The Impella Recover microaxial left ventricular assist device reduces mortality for postcardiotomy failure: A three-center experience

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Background: We evaluated patient outcomes and complications associated with the microaxial Impella Recover left ventricular assist device (Impella Cardiosystems AG, Aachen, Germany) for postcardiotomy low-output syndrome. This low-cost device is inserted across the aortic valve through a 10-mm vascular graft sewn to the ascending aorta.

Methods: Impella patients were compared with 198 patients treated with an intra-operative intra-aortic balloon pump between January 2000 and December 2002. Three risk scores were used: the Hausmann score, the Texas Heart Institute score, and the Cleveland intensive care unit score. Between September 2001 and March 2003, 24 patients were treated with the Impella Recover for low-output syndrome. Before device insertion, 21 could not be separated from cardiopulmonary bypass, and 3 had postoperative hemodynamic instability despite high-dose catecholamines. Sixteen were treated with the Impella and intra-aortic balloon pump and 8 with the Impella alone (no intra-aortic balloon pump because of peripheral vascular disease or because deemed unnecessary).

Results: No technical problems with device insertion occurred. Pump flow was 3.3 ± 0.7 L/min at $28,000 \pm 4500$ RPM. Support time was 61 ± 56 hours (range, 7-228 hours). Four devices required repositioning. One device failed (leaking purge line) and was removed. Hemolysis was minimal (lactate dehydrogenase levels of 540 ± 260 U/dL for Impella survivors). Mortality for Impella patients was 54% (13/24), similar to that for high-risk intra-aortic balloon pump patients (Hausmann score ≥ 2 [57%], intensive care unit score ≥ 2 [51%], Texas Heart Institute score ≥ 0.75 [55%], and cardiac index ≤ 2.3 [45%]). Cardiac output data were available in 19 Impella patients. Impella patients able to increase their cardiac output to 1 L/min or more above the pump flow of the Impella Recover had a 10% (1/10) mortality, versus 88% (8/9) in patients with a residual cardiac function of 1 L/min or less ($P = .001$). Comparison of high-risk intra-aortic balloon pump patients with Impella patients with residual cardiac function of 1 L/min or more showed a significant reduction in mortality, regardless of the high-risk definition used. Residual cardiac function was the strongest predictor of survival in Impella patients.

Conclusions: The Impella Recover device provides 3 to 4 L/min flow. It improves survival in patients with low-output syndrome if the heart is able to pump 1 L/min or more above device flow.

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Postcardiotomy low-output syndrome (LOS) remains one of the leading causes of death after cardiac surgical procedures.^{1,2} Death is usually attributed to multiorgan failure and not to the underlying period of low cardiac output causing subsequent multiorgan failure.

We used the Impella Recover left ventricular assist device (Impella Cardiosystems AG, Aachen, Germany) to treat postcardiotomy LOS in 21 patients unable to be separated from cardiopulmonary bypass and in 3 with hemodynamic instability despite maximal catecholamine therapy before insertion. This microaxial assist device with a diameter of 7.3 mm is inserted retrograde into the left ventricle across the aortic valve through a 10-mm polyester graft (Gelweave; Vascutek, Ltd, Renfrewshire, Scotland) sewn to the ascending aorta. We evaluated patient outcomes and complications associated with this device and analyzed the possible effect on survival of this novel low-cost device by using 2 risk scores developed specifically for intra-aortic balloon pump (IABP) patients^{3,4} and an intensive care unit (ICU) admission score for postoperative cardiac surgical patients.⁵

Methods

IABP Patients

In a retrospective review, data of all patients treated with an intraoperative IABP from January 2000 to December 2002 were analyzed. Patients who received a preoperative IABP, as well as those with their IABP inserted 4 or more hours after the operation, were excluded from the analysis. Of the 271 patients treated with an intraoperative IABP, 15 were excluded because of the use of extracorporeal membrane oxygenation or the use of another assist device. Of the remaining 256 patients, 198 complete charts (77%) were available for review, and 58 charts (23%) were incomplete or missing. Hospital mortality was defined as any mortality that occurred during the initial hospital stay.

Impella Patients

All 24 Impella devices were inserted between September 2001 and March 2003. The device was used according to the attending surgeon's judgment, with no standard protocol for use of the device. Most patients were unable to be separated from cardiopulmonary bypass. All charts were available for review. Electronic flow data were available in 13 Impella patients. In 8 patients, the ICU flow sheet had hourly device flow rates recorded. Both cardiac output data and device flow rates were present in 19 patients. All postoperative events, including surgical and device-related complications, were recorded. Estimated residual cardiac function in patients with the Impella device was defined as follows:

Estimated residual cardiac function

=cardiac output on the device – device flow

Cardiac output was measured with a Swan-Ganz catheter (Arrow International, Inc, Reading, Pa) at full device speed. Successful weaning was defined as a stable patient who was alive for at least 72 hours after explantation of the Impella Recover device.

