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Supported Complex and High Risk Coronary Angioplasty

edited by
Fayaz A. Shawl

**SUPPORTED COMPLEX AND HIGH RISK
CORONARY ANGIOPLASTY**

INTERVENTIONAL CARDIOLOGY

AMAR S. KAPOOR, SERIES EDITOR

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SUPPORTED COMPLEX AND HIGH RISK CORONARY ANGIOPLASTY

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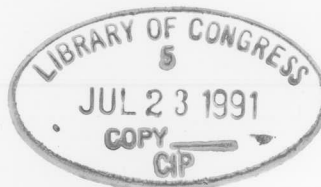
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DEDICATION

I would like to dedicate this book to the memory of my late father,
Mohammad Saleem Shawl.

Contributing authors

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Foreword

Preface

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1. Identification of the High-Risk Angioplasty Patient

STANLEY L. HALL

2. Myocardial Protection

DANIEL W. HALL

SECTION II

1. Extracorporeal Circulation Support: A Historical and Current Perspective

L. KENNETH HARRIS

2. Basic Principles of Cardiopulmonary Bypass

DAVID A. HARRIS

Electrocardiographic and Hemodynamic Changes During Perfusion
Cardiopulmonary Bypass Support

DAVID A. HARRIS, JR., DARRYL A. WATSON, JR.

Perfusionless Cardiopulmonary Bypass Support: Techniques, Indications,
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Fayaz A. Shawl, M.D.

FOREWORD

Interventional cardiology is a creative, innovative, and rapidly advancing frontier of cardiology. There has been mind-boggling proliferation of technology in this field, the use of which requires extraordinary skills and know-how. In order to keep pace with the innovative genius of interventional cardiologists, it is indeed desirable to have specialty issues updating us on technology-orientated therapeutic procedures.

Contemporary interventional cardiology care is a highly specialized art, dependent on critical decision making, selection of the most appropriate interventional procedure, and the operator possessing extraordinary skills and compassion.

This first volume of the new series, *Supported Complex and High Risk Coronary Angioplasty*, attests to the preceding statement. Dr. Fayaz Shawl has mastered the procedure and has been very thoughtful and innovative in the clinical application of the percutaneous cardiopulmonary bypass support technique. This book provides to an interventionist the basic principles of cardiopulmonary bypass, identification of the high risk coronary angioplasty patient, and other alternate support devices for myocardial protection. Dr. Shawl and his team of talented contributors are to be complimented for providing us with this impressive volume on high technology.

There will be ongoing specialty issues in this series highlighting the developments, complications, and advances in interventional cardiology.

PREFACE

The practice of cardiology has changed dramatically since the introduction of percutaneous transluminal coronary angioplasty. The indications for coronary angioplasty are evolving from the classical single-vessel proximal, concentric, noncalcified subtotal obstruction to the very high risk patients, including those deemed inoperable. The evolving changes reflect the expanding horizons in the technology-oriented therapeutic alternatives and the blossoming of innovative, sophisticated technologies. Catheter-based interventional cardiology has gained widespread acceptance and its applications in a significant number of patients attests to its safety and feasibility. It appears the balloon and the wire can tackle any anatomic lesions or location, but can cause hemodynamic collapse if coronary angioplasty is performed in high risk patients. Such patients generally have severely depressed left ventricular function and/or only one remaining patent vessel or a target vessel that supplies greater than one half of the remaining viable myocardium. In such cases, an abrupt closure may spell hemodynamic crisis with imminent death.

To make the procedure safe and feasible, and to reduce the prohibitive risk of the procedure, an innovative technology has emerged from the operating room. This is the development of percutaneous cardiopulmonary bypass support (PCPS), which can circumvent the potential problems of the high risk procedure, provide hemodynamic support, and facilitate emergency coronary angioplasty, even in the most high risk patients. In addition, early institution of PCPS can stabilize patients who suffer cardiac arrest in the catheterization

laboratory, as well as facilitate coronary angioplasty or transfer to the operating room for coronary bypass graft surgery.

This is a specialized procedure and hence this book is intended to provide detailed information on all aspects of the procedure and potential procedure-related risks and complications. I must caution that decisions about the selection of complex cases and the strategy for the complete procedure should be made in concert with the referring physician, cardiac surgical team, and interventional team. Analysis of many complex factors must be taken into account before embarking on this path of salvaging myocardium and life.

The complete procedure, which includes insertion and operation of PCPS, performance of coronary angioplasty, and termination of bypass, is indeed a complex and multifaceted technique. Extraordinary skills and well-thought-out management strategy will enhance the success and safety of the procedure. The basic principles of cardiopulmonary bypass physiology will be discussed, and an approach to supported angioplasty in high risk patients will be developed. The results of cardiopulmonary bypass supported interventions will be discussed.

This book also attempts to describe the most up-to-date technology of various other support devices, which may be beneficial in supporting certain subgroups of patients undergoing high risk coronary intervention. Present prospects and future developments will be explored with an innovative bend.

Fayaz A. Shawl
Editor

14. CLINICAL EXPERIENCE WITH THE HEMOPUMP LEFT VENTRICULAR ASSIST DEVICE

RICHARD K. WAMPLER AND RAYMOND A. RIEHLE

INTRODUCTION

An estimated 150,000 cases of cardiogenic shock occur each year in the United States. In spite of conventional therapy, which includes emergency revascularization, pharmacologic therapy, and intraaortic balloon pump counterpulsation, the reported mortality for cardiogenic shock is 80–90% [1–3]. The limited use of left ventricular assist devices (LVADs) in cases of cardiogenic shock has shown a significant potential to decrease mortality [4–11], however, the necessity for a major surgical procedure has confined the use of LVADs to postcardiotomy patients.

