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Is Off-Pump Revascularization Better for Patients with Non–Dialysis-Dependent Renal Insufficiency?

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ABSTRACT

Background: Renal dysfunction is a well-recognized complication following coronary artery bypass grafting (CABG). Coronary revascularization without cardiopulmonary bypass (CPB) has been shown to minimize renal injury in patients with normal preoperative renal function who undergo elective procedures. The purpose of this study was to define the effect of an off-pump revascularization strategy on the incidence of postoperative renal failure and survival of patients with preexisting renal dysfunction.

Methods: From January 1, 1999, to December 1, 2002, a total of 371 patients were identified as having a preoperative creatinine concentration greater than or equal to 1.5 mg/dL. This number included 291 patients who did not need hemodialysis or peritoneal dialysis to support renal function. These patients were subdivided into those undergoing traditional CABG with CPB (103 patients) and those undergoing off-pump revascularization (188 patients) whose demographic, operative, and outcome information was retrospectively reviewed and compared.

Results: The off-pump cohort was older than the on-pump cohort (70 ± 9.6 versus 66 ± 10.9 years; $P = .002$), had a lower prevalence of previous myocardial infarction (35% versus 50%; $P = .008$), and had a modestly higher mean left ventricular ejection fraction (0.47 ± 0.01 versus 0.43 ± 0.01; $P = .017$). Otherwise the groups were well matched. The mean preoperative serum creatinine and creatinine clearance values were not significantly different (1.8 ± 0.5 versus 1.9 ± 0.6 mg/dL [$P = .372$] and 45.1 ± 15.5 versus 46.8 ± 17.2 mL/min [$P = .376$] for the off-pump and on-pump cohorts, respectively). There was a significant reduction in postoperative renal failure (17% versus 9% of patients; $P = .020$) and need for new dialysis (10% versus 3% of patients; $P = .022$) when CPB was eliminated. Intermediate-term survival analysis revealed a survival benefit for the off-pump group (70% versus 57%) at 42 months, although this value did not reach statistical significance ($P = .143$).

Conclusion: The results of this study suggested that patients with preoperative non–dialysis-dependent renal insufficiency have more favorable outcome when revascularization is done off pump. Avoidance of CPB results in (1) a reduction in the incidence of postoperative renal failure; (2) a reduction in the need for new dialysis; and (3) improved in-hospital and midterm survival.

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INTRODUCTION

Renal dysfunction is a well-recognized complication following coronary artery bypass grafting (CABG). The reported incidence varies considerably (from 1% to 40%) [Abel 1976, Ascione 2001, Tang 2002]. The etiology is multifactorial and includes advanced age, preexisting renal insufficiency, compromised preoperative ventricular function, prolonged aortic cross-clamp time, postoperative low cardiac output state, and the use of cardiopulmonary bypass (CPB) [Ascione 2001, Loef 2002, Tang 2002]. The deleterious action of CPB on renal function is mediated by several mechanisms, including the systemic inflammatory response, nonpulsatile flow, hypoperfusion, emboli, and myocardial dysfunction [Ascione 2001, Gerritsen 2001, Tang 2002]. These effects result in damage to the glomerular and tubular structures. This damage can lead to renal dysfunction, especially in the presence of additional risk factors [Loef 2002].

Coronary revascularization without CPB has been shown to minimize renal injury in patients with normal preoperative renal function who undergo elective procedures [STS 2003]. This benefit has recently been extended to include patients with non–dialysis-dependent renal insufficiency (NDDRI) [Ascione 2001]. The purpose of this study was to assess the effect of off-pump coronary revascularization in patients with preoperative NDDRI.

MATERIALS AND METHODS

Our prospectively updated database was queried to identify all patients who underwent isolated coronary revascularization at Newark Beth Israel Medical Center and Saint Barnabas Hospital between January 1, 1999, and December 1, 2002. A total of 2747 patients were identified, 371 of whom had a preoperative creatinine concentration ≥1.5 mg/dL. This number included 291 patients who did not need hemodialysis or peritoneal dialysis to support renal function. This subset was divided into those undergoing traditional CABG with

CPB and those undergoing off-pump coronary artery bypass (OPCAB). The decision for which technique was used was decided by the individual surgeon at the time of operation. The database query yielded 103 CABG patients and 188 OPCAB patients, whose demographic and clinical information was retrospectively reviewed.

General Operative Technique

All patients underwent revascularization under general endotracheal anesthesia. Continuous-output Swan-Ganz catheter, transesophageal echocardiography (TEE) probe, and arterial pressure monitoring lines were placed. A thorough TEE examination was performed to assess wall-motion abnormalities, presence and degree of mitral regurgitation, severity of atherosclerotic disease of the aorta, and right and left ventricular function. Significant atherosclerotic disease (eg, mobile atheromata and wall thickening) of the aortic arch and/or descending aorta at times prompted evaluation of the ascending aorta with an epicardial echo probe. Presence of >2+ mitral insufficiency precluded an off-pump procedure, and conventional CPB was undertaken with mitral valve repair (these patients were not included in the study group because any patients undergoing any combined procedures were excluded).