Impella Recover Left Ventricular Assist Device

The Impella Recover device is a microaxial left ventricular assist device with a diameter of 6.4 mm at the body of the pump and a 7.3-mm diameter at the level of the outflow opening (Figure 1, A). A small electric motor is built into the device, and the thin (2.8-mm) cable leading to the device contains the electrical power supply, which is connected to an external control unit as well as a purge line connected to a purge perfusor, through which heparin (concentration of 1000-2500 IU in 50 mL of glucose 40% solution) is flushed continuously with a pressure of 300 to 700 mm Hg. The heparin/glucose solution is delivered at the level of the pump, and the patient does not need systemic anticoagulation in the early postoperative phase. Once the bleeding has subsided, it is recommended to heparinize the patient to an activated clotting time of 160 seconds or an activated partial thromboplastin time of 50 to 60 seconds. The glucose 40% solution is added to increase the viscosity of the purge-line solution to achieve the required purge-line pressure without giving large amounts of volume to the patient. The usual amount of volume given is approximately 5 mL/h, equivalent to a heparin dose of 250 U/h. The device can be set at 10 different speed levels, up to 33,000 RPM. At this speed, depending on the afterload of the device, a pump performance of approximately 3.5 to 5.0 L/min is possible, according to the manufacturer (Impella Cardiosystems AG). A memory chip built into the controller console allows pump flow and pump speed data collection. The different speed levels allow for gradual weaning to the lowest setting (10,000 RPM), at which the net device flow is 0, because the device overcomes only the mild aortic insufficiency it induces.

Even though the device is similar to the previously used Hemopump (Medtronic, Inc, Minneapolis, Minn), there are technical differences, including no cumbersome driveline, easier placement with the pressure-differential display, monitoring of pump flow, and a smaller size. A model for use via a femoral approach in the cardiac catheter laboratory is also available.

Operative Technique

A 10-mm vascular graft was sewn to the ascending aorta (Figure 1, B), and the device was inserted retrograde across the aortic valve from the ascending aorta into the left ventricle (Figure 1, C). Positioning of the device occurred via a pressure-differential curve on the device console, as well as with transesophageal echocardiographic control (Figure 1, C). The vascular graft with the device was brought out of the skin either through the apex of the sternotomy incision or a small stab wound near the upper aspect of the sternotomy. The sternum was left open with either a primary skin closure or closure of the incision with an Epigard patch (Biovision GmbH, Ilmenau, Germany). Once the patient was weaned from ventricular support, the device was pulled out of the Dacron graft, which was then either ligated flush with the ascending aorta or was oversewn, followed by standard closure of the sternotomy.

Risk Scores

Table 1 shows the risk scores described by Baldwin and colleagues³ and Hausmann and colleagues⁴ for all IABP patients and the risk score of Higgins and associates⁵ for patients who have had cardiac operations. The 3 risk scores were applied to all IABP and Impella patients. The risk scores were validated on our patient cohort and were subsequently used to identify high-risk patients.

Figure 1. A, Dimensions of the pump head of the Impella Recover microaxial left ventricular assist device. The device body is a flexible, wire-reinforced plastic tube to avoid potential mechanical damage by the pump head. B, The Impella Recover system is secured to the 10-mm Dacron prosthesis. C, An intraoperative transesophageal echocardiogram shows a correct position across the aortic valve.

Texas Heart Institute Score

The Texas Heart Institute (THI) score is based on preoperative factors and postoperative pacemaker dependence (Table 1). All data had to be present to be included in the analysis. The use of a pacemaker is the strongest predictive factor for mortality in this score; according to the authors, this is due to an extensive anterior wall infarction involving the septum and leading to a complete heart block. One of our centers used atrioventricular pacing in virtually all patients who arrived in the cardiac surgical ICU. No

note was made if patients were truly pacemaker dependent. Therefore, the THI score of this center had little predictive power and was excluded from the analysis. Complete data were available in 98 IABP patients and in 18 Impella patients.

ICU Admission Score

This complex risk score includes multiple preoperative, intraoperative, and postoperative parameters that are predictive of morbidity and mortality (Table 1). Patients with more than 1 missing data

point were excluded from the analysis unless they had already accumulated a score of 21 or more, which put them in the highest risk category regardless of missing data. Data of the ICU admission score were available for analysis in 158 IABP patients and in all 24 Impella patients.