The goal of temporary mechanical circulatory assistance in the treatment of cardiogenic shock is to reduce the work of noncontractile but viable or “stunned” myocardium until ventricular contractility returns [12–15]. Temporary assist devices include a variety of experimental left ventricular assist devices (LVADs) [4,5,9,10,16–20], which are primarily adaptable to use in surgical patients, and the commercially available intraaortic balloon pump (IABP).

In the United States the IABP is widely used because it is readily available, easily implemented, and its use is associated with a relatively low risk. It is effective when treating mild to moderate cardiogenic shock. However, since it can only increase the cardiac output by about 15%, most patients with severe cardiogenic shock die when treated only with the IABP. Since synchronization is timed to the electrocardiogram, the IABP is ineffective in patients who suffer from moderate to severe dysrhythmia.

Postcardiotomy shock has been effectively treated with a variety of LVADs that are capable of taking over 80–100% of the cardiac work load [12,13,21]. Left ventricular assist devices have a significant advantage over the IABP in treating severe cardiogenic shock because of their ability to provide better hemodynamic support. Indeed, existing LVADs have demonstrated improved survival of patients suffering from postcardiotomy cardiogenic shock. Unfortunately, they have not been extensively used to treat cardiogenic shock secondary to acute myocardial infarction because of the associated risks and complexity of the devices.

A large number of patients with cardiogenic shock need more circulatory assistance than can be provided by the IABP, but are not candidates for an LVAD. An intermediate device would benefit patients who fall in this therapeutic gap. A device that had the capability of the LVAD to support the majority of the hemodynamic work of the left ventricle, while exposing the patient to a degree of risk incumbent to the IABP, would be very useful clinically. However, widespread use of LVADs has awaited the development of a practical technology that can be implemented rapidly with minimal surgical risk and complications. The Hemopump is a catheter-mounted, peripherally introduced, mechanical assist device that is capable of supporting the majority of the circulatory requirements of a patient while providing a significant reduction in left ventricular work. This chapter presents an overview of the concept and operation of the Hemopump and the results of an ongoing trial evaluating the utility of the Hemopump in the treatment of cardiogenic shock. In addition, a pilot experience involving the use of the Hemopump for supported, high risk angioplasty is summarized. Finally, new horizons for use of a new 14 (Fr) percutaneous Hemopump as an interventional modality in the treatment of acute myocardial infarction to effect salvage of myocardium is discussed.

THE HEMOPUMP

The Hemopump is a new circulatory assist device capable of supporting the left ventricle without the need for a major surgical procedure [22,23]. In clinical trials, the Hemopump has shown promise in the treatment of cardiogenic shock and has been accompanied by acceptable risk. A description of the Hemopump, including the concept, operation, and results of clinical use, are discussed below.

System Description

The Hemopump is a temporary left ventricular assist device utilizing axial flow technology to draw blood out of the left ventricle and expel it into the aorta (Figure 14-1) [22]. The Hemopump can be placed via a peripheral vascular access and support up to 80% of the left ventricular work load. The Hemopump can provide up to 3.5 l/min of flow without the need for a contribution from the left ventricle or synchronization. Since the inflow cannula

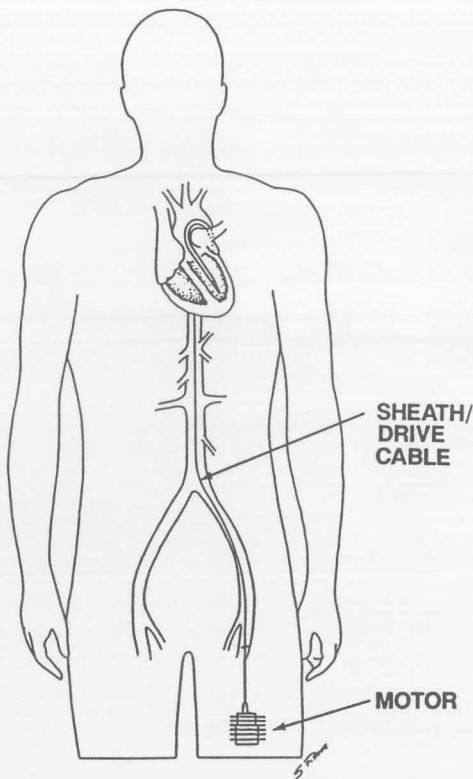


Figure 14-1. Anatomical placement of Hemopump.

is placed within the left ventricle, Hemopump assistance results in a significant degree of left ventricular decompression.

The pump (Figure 14-2) is contained within a 7-mm diameter (21 Fr), 16-mm long cylindrical housing. Attached distally to the pump housing is a 7-mm diameter by 26-cm long, curved inflow cannula. The inflow cannula resides in the left ventricle and the exhaust of the pump resides in the descending aorta. Proximal to the pump and inflow cannula is a 3-mm diameter (9.5 Fr) by 107-cm long, flexible drive cable housed in a polyurethane sheath. At the proximal end of the drive cable/sheath is a motor magnet that couples magnetically to a drive motor stator.

The console (Figure 14-3) is an integrated electronic controller incorporating all of the power, control, and diagnostic/alarm systems required to operate the pump and supply it with purge fluid. It also includes the roller pump that controls the delivery and collection rates of the purge fluid lubricant. The console has 30 minutes of battery backup.

