transplant candidates awaiting a suitable donor. Because these patients are at risk for sudden death from arrythmia or myocardial infarction, prophylactic PTCA, using ECMO for cardiopulmonary support, may be an effective "bridge" to cardiac transplantation. Application of this technique may reduce the cost of medical care and the increased morbidity associated with prolonged pretransplant hospitalization.

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