Hausmann Score

This score is mainly based on patients' hemodynamic status (Table 1). Patients with more than 1 possible score point missing were excluded from the analysis. Because no left atrial pressure was measured at our institutions, we substituted the pulmonary capillary wedge pressure for the left atrial pressure used in the original publication. Patients with a score of 3 or higher were included in the analysis, because they were already in the highest-risk group for mortality, regardless of missing data. Data were available for analysis in 137 IABP patients and 20 Impella patients.

Statistical Analysis

Data are presented as mean $\pm$ SD for quantitative variables and as absolute and relative frequencies for qualitative variables. Group comparisons were performed with Student *t* tests and Wilcoxon rank sum tests for quantitative data, as appropriate, and with the Fisher exact test for qualitative data. Logistic regression analysis was used to calculate odds ratios for clinical covariates with respect to survival. All significance tests were 2 sided. Data analysis was performed with SAS software (SAS Institute, Inc, Cary, NC).

Results

Patient Demographics

Table 2 shows patient demographics and risk scores in Impella and ICU patients. Patient demographics and preoperative risk profiles were similar; there was no difference between the various risk scores between Impella and IABP patients.

Surgical and Device-Related Data

There were no technical difficulties with device insertion. In 1 patient, who had a slightly calcified aortic valve, device insertion was difficult, and several attempts were necessary to get the device past the aortic valve. After implantation, the skin was closed in 12 patients (skin and sternum in 6), a skin-patch closure was used in 9, and in 3 patients the wound closure was not specified. Four devices required repositioning because they were advanced too far into the left ventricle. This was noticed with insufficient pump flow and the lack of a pressure-differential curve. One device developed a leaking purge line, which led to malfunction of the device. The device had to be removed.

Heparin was fully reversed after cardiopulmonary bypass in 19 patients, and 5 had a partial reversal of their heparin. Most patients were given low-dose heparin through the Impella purge perfusor in the early postoperative period until the chest tube drainage had slowed down, and they were subsequently heparinized. Five surgical revisions for

TABLE 1. Risk scores

Variable	Score points
ICU admission score⁵	
Preoperative factors	
BSA $\leq 1.72 \text{ m}^2$	1
Prior heart operation	
One prior operation	1
Two or more prior operations	2
History of operation or angioplasty for peripheral vascular disease	3
Age ≥ 70 y	3
Preoperative creatinine $\geq 1.0 \text{ mg/dL}$	4
Preoperative hematocrit $\leq 34\%$	5
Intraoperative factors	
CPB time ≥ 160 min	3
Use of IABP	7
ICU admission physiology	
Alveolar-arterial gradient ≥ 250 mm Hg	2
Heart rate ≥ 100 beats/min	3
Cardiac index $\leq 2.1 \text{ L/min}$	3
Central venous pressure ≥ 17 mm Hg	4
Arterial bicarbonate $\leq 21 \text{ mmol/L}$	4
Calculation of ICU-score: sum of all points	
Hausmann score⁴	
Epinephrine dose $\geq 0.5 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$	2
Diuresis $< 100 \text{ mL/h}$	1
$\text{SvO}_2 < 60\%$	1
Left atrial pressure $> 15 \text{ mm Hg}$	1
Calculation of Hausmann score: sum of all points	
THI score^{3*}	
Pacing	Yes = 1, no = 0
Age	Value in years
Preoperative BUN	Value in mg/dL
Sex	Female = 1, male = 0
Calculation of THI score*	

ICU, Intensive care unit; CPB, cardiopulmonary bypass; IABP, intra-aortic balloon pump; SvO_2 , mixed venous oxygen saturation; BSA, body-surface area; THI, Texas Heart Institute; BUN, blood urea nitrogen.

*Predicted mortality = $\exp(\Sigma \text{Bi}/\text{Xi}) / [1 + \exp(\Sigma \text{Bi}/\text{Xi})]$, where $\text{BiXi} = -3.44601 + 0.9079921$ (pacing requirement) + 0.0413888 (age) + 0.0188389 (BUN) + 0.6055711 (sex).

bleeding were necessary in 4 Impella patients (5/24; 21%), and no surgical source of the bleeding could be found in 3. Anticoagulation and bleeding data of the Impella patients are shown in Figure 2. The incidence of surgical revision for bleeding in Impella patients was similar to that in high-risk IABP patients, with a reoperation rate for bleeding of 8% to 14%, depending on the high-risk definition used (such as a THI score ≥ 0.75 , a Hausmann score ≥ 2 , an ICU admission score ≥ 21 , an epinephrine dose $\geq 0.14 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$, or a cardiac index at 6 hours of $\leq 2.3 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$).