Rotary motion is imparted to the pump drive by means of a magnetic coup-

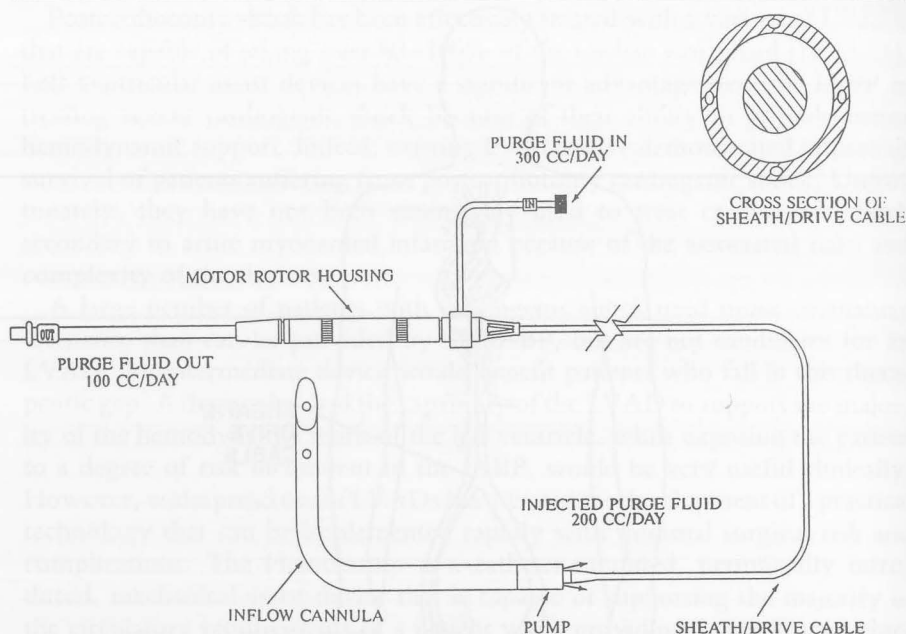


Figure 14-2. Schematic of the Hemopump.

ling, and is transmitted via a flexible drive cable to the pump rotor. Blood is removed from the left ventricle and expelled into the aorta as a result of the hydraulic gradient produced by the spinning pump rotor (Figure 14-4). The pump is a two-stage axial flow pump with a rotor (rotating blades of the pump) and a stator (nonrotating blades of the pump). With the pump spinning, blood flows from the tip of the cannula, across the rotor, and then across the stator into the systemic circulation.

Lubrication for the pump is provided by continuous infusion of 40% dextrose in water (D40W). Approximately 300 cc/day of D40W is pushed by a roller pump through purge tubing toward the pump via four outer lumens in the sheath. About 200 cc/day of the purge fluid flows across the seal into the patient and prevents blood elements from migrating into the pump. In addition, the dextrose lubricates the bearing surfaces and the flexible drive cable. The remaining 100 cc/day of the purge fluid is drawn away from the pump around the drive cable and motor magnet to a return bag, flushing cable-generated debris away from the pump.

Insertion procedure

The Hemopump system is set up on a sterile field with the entire pump, motor, and approximately 100 cm of purge tubing within the sterile field. A

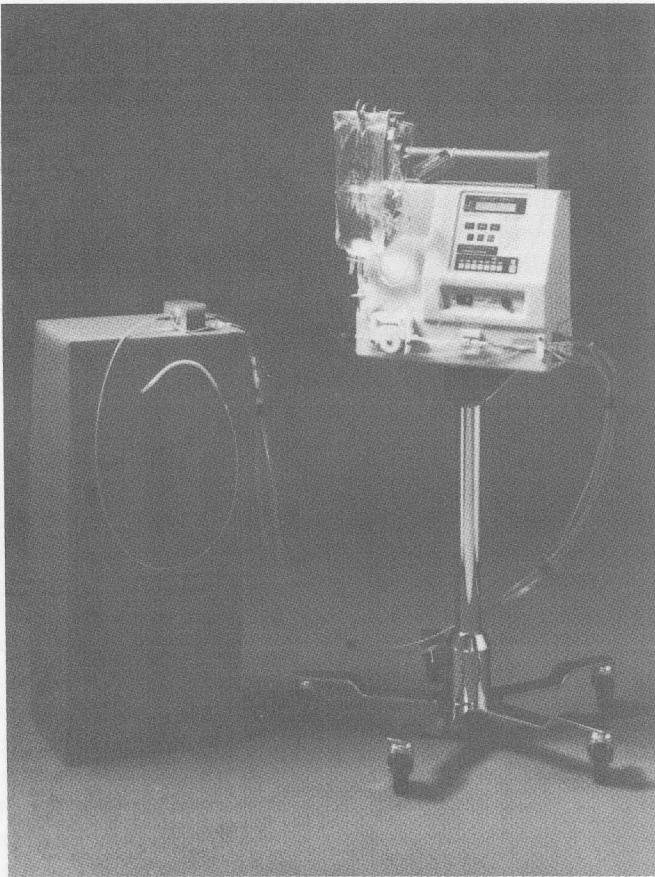


Figure 14-3. Hemopump system.

30-cm length of 12-mm graft is anastomosed end-to side to the insertion vessel. The Hemopump and a silicon graft plug (an 11.5-mm diameter by 20-mm long cylinder of silicon with a lengthwise hole the diameter of the drive cable sheath) is then inserted into the graft. The purpose of the graft plug is to maintain hemostasis while the pump/cannula is inserted.

There are three surgical approaches that can be used to insert the Hemopump. Initially the anastomosis of a 12-mm vascular graft to the insertion site on the artery was employed, but alternate methods have been employed [29]. The preferred approach is through the femoral artery. If the femoral artery is too small or is too severely atherosclerotic, an approach through the iliac artery is acceptable. In patients who have femoral and iliac vessels that are too small or too diseased for Hemopump insertion, a retroperitoneal approach through

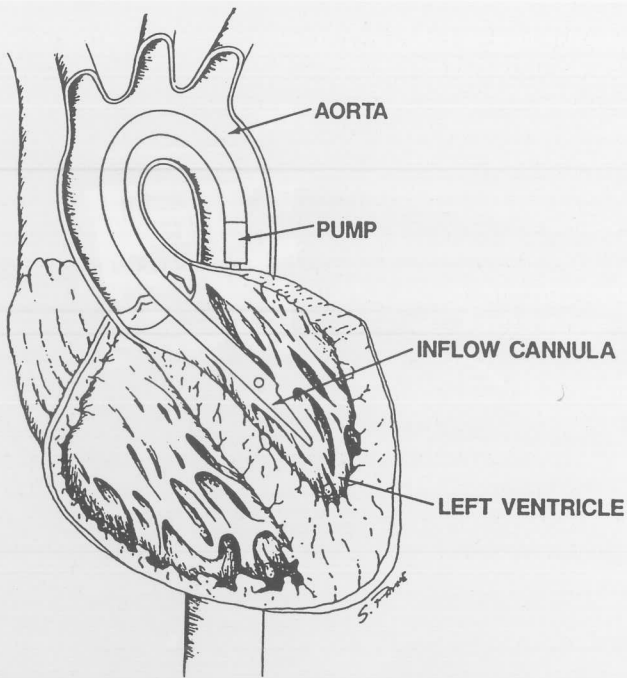


Figure 14-4. Position of Hemopump in the heart.

the abdominal aorta has been successful. With the use of the retroperitoneal approach, an 8-year-old child was successfully supported and weaned [26].

The patient is administered a heparin dose of 1–2 mg/kg prior to inserting of the pump into the artery. Once the pump is well into the abdominal aorta, it is turned on to a low speed. The pump is advanced through the aorta, around the aortic arch and across the aortic valve into the left ventricle. The insertion procedure is best performed under fluoroscopic visualization. Catheter guidance can be employed in cases where advancement of the cannula into the ventricle is difficult.

After proper position is established the pump is secured with the use of the silicone graft plug and the wound is closed with the drive cable exiting the lower margin. The Hemopump motor may be positioned on the patient's leg or on the abdomen.

CLINICAL TRIAL: CARIOGENIC SHOCK

A clinical trial was conducted in the United States under an Investigational Device Exemption approved by the Food and Drug Administration. The purpose of this study was to evaluate the value of the Hemopump in the treatment of cardiogenic shock.

Patient selection

Eighty-seven patients with cardiogenic shock — defined as a cardiac index $<2.01/\text{min}/\text{m}^2$, pulmonary capillary wedge pressure $<18\text{ mmHg}$, systolic blood pressure $<90\text{ mmHg}$ or a left ventricular work index (LVWI) $<1500\text{ gm}/\text{m}^2/\text{min}$ and refractoriness to volume and pharmacologic therapy — were prospectively selected for treatment with Hemopump assistance. Sixty-six patients (58 males, 8 females) were supported for a mean time of 59.8 hours (range 1–194 hours). Cardiogenic shock was secondary to acute myocardial infarction in 25 (37.9%), failure to wean from cardiopulmonary bypass in 21 (31.8%), postcardiotomy shock in 10 (15.1%), and other etiologies in 10 (15.1%). The mean age was 54.3 years (range 8.6–80.0 years). Patients with significant blood dyscrasia, aortic prosthetic valve, severe aortic stenosis or regurgitation, or known dissecting aneurysm were not considered for Hemopump support. The intraaortic balloon pump had been used immediately prior to Hemopump insertion in 66.7% of the patients assisted [30]. Patients were maintained on heparin anticoagulation to a therapeutic range of 1.5–2.0 times control of either the activated clotting time or the partial thromboplastin time. Anticoagulation was not initiated in postsurgical patients until the cessation of active bleeding.

Hemodynamic and laboratory studies

Samples for analysis of plasma free hemoglobin, CBC, platelets, serum haptoglobin, and routine chemistries were drawn prior to pump insertion, during pump assistance, and after pump removal. Cardiac index, pulmonary capillary wedge pressure (PCWP), and systolic and mean blood pressure were recorded prior to pump insertion at selected intervals during pump assistance and following pump removal. Comparison of the mean of the cardiac index, PCWP, mean aortic pressure, and calculated left ventricular work index at preinsertion, during operation, and postremoval were then used to determine the hemodynamic response to Hemopump assistance.

The 30-day follow-up included physical and cardiologic examination, including functional status, echocardiography, complete blood count, platelets, and plasma free hemoglobin level. Postmortem examination was performed on 30 patients. Evidence of minor injury to the aortic valve was noted in one patient. No evidence of device related damage to cardiac structures or the aorta were recorded. Autopsy findings were consistent with the underlying disease state of the patients. No evidence of device related systemic infarctions thought to be secondary to thromboembolism were documented in the autopsy reports.

CLINICAL TRIAL: SUPPORTED ANGIOPLASTY

The recent introduction of supported, high risk angioplasty with the use of percutaneous cardiopulmonary bypass support has resulted in a significant degree of acceptance and use in the catheterization laboratory [31,32]. The

potential benefit to selected patients who are poor candidates for surgical treatment and who were considered to have a high risk for angioplasty prompted the adaptation of the Hemopump to use in supported angioplasty.

Although the current, 21 Fr device is not percutaneously inserted, there are three potential advantages of the Hemopump when compared to support with percutaneous cardiopulmonary bypass:

1. The Hemopump requires only minimal anticoagulation relative to the level needed for cardiopulmonary bypass with an oxygenator, and a perfusionist is not needed.
2. If the patient suffers complications during the procedure, the patient can be safely supported for up to 7 days on the Hemopump.
3. The Hemopump provides significant left ventricular decompression in nearly all patients.

The first Hemopump supported angioplasty was reported by D. Loisance et al. [29] on eight patients. Patients were considered for supported PTCA if they met the following four criteria:

1. Evolving acute myocardial ischemia, unresponsive to medical therapy.
2. Ischemia related to a substantial stenosis with a patent distal runoff.
3. The patient was considered to have exceptionally high operative risk, or had been turned down for surgery.
4. The culprit lesion was present in the only patent vessel.