No clinically significant hemolysis was observed in the Impella patients. Lactate dehydrogenase levels in Impella sur-

TABLE 2. Patient demographics

Variable	Impella patients (n = 24)	IABP patients (n = 198)	P value
Preoperative parameters			
Female sex	4/24	66/198	.109
Age (y)	66 ± 8	68 ± 10	.051
BSA (m ²)	2.0 ± 0.2	1.9 ± 0.2	.047
Peripheral vascular disease	4/24	22/197	>.3
Diabetes	4/24	43/198	>.3
Creatinine (mg/dL)	1.1 ± 0.5	1.1 ± 0.4	>.3
Blood urea nitrogen (mg/dL)	54 ± 48	54 ± 34	.154
Hematocrit (%)	38 ± 5	39 ± 10	>.3
Previous cardiac operation	4/24	43/195	>.3
Acute myocardial infarction	11/24	67/197	.265
Unstable angina	2/24	28/197	>.3
Operative parameters			
CPB time (min)	148 ± 86	138 ± 79	>.3
Crossclamp time (min)	59 ± 47	68 ± 44	.223
CABG	19/24	134/197	>.3
CABG + valve	2/24	33/197	>.3
Valve	3/24	26/197	>.3
Other	0/24	4/197	>.3
Postoperative parameters			
Cardiac index 6 h (L · min ⁻¹ · m ²)	2.5 ± 0.8*	2.8 ± 0.8	.101
Cardiac index 12 h (L · min ⁻¹ · m ²)	2.7 ± 0.6*	2.9 ± 0.8	.278
A-a gradient (mm Hg)	327 ± 168	242 ± 141	.019
Pacing	16/24	131/195	>.3
Heart rate (beats/min)	100 ± 18	102 ± 18	>.3
Arterial bicarbonate (mmol/L)	20 ± 3	20 ± 3	>.3
CVP (mm Hg)	17 ± 5	14 ± 6	.033
PAWP at 6 h (mm Hg)	19 ± 8	15 ± 5	.040
Lactate at 6 h (mmol/L)	9 ± 7	7 ± 6	>.3
Epinephrine ≥0.15 μg · kg ⁻¹ · min ⁻¹	12/24	96/193	>.3
Epinephrine ≥0.5 μg · kg ⁻¹ · min ⁻¹	2/24	27/193	>.3
Urine output at 8 h (mL/h)	73 ± 57	176 ± 202	.0001
Risk scores			
THI score ³	0.6 ± 0.2	0.7 ± 1.8	.116
Hausmann score ⁴	1.5 ± 1.0	1.0 ± 1.1	.021
ICU score ⁵	18.9 ± 6.0	17.7 ± 5.2	.272

A-a gradient, Alveolar-arterial oxygen gradient; BSA, body-surface area; CPB time, cardiopulmonary bypass time; CVP, central venous pressure; IABP, intra-aortic balloon pump; residual cardiac function, cardiac output on the device (at full device speed) – device flow; PAWP, pulmonary artery wedge pressure; CABG, coronary artery bypass graft; THI, Texas Heart Institute; ICU, intensive care unit.

*These values include the Impella Recover pump flow.

vivors and nonsurvivors were 540 ± 260 IU/L and 2747 ± 3070 IU/L, respectively, with no difference compared with the lactate dehydrogenase levels of all IABP patients (n = 198; survivors, 612 ± 387 IU/L; nonsurvivors, 1422 ± 1696 IU/L; $P > .3$). After weaning (16 patients), device removal was followed by ligation or oversewing of the vascular graft in all patients. No graft was entirely removed. Subsequently, heparin anticoagulation was stopped. There were no sternal wound infections in the Impella patients. Six (3%) of 198 IABP patients required a surgical groin revision for bleeding or ischemia.