The Hemopump was placed using local anesthesia. The pump was introduced into the femoral artery without the use of an introduction graft. Blood loss during insertion was controlled by means of a special silicone rubber adapter fitted to the pump during insertion. The pump was advanced into the ventricle and assistance initiated prior to the angioplasty. No difficulty controlling the catheters in the presence of the Hemopump was encountered. Angioplasty was then performed while monitoring the electrocardiogram, hemodynamic status, and patient condition. The plasma free hemoglobin was measured after pump removal. The patient outcome from 3 to 7 months has been completed.

RESULTS OF CARDIOGENIC SHOCK TRIAL

Overall patient survival

Forty (60.6%) of Hemopump patients died on support or immediately after pump removal, 26 (39.4%) were successfully weaned from support, and 17 (25.8%) patients supported by the Hemopump survived to 30-day follow-up. Cardiogenic shock secondary to acute myocardial infarction demonstrated a survival of 8 of 25 (32.0%) compared to 5 of 21 (23.8%) for patients who could not be weaned from cardiopulmonary bypass, 1 of 10 (10.0%) for postcardiotomy shock, and 3 of 10 (30.0%) for other etiologies.

95% Error Bars for Cardiac Index All Patients

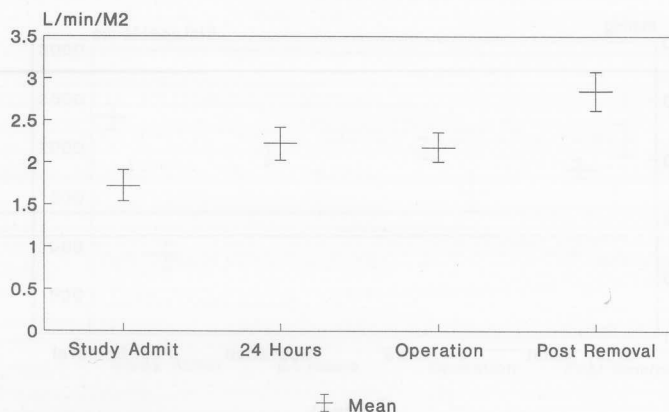


Figure 14-5. Cardiac index of patients in cardiogenic shock trial.

Hemodynamic changes on the Hemopump

The mean cardiac index (Figure 14-5) prior to pump insertion was 1.72 l/min/m². After 24 hours of operation the cardiac index rose to 2.27 l/min/m² ($p = .0005$). The mean cardiac index during pump operation was 2.31 l/min/m² ($p = .0001$). In patients who survived to weaning, the mean cardiac index was 2.76 l/min/m² ($p = .0002$).

The mean arterial blood pressure (MAP) prior to Hemopump insertion (Figure 14-6) was 56.92 mmHg; after 24 hours of assistance the MAP was 62.23 mmHg ($p = .034$). The MAP during pump operation was 65.45 mmHg ($p = .0002$). In patients who survived to weaning, the mean MAP was 105 mmHg ($p = .0001$). The mean preinsertion PCWP was 24.87 mmHg, and fell to 15.21 mmHg ($p = .0001$) after 24 hours of pump operation (Figure 14-7). The mean PCWP during operation was 15.92 mmHg ($p = .0001$). In patients who survived to weaning, the mean PCWP was 18.0 mmHg ($p = 0.0044$).

The left ventricular work index (Figure 14-8), or ventricular power, is calculated using the cardiac index (CI), PCWP, and MAP as follows:

$$\text{Left ventricular work index (LVWI)} = \text{CI} \times (\text{MAP} - \text{PCWP}) \times 13.6 \text{ g-m}^2/\text{min}.$$

The mean LVWI was calculable at pump insertion for 34 of 66 patients. Based on the Hemopump admission criteria, the calculated maximum LVWI for inclusion in the trial would have been 1500 g-m²/min.

Prior to pump insertion, the LVWI (Figure 14-8) was 952 g-m²/min, which rose to 1484 g-m²/min ($p = .0005$) after 24 hours of operation. The

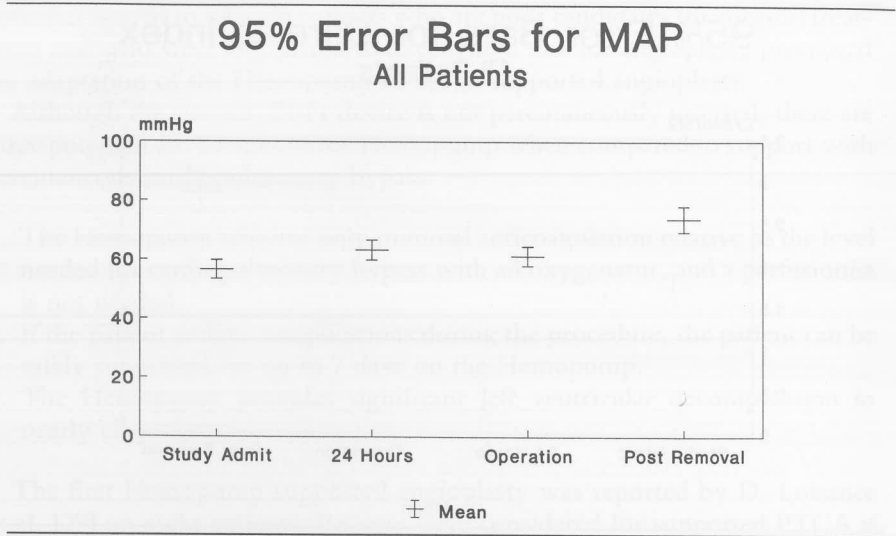


Figure 14-6. Mean arterial pressure of patients in cardiogenic shock trial.

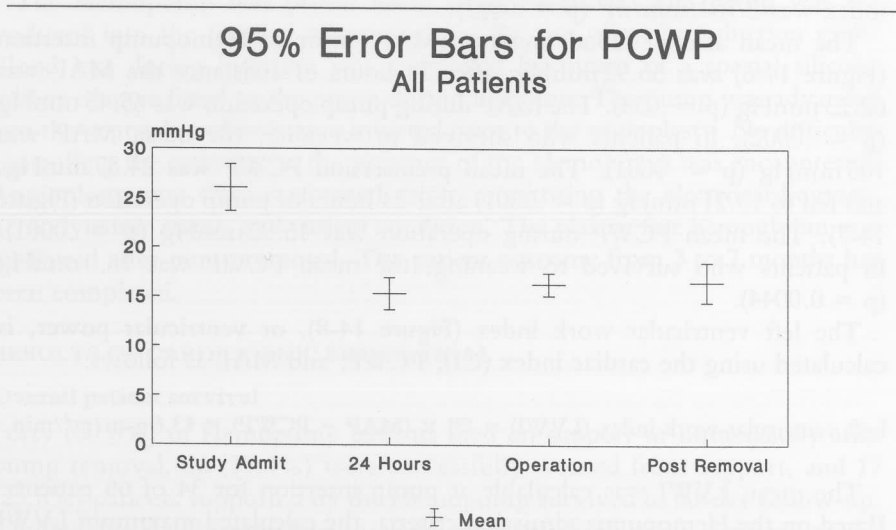


Figure 14-7. PCWP in cardiogenic shock patients. PCWP = pulmonary capillary wedge pressure.

95% Error Bars for LVWI All Patients

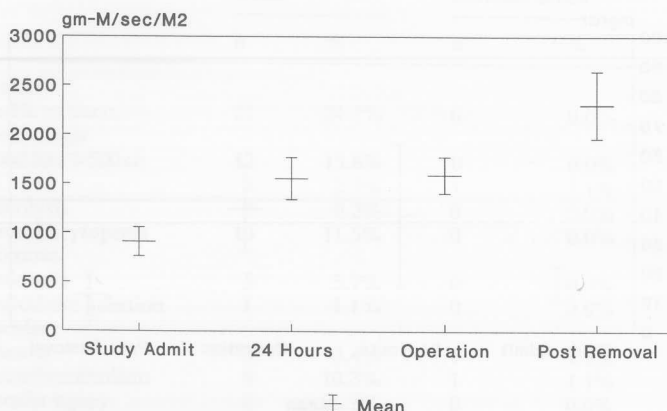


Figure 14-8. LVWI in cardiogenic shock patients. LVWI = left ventricular work index.

mean LVWI during operation was $1639 \text{ g-m/m}^2/\text{min}$ ($p = .0001$). In patients who survived to weaning, the mean LVWI was $2210 \text{ g-m/m}^2/\text{min}$ ($p = .0001$).

Effect on plasma free hemoglobin and platelets

Plasma free hemoglobin levels (Figure 14-9) at preinsertion, postinsertion, prior to pump removal, and at 30-day follow-up for all patients were measured. The mean level of plasma free hemoglobin during pump operation was 16 mg% for the nonsurgical group and 37 mg% for the failure to wean from cardiopulmonary bypass and postcardiotomy group. A transient minor rise was seen in most patients during the first 24 hours of operation, after which the level of plasma free hemoglobin stabilized for the duration of the pump assistance.

Platelet levels (Figure 14-10) for all surgical and nonsurgical patients were measured. The reduction in platelets occurring during Hemopump assistance was observed. The mean platelet level fell from $205,000/\text{mm}^3$ to $110,000/\text{mm}^3$ during operation. Thrombocytopenia was not associated with spontaneous bleeding. The platelet level returned to normal within 2 days of pump removal.

Complications and adverse events

The patient complications and adverse events during hospitalization are listed in Table 14-1. No patient death was reported to be a result of the Hemopump. No leg ischemia was observed.

One of the major safety concerns related to the use of the Hemopump was the potential for injury to blood cellular elements, particularly erythrocytes.

95% Error Bars for Free Hemoglobin All Patients

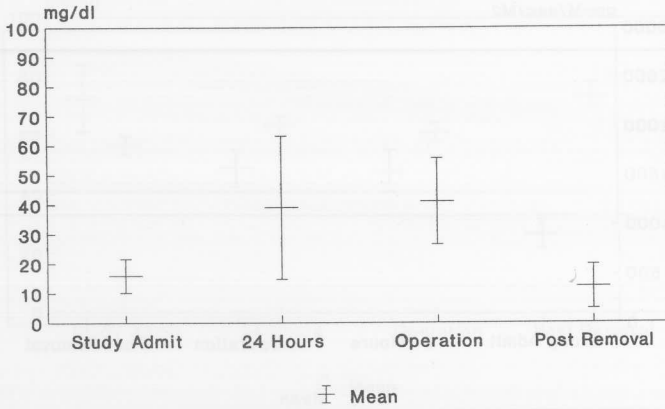


Figure 14-9. Plasma free hemoglobin of patients in cardiogenic shock trial.

95% Error Bars for Platelets All Patients

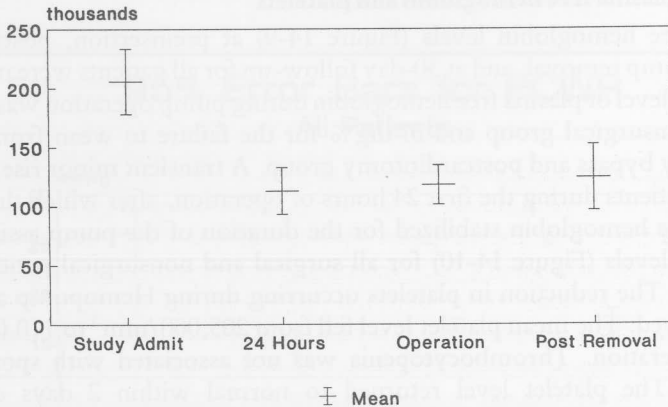


Figure 14-10. Platelet counts of patients in cardiogenic shock trial.