Device Flow Data

The average pump flow was 3.3 ± 0.7 L/min in the first 12 hours. Figure 3 shows pump flow and device rotations per

minute for all patients. To evaluate maximal pump performance, all patients with the device set at a speed of 27,000 RPM or more were analyzed, resulting in a maximal pump flow of 3.5 ± 0.5 L/min. Average support time was 61 ± 56 hours (range, 7-228 hours): 60 ± 37 hours (range, 22-123 hours) in survivors and 62 ± 69 hours (range, 7-228 hours) in nonsurvivors. Sixteen patients were weaned off the device, and successful weaning with a survival time of longer than 72 hours was observed in 15 patients (63% of all Impella patients). Weaning practice was variable. Average weaning time was 19 ± 13 hours (range, 2-42 hours), with a tendency toward longer weaning times as experience with the device grew. Weaning usually consisted of gradually reducing the device flow as tolerated. The lowest pump

Figure 2. Bleeding and anticoagulation data of all Impella patients. A and B, Patients' chest tube output and transfusion requirements. C and D, Cumulative heparin dose given and results of the coagulation tests performed. The triangles (▲) represent patients who underwent a revision for bleeding; the other patients did not undergo surgical revision. ACT, Activated clotting time; aPTT, activated partial thromboplastin time; PRBC, packed red blood cells.

setting with a net flow of 0 was tested only for a few minutes at a time, and no patient remained on this minimal setting for a prolonged period of time.

Risk Scores

All risk scores had significant power to predict mortality in the cohort of IABP patients. Figure 4 shows the mortality rates of IABP patients (with 95% confidence interval) estimated from a logistic regression model by using each of the 3 risk scores as a covariate. The only risk score that seemed to correlate with mortality in Impella patients was the score described by Hausmann and colleagues⁴ (Table 3; $P = .051$).

Mortality

Table 3 shows the analysis of factors potentially associated with mortality in the Impella cohort. Patients with a residual cardiac output of 1 L/min or more above the pump flow of

the Impella device (estimated residual cardiac function) had a 10% (1/10) mortality, as opposed to 88% (8/9) in those with a residual cardiac function of 1 L/min or less ($P = .001$). Even though the cardiac index was also correlated with mortality, the strongest predictor for mortality was the residual cardiac function of the patients at 2, 6, and 12 hours. Nine of 10 patients with a residual cardiac output of 1 L/min or more survived and were discharged from the hospital. Figure 5 displays the relationship of residual cardiac function and survival.

The 10 patients with a residual cardiac function of 1 L/min or more had a significantly lower mortality compared with high-risk IABP patients, defined by a THI score of 0.75 or more ($n = 49$; mortality 55%; $P = .013$); a Hausmann score of 2 or more ($n = 28$; mortality 57%; $P = .012$); an ICU admission score of 21 or more ($n = 49$; mortality 51%; $P = .032$); an epinephrine dose of $0.14 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$

Figure 3. The average pump flow (A) and pump rotations (B) per minute of the Impella Recover.

or more, equivalent to high-dose epinephrine as defined by Samuels and colleagues² ($n = 96$; mortality 44%; $P = .046$); or a cardiac index at 6 hours of $2.3 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$ or less ($n = 43$; mortality 42%; $P = .039$).

The 4 patients who did not survive their hospital stay but were able to be successfully weaned from the device had a residual cardiac output between 0 and 1 L/min. No patient with a negative number of the residual cardiac function in the early postoperative phase could be weaned off the device.

In 6 patients, cardiogenic shock had been present for 4 or more hours before Impella insertion. All of them died. Causes of death in the Impella patients included multisystem organ failure in 10, ventricular arrhythmia in 2, and an intracranial hemorrhage in 1 patient that occurred 18 days after removal of the device.

Discussion

We present an early experience of 24 patients treated with the novel Impella Recover microaxial flow device for postoperative LOS. We were able to distinguish 2 subgroups of patients treated with the Impella Recover device. The first subgroup, patients with a residual cardiac function of 1 L/min or more, had a significantly lower mortality (10%) than high-risk IABP patients, regardless of the high-risk definition used. On the basis of patients' hemodynamics 2 hours after implantation, successful support and survival with the Impella Recover device was predictable in 9 of 10 patients with a residual cardiac output of 1 L/min or more. This is similar to another experience with the Hemopump device, where postoperative hemodynamics was the only predictive factor associated with patient survival.⁶ Contributing factors for better recovery in these patients have not

Figure 4. Mortality rates (with 95% confidence interval) estimated from a logistic regression model with the (A) ICU score ($n = 158$), (B) THI score ($n = 98$), and (C) Hausmann score ($n = 137$) as a covariate in IABP patients. The solid boxes are the observed mortality rates within the different risk scores in the same population. The black circle (●) shows the actual survival in Impella patients with a residual cardiac function of 1 L/min or more ($\pm$ SD), and the black triangle (▲) shows the survival of Impella patients with a residual cardiac function of 1 L/min or less ($\pm$ SD).