Normal levels are <15 mg% and elevations to 100–200 mg% can be observed following cardiopulmonary bypass. Plasma free hemoglobin is relatively nontoxic unless it precipitates in the renal tubules. The renal threshold for plasma hemoglobin is nominally 100 mg%. The mean levels of plasma free

Table 14-1. Adverse effects and complications

	Total		Residual deficit		Contributed to death	
	n	%	n	%	n	%
Device						
Unable to insert	21	24.1%	0	0.0%	0	0.0%
Hematologic						
Blood loss >500 cc	12	13.8%	0	0.0%	2	2.3%
DIC	2	2.3%	1	1.1%	0	0.0%
Hemolysis	8	9.2%	0	0.0%	0	0.0%
Thrombocytopenia	10	11.5%	0	0.0%	0	0.0%
Infections						
Septicemia	5	5.7%	0	0.0%	1	1.1%
Surgical site infection	1	1.1%	0	0.0%	0	0.0%
Vascular						
Ischemia	3	3.4%	1	1.1%	0	0.0%
Thromboembolism	9	10.3%	1	1.1%	1	1.1%
Vascular injury	6	6.9%	0	0.0%	0	0.0%
Other						
Cardiac arrest	2	2.3%	0	0.0%	0	0.0%
Death—operation	41	47.1%	0	0.0%	0	0.0%
Dysrhythmias	53	60.9%	0	0.0%	1	1.1%
Renal failure	7	8.0%	0	0.0%	2	2.3%

hemoglobin during hemopump operation were considered to pose a minimal risk to the patient.

Other complications

Thromboembolism

A total of nine embolic events were recorded in eight patients. A small renal infarction was found at postmortem exam in one patient and is likely to have occurred during pump operation. Two patients suffered hemiparesis after pump removal, associated with atrial fibrillation in one and preexisting mural thrombus in the other. A late femoral embolism was related to preexisting mural thrombus and was successfully managed with thrombectomy. The pump-related thromboembolism rate was 3.5%. A total incidence of systemic thromboembolism during and after pump operation was 10.5%. The incidence of thromboembolic events in patients suffering from acute myocardial infarction, mural thrombus, or undergoing LVAD implantation ranges from 5 to 15% [33,34,35,19].

Ventricular dysrhythmia

Patients undergoing open-heart surgery or suffering from myocardial infarction commonly present with ventricular ectopy and may develop ventricular tachycardia or fibrillation. The Hemopump cannula, representing a large

foreign body within the ventricular cavity, would be expected to produce a degree of ventricular ectopy. The clinical significance of ventricular ectopy and malignant rhythms relates to the hemodynamic compromise associated with these rhythms. It has been observed during the trials that cardiac output and mean arterial pressure are well maintained during periods of severe dysrhythmia during Hemopump assistance. Dysrhythmia observed include sustained ventricular tachycardia and on one occasion ventricular fibrillation. One patient was supported during ventricular fibrillation for 45 minutes. He was conscious during this episode and was successfully defibrillated.

Factors in favor of survival

Predictably, survival diminishes as the severity of illness increases. Thus, patient selection and early intervention would be expected to result in a significant increase of survival of patients in cardiogenic shock treated with the Hemopump. Calculated left ventricular work has been shown to have value as a prognosticator of survival in the setting of cardiogenic shock secondary to acute myocardial infarction and postcardiotomy shock.

Left ventricular work index (Figures 14-11 and 14-12)

The left ventricular work index prior to insertion is stratified and then compared to the probability of surviving to weaning, and surviving to 30 days. Increasing preinsertion LVWI is associated with an increased probability of survival.

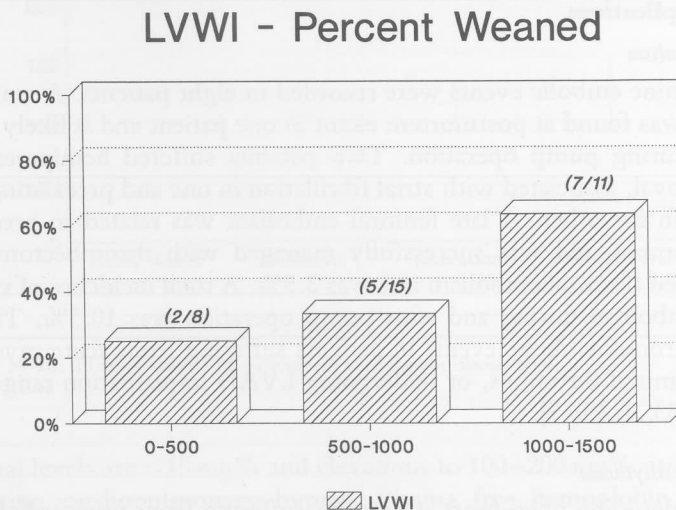


Figure 14-11. Survival to weaning as a function of preinsertion LVWI. LVWI = left ventricular work index.

LVWI - Percent Survivors

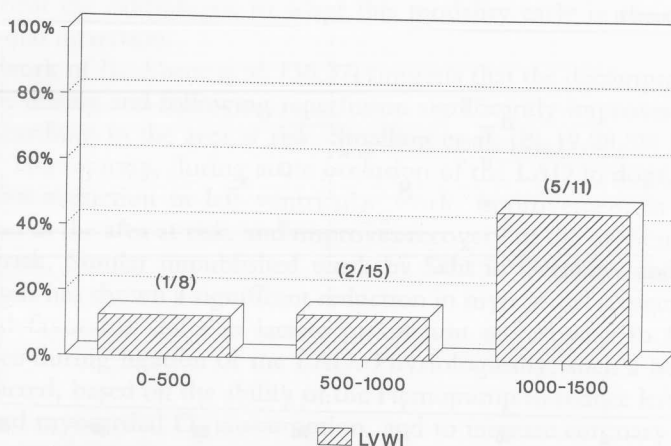


Figure 14-12. Survival to 30 days as a function of preinsertion LVWI. LVWI = left ventricular work index.