TABLE 3. Univariate analysis of mortality in Impella patients

Variable	Odds ratio	95% Confidence interval	P value
Preoperative parameters			
Creatinine	999.00	3.11-999.00	.026
Blood urea nitrogen	1.002	0.98-1.02	>.3
Hematocrit	0.93	0.77-1.12	>.3
Operative parameter			
Cardiopulmonary bypass time	0.99	0.98-1.00	.174
Postoperative parameters			
Cardiac index 6 h	0.34	0.10-1.17	.088
Cardiac index 12 h	0.064	0.01-0.78	.032
Residual cardiac function at 2 h	0.31	0.10-0.95	.041
Residual cardiac function at 6 h	0.27	0.08-0.87	.028
Residual cardiac function ≥ 1 L/min, 2 h	0.02	0.001-0.357	.008
Residual cardiac function ≥ 1 L/min, 6 h	0.01	0.001-0.260	.004
Residual cardiac function ≥ 1 L/min, 12 h	77.00	2.67-2222.00	.001
Pacing	21.0	1.94-227.2	.012
Heart rate	0.97	0.93-1.02	.290
Arterial bicarbonate	0.84	0.61-1.16	.29
Central venous pressure	1.10	0.92-1.33	.298
PAWP at 6 h	0.92	0.79-1.07	.295
Lactate at 6 h	1.14	0.96-1.36	.134
Epinephrine dose $>0.5 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$	127.9	0.28-999.00	.121
Epinephrine dose $>0.15 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$	6.00	1.02-35.37	.048
Urine output at 2 h	0.99	0.98-1.01	.237
Urine output at 8 h	0.98	0.96-1.00	.034
Risk scores			
THI score ³	5.61	0.06-542.40	>.3
Hausmann score ⁴	8.37	0.99-69.73	.051
ICU score ⁵	0.99	0.88-1.16	>.3

PAWP, Pulmonary artery wedge pressure; *residual cardiac function*, cardiac output on the device (at full device speed) – device flow; *THI*, Texas Heart Institute; *ICU*, intensive care unit. The following variables had no demonstrable correlation with mortality ($P > .3$): Preoperative factors—age, body-surface area, peripheral vascular disease, diabetes, hematocrit, previous cardiac operation, and acute myocardial infarction; operative factors—crossclamp time and postoperative revision; postoperative factors—lactate 2 h after surgery and alevolar-arterial oxygen gradient.

been well defined but possibly consist of partial left ventricular unloading by the device, adequate whole-body perfusion, and fewer catecholamine requirements.

In the second subgroup of Impella patients, we were able to identify patients who will not benefit from the Impella Recover device. Patients with a residual cardiac function of 1 L/min or less had an 88% chance of death. This observation is likely due to 2 factors. First, the Impella Recover device provides insufficient support in the presence of virtually absent myocardial function; second, patients with more extensive myocardial damage have less potential for myocardial recovery. The likely failure of therapy and the high probability of death in patients with a residual cardiac function of 1 L/min or less were predictable in 6 of 7 available cardiac function measurements at 2 hours after implantation. This seems important, because before leaving the operating room the decision to implant a conventional assist device can be made. Even without waiting 2 hours, these patients can probably easily be identified if they do not have any pulsatile output when CPB flow decreases to less than 2 to 2.5 L/min despite adequate filling. Such patients,

to have a realistic chance of survival, should receive a conventional assist device that is able to replace the entire left heart function. A significant early increase in residual cardiac function between 2 and 12 hours leading to survival was observed in only 1 patient (Figure 5). One patient had a significant decline in cardiac function between 6 and 12 hours after surgery, when he approached the cutoff point of a residual cardiac function of 1 L/min; this ultimately led to his death (Figure 5). If such a course were observed clinically in the future, a switch to a different device could be considered.

The surgical complication rate in Impella patients was similar to that in high-risk patients treated with IABP alone, which was lower than other experiences with left ventricular assist support.^{7,8} The observed device-related complications were minimal, with 1 device failure and 4 device repositions, all performed in the ICU. No observations of familiar problems associated with axial flow technology were made, including hemolysis and thromboembolic events, and no wound- or device-related infections were observed.

Figure 5. The residual cardiac function (cardiac output on the device – device flow) of 19 Impella patients is shown. Most patients with a residual function of 1 L/min or more survived (90%), as opposed to those with a residual function of 1 L/min or less (12%; $P = .001$).

It is interesting to note that the only risk score with predictive power in Impella patients was the Hausmann score ($P = .051$), despite a relatively low risk discrimination, as illustrated in Figure 4, C. This is most likely due to its focus on patient hemodynamics, which seem to outweigh most preoperative risk factors.

Our data do not support the indiscriminate use of this device, because no evidence could be shown that the use of the Impella Recover device in all patients with severe LOS can reduce mortality compared with high-risk IABP patients. It has to be re-emphasized that the Impella patients were substantially more ill, because they could not be separated from cardiopulmonary bypass or were hemodynamically unstable despite high doses of catecholamine support. Hence, the comparable overall mortality in all Impella patients and high-risk IABP patients gives only indirect evidence for a potential patient benefit with indiscriminate use of this device. Patients who become device dependent for postcardiotomy LOS have a mortality rate of 75% to 80%.⁸⁻¹⁰ Even in a recently published revised screening scale for left ventricular assist device recipients, the presence of postcardiotomy LOS was highly predictive of mortality.¹¹

Even when compared with all IABP patients, Impella patients with a residual cardiac function of 1 L/min or more seemed to have a survival benefit. Plotting their risk scores on the risk score survival curves of all IABP patients (including high- and low-risk patients) showed a higher survival than predicted, at the border of the 95% confidence interval (Figure 4).

The stratification of the Impella patients into those with a residual cardiac function of 1 L/min or more and those with virtually absent myocardial function (residual heart

function ≤ 1 L/min) allowed us to identify the patient cohort with a dramatic survival benefit. This observation seems to hold true despite the retrospective nature of this study, as well as the lack of a standard protocol for use of the Impella Recover device in this series. The analysis of this data mandates a standardized protocol for implantation of the Impella Recover device in patients with postcardiotomy LOS. The indications for the use of this device should be expanded for IABP patients with a high predicted mortality, and this device should no longer be used in patients with virtually absent myocardial function, because it is a true assist device that is unable to replace the entire left ventricular function.

In summary, the Impella Recover device is a low-cost microaxial assist device that pumps 3 to 4 L/min and is associated with a low complication rate. This study showed a survival benefit in mortally ill patients with postcardiotomy LOS if the patient's heart is able to contribute at least 1 L/min to the cardiac output in the immediate postoperative period.

References

1. Pae WE Jr, Miller CA, Matthews Y, Pierce WS. Ventricular assist devices for postcardiotomy cardiogenic shock. A combined registry experience. *J Thorac Cardiovasc Surg.* 1992;104:541-52; discussion 552-3.
2. Samuels LE, Kaufman MS, Thomas MP, Holmes EC, Brockman SK, Wechsler AS. Pharmacological criteria for ventricular assist device insertion following postcardiotomy shock: experience with the Abiomed BVS system. *J Card Surg.* 1999;14:288-93.
3. Baldwin RT, Slogoff S, Noon GP, Sekela M, Frazier OH, Edelman SK, et al. A model to predict survival at time of postcardiotomy intraaortic balloon pump insertion. *Ann Thorac Surg.* 1993;55:908-13.
4. Hausmann H, Potapov EV, Koster A, Siniawski H, Kukucka M, Loebe M, et al. Predictors of survival 1 hour after implantation of an intra-aortic balloon pump in cardiac surgery. *J Card Surg.* 2001;16:72-7.

5. Higgins TL, Estafanous FG, Loop FD, Beck GJ, Lee JC, Starr NJ, et al. ICU admission score for predicting morbidity and mortality risk after coronary artery bypass grafting. *Ann Thorac Surg.* 1997;64:1050-8.
6. Meyns B, Sergeant P, Wouters P, Casselman F, Herijgers P, Daenen W, et al. Mechanical support with microaxial blood pumps for postcardiotomy left ventricular failure: can outcome be predicted? *J Thorac Cardiovasc Surg.* 2000;120:393-400.
7. Goldstein DJ, Oz MC, Rose EA. Implantable left ventricular assist devices. *N Engl J Med.* 1998;339:1522-33.
8. Noon GP, Ball JW Jr, Short HD. Bio-Medicus centrifugal ventricular support for postcardiotomy cardiac failure: a review of 129 cases. *Ann Thorac Surg.* 1996;61:291-5; discussion 311-3.
9. Pae WE Jr. Ventricular assist devices and total artificial hearts: a combined registry experience. *Ann Thorac Surg.* 1993;55:295-8.
10. Helman DN, Morales DL, Edwards NM, Mancini DM, Chen JM, Rose EA, et al. Left ventricular assist device bridge-to-transplant network improves survival after failed cardiomy. *Ann Thorac Surg.* 1999;68:1187-94.
11. Rao V, Oz MC, Flannery MA, Catanese KA, Argenziano M, Naka Y. Revised screening scale to predict survival after insertion of a left ventricular assist device. *J Thorac Cardiovasc Surg.* 2003;125:855-62.