Cardiac index versus PCWP (Figure 14-13)

The prognosis after initiation of therapy can be evaluated after 24 hours of assistance. The figure is a display of cardiac index versus PCWP of all patients alive at 24 hours. It can be seen that 73% (11/15) of patients with a cardiac index $>2.01 \text{ l/min/m}^2$ and a PCWP $<18 \text{ mmHg}$ after 24 hours of assistance survived to weaning. In the same group of patients 40% (6 of 15) survived to 30 days. Of the eight patients who died, only three died from cardiac causes. In the same group, two additional patients weaned with normal ejection fractions but later died of noncardiac etiologies.

RESULTS OF THE SUPPORTED ANGIOPLASTY TRIAL

The Hemopump was successfully placed in 5 of the 8 patients. Peripheral vascular disease precluded placement in three. Angioplasty was completed in the five supported patients. All of the supported patients tolerated their procedure well, in spite of significant arrhythmia and evidence of acute left ventricular dysfunction during dilation in four. Four of the five were symptom free under medical therapy at 3–7 months. The fifth patient was successfully revascularized after 3 weeks following improvement in permanent myocardial ischemia. Two of the three noninsertions died. One died during attempted angioplasty and the other after 10 days without intervention. The third non-insertion was taken to surgery after an organ donor became available and was successfully bypassed without the need for transplantation.

Scattergram for CI vs. PCWP at 24 Hours

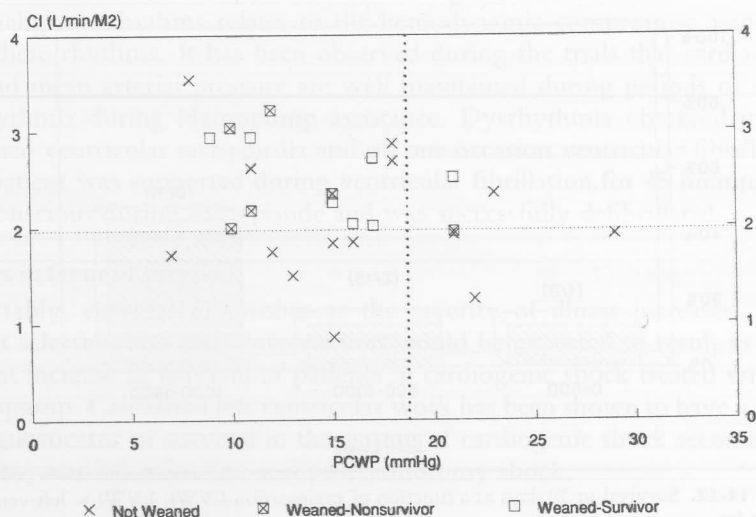


Figure 14-13. Survival as a function of CI and PCWP after 24 hours of assistance. CI = cardiac index; PCWP = pulmonary capillary wedge pressure.

Comments on the cardiogenic shock study

The clinical study has demonstrated the hemodynamic effectiveness and safety of the Hemopump when used in the treatment of cardiogenic shock. Hemopump therapy resulted in a significant decrease in pulmonary capillary wedge pressure, and an increase in the systolic blood pressure, cardiac index, and left ventricular work index. The hemodynamic effectiveness of the Hemopump resulted in a significant increase in patient survival in selected patients and was associated with acceptable risk. It is concluded that the Hemopump is an effective, safe, and practical left ventricular assist device and may play a significant role in the treatment of cardiogenic shock.

Comments on the supported angioplasty trial

Patients supported during angioplasty have demonstrated stable or improved hemodynamics during the procedure, even though arrhythmia and left ventricular dysfunction was frequently observed during dilation. The Hemopump offers a new approach to the support of high risk patients during angioplasty and may offer advantages over current techniques.

NEW HORIZONS

Advances in Hemopump technology have supported the development of a smaller pump (14 Fr) that has been adapted to percutaneous, wire-guided

insertion. This device may be available in 1993 for investigational use; the ability to implement left ventricular assistance, percutaneously, in the cath lab will permit the cardiologist to adapt this modality early in the treatment of myocardial infarction.

The work of Buckberg et al. [36,37] suggests that the decompression of the ventricle during and following reperfusion significantly improves the salvage of myocardium in the area at risk. Smalling et al. [21,19,28,38] have shown that the Hemopump, during acute occlusion of the LAD in dogs, results in a significant reduction in left ventricular work, improvement in myocardial perfusion in the area at risk, and improves recovery of the myocardium in the area at risk. Similar unpublished work by Scht in Germany and Flemming in Brussels has shown a significant reduction in myocardial oxygen consumption and favorable shifts in lactate production in response to Hemopump assistance during ligation of the LAD. Physiologically, such a benefit might be predicted, based on the ability of the Hemopump to reduce left ventricular work and myocardial O_2 consumption, and to increase coronary perfusion.

Thus, mechanical assistance may be employed in the treatment of acute coronary occlusion to minimize the loss of myocardium in the area at risk. The clinical utility of such an application can only be defined after completion of human clinical trials designed to evaluate the efficacy of such a therapy.

CONCLUSIONS

The ability to support the circulation and reduce left ventricular work may significantly benefit patients with cardiogenic shock and its complications. At the present time, the technological innovation of the Hemopump provides a unique and practical means of beginning to understand the role of mechanical assistance in the treatment of cardiogenic shock and acute myocardial infarction. The initial clinical trial, treating cardiogenic shock has been most encouraging. Pilot experience with supported angioplasty has been promising. The limitations of the 21 (Fr) device have spawned the development of a percutaneously inserted device that may find broad application in the treatment of acute myocardial infarction. The role of this evolving technology in clinical therapy will be defined as a result of continuing clinical study.

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