Discussion

Dr Ludwig K. von Segesser (Lausanne, Switzerland). Dr Siegenthaler, I would like to congratulate you for this excellent presentation on an important topic.

There has been significant progress in the development of axial flow pumps for temporary assist, and you can see in the background [slide] the initial Hemopump for peripheral access, then in the middle the one for central access, and finally the percutaneous one. These pumps had a drive shaft, and I think one of the major improvements with the current Impella device is that the drive shaft has disappeared; the second major difference is that there are sensors now available that give us some information about pump positioning and flow.

I have 3 questions. You have already alluded to the bleeding issue. I would like to know if there was a problem with platelet consumption with this pump and if any of the deaths were related to bleeding.

The second question is about thrombosis. There have been emboli, I think, central emboli, but have the explanted pumps been analyzed, and, if yes, were there any deposits?

Finally, what is your weaning protocol, or, in other words, what would be the mean pump speed (RPM) required for 0 flow at a mean arterial pressure of about 60 mm Hg?

Dr Siegenthaler. Thank you very much for those kind comments and questions. Four Impella patients needed to go back to the operating room because of bleeding. All required several transfusions. In 3 of them, no surgical source of bleeding was evident. The question of whether bleeding was responsible for the patients' deaths is difficult to answer. Certainly, no patient died directly related to exsanguinating hemorrhage. Also, the incidence of bleeding was no different in Impella patients than in high-risk IABP patients. The cause of death in most of the 13 nonsurvivors with the Impella pump was multisystem organ failure. Transfusions certainly can be a contributing factor to such a syndrome and therefore also could have been a factor leading to adverse outcomes. We observed no platelet consumption.

As to thromboembolic events, we know from the carotid literature that surgeons do not have the same horizon to detect such events as neurologists. I can tell you with certainty only that there were no obvious strokes. One patient had a major intracranial hemorrhage from which he died 18 days after successful removal of the device, and we cannot rule out completely that he had bleeding into a small and previously asymptomatic embolic area of his brain.

We looked at all the pumps when we explanted them, and we could not see any residual fibrin or thrombi in the pumps. But this information has to be viewed with caution, as there was no systematic analysis of these pumps.

The pump is suitable for a slow weaning process, as it can be set at 10 different speed levels, up to 33,000 RPM. At the lowest pump setting, the pump just overcomes the mild aortic insufficiency that it causes. This allows assessment of the patient's native heart function at the bedside. Gradual weaning has been more successful than our initial procedure, in which we evaluated the ventricular performance with echocardiography at full or only slightly reduced device speed. If satisfactory contractility was found, we went to the operating room and tried to turn off the pump. This approach was sometimes not well tolerated. We now try to observe the patient in the ICU at a low pump setting after a slow weaning process before proceeding to the operating room to explant the device.

Dr O. Howard Frazier (Houston, Tex). This pump, of course, is an extension and refinement of the Hemopump we first used in 1988. The Hemopump was powered by a cable, and its most effective use was in the postcardiotomy patient. This was aborted because the investors felt that there was not a big enough market, and I have always felt that this was the 1 technology that would be so important to directly unload the ventricle without requiring heparinization or anticoagulation, which we did not use in the immediate postoperative period with the Hemopump. Because the Hemopump had a cable, we sewed the graft on to keep the cable from fracturing.

Now, this pump is powered with an electric wire, and it is much more effective from that standpoint. Do you think you could get rid of the graft altogether, since those grafts are not inexpensive and simply use a purse-string suture? The other question is, was heparinization continued in the immediate postoperative period?

Dr Siegenthaler. Thank you very much for those questions. Vascular grafts are expensive indeed; we pay about 500 Euro for such a 10-mm Vascutek graft at our institution.

Nobody at our institutions has tried to insert the device without a vascular graft, just by using a purse-string suture with a tourniquet. I could imagine that in a patient with a soft aorta this might be actually possible, similarly to how we do it for thoracic intra-aortic balloon pumps. But I think it would be risky to avoid the use of a graft in the presence of a diseased aorta.

We use no anticoagulation therapy in the early postoperative period until bleeding has subsided. Then we start heparin at 500 U/h and gradually increase it to a partial thromboplastin time of 50 to 60 seconds. The risk of pump thrombosis seems small even if patients are not systemically anticoagulated, because the pump is continuously purged with a low-dose heparin-containing solution.