Technique of Off-Pump Coronary Artery Bypass

All operations were performed through a median sternotomy incision. Briefly, the conduits (left internal mammary artery, radial artery, and/or saphenous vein) were harvested, and the pericardium was opened widely. Elevation and stabilization of the heart were accomplished with 4 deep pericardial sutures and snare protectors. The right pleura was opened widely. Pericardial sutures were not routinely used on the right side of the heart. In general, distal anastomoses were performed first, and the aorta was partially occluded only once. Collateralized vessels were grafted first. The anastomoses were performed with the aid of the Octopus 2 or Octopus 3 (Medtronic, Minneapolis, MN, USA) stabilizing system. Full systemic heparinization and complete protamine reversal were used in most instances. No antifibrinolytic therapy (ie, aminocaproic acid, aprotinin) was used. Intracoronary shunts were occasionally used for grafting a large dominant right coronary artery system. No partial bypass circuits or adjunctive apical retracting devices were used. Selective graft flow assessment with intraoperative Doppler (Medi-Stim butterfly flowmeter; Medtronic) was performed after all distal anastomoses were completed at the surgeon's discretion.

Technique of Conventional CABG

Briefly, preparation for CPB included activated clotting time–guided heparinization, cannulation of the ascending aorta, and atrial cannulation. Operations proceeded under moderate hypothermia (32°C) and with the use of antegrade and retrograde cold blood cardioplegia. In most instances, proximal anastomoses were created with a 1-clamp technique.

Definitions

NDDRI was defined as a serum creatinine concentration of 1.5 mg/dL or greater not requiring hemodialysis [STS 2003]. Postoperative acute renal failure was defined according to STS guidelines as doubling of the preoperative creatinine level or new need for dialysis. Creatinine clearance was calculated with the Cockroft-Gault equation [Cockcroft 1976]. Postoperative creatinine clearance was calculated with the highest postoperative creatinine value.

Statistical Analysis

Data were analyzed with the SigmaStat for Windows statistical software package (SPSS Science, Chicago, IL, USA). Clinical information was summarized by mean ± SD for continuous variables and absolute number with percentage for categorical variables. Univariate analyses of continuous variables were completed with independent-samples *t* test. Categorical values were analyzed with χ^2 or Fisher exact test when appropriate. Survival analyses were completed with Kaplan-Meier techniques to determine actuarial survival and were compared using the log-rank statistic (WinSTAT; R. Fitch Software, Staufen, Germany). Predictors of postoperative renal failure were determined with univariate analysis, and values deemed significant were subjected to multivariate logistic regression analysis. A *P* value less than .05 was used to assign statistical significance.

All-cause mortality through November 30, 2002, was ascertained by telephone interview and use of the National Death Index (US Department of Health and Human Services). Queries were conducted with a combination of Social Security number, name, date of birth, and state of last known residence. The sensitivity of the National Death Index for identifying deaths is between 92% and 99%, depending on the identifiers available [Williams 1992].

RESULTS

Two hundred ninety-one consecutive patients with NDDRI underwent coronary revascularization during the study period. The ages ranged from 37 to 89 years with a mean age of 69 years. Nineteen percent (54) of the patients were female, 55% (162) had preexisting diabetes mellitus, and 65% (190) had a history of hypertension. Figure 1 depicts the creatinine clearance of the study population according to the Cockroft-Gault formula.

The demographic profiles and clinical characteristics of the CABG and OPCAB groups are compared in Table 1. The off-pump group proved to be older than the on-pump cohort (70 ± 9.6 years versus 66 ± 10.9 years; *P* = .002) and had a lower prevalence of previous myocardial infarction (35% versus 50%; *P* = .008). Furthermore, the mean left ventricular ejection fraction of the OPCAB group was 47% ± 1.0%, a value significantly better than that of the CABG group (43% ± 1.4%; *P* = .017). Otherwise the groups were well matched. The use of preoperative inotropes and other medications was similar in the two groups.

The operative profile is summarized in Table 2. All patients underwent isolated coronary revascularization; however, there were 20 reoperations (11% in the CABG group versus 5% in the OPCAB group; *P* = .05). When possible, arterial conduits were used (the internal mammary and/or the

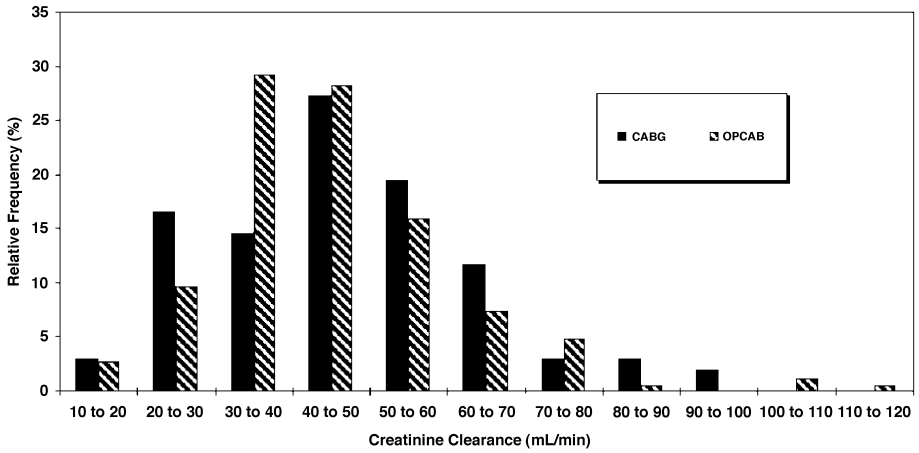

Figure 1. Histogram depicting the estimated creatinine clearance values in the study population. CABG indicates coronary artery bypass grafting; OPCAB, off-pump CABG.

radial artery was used in 91% of OPCAB and 89% of CABG cases). Off-pump operations were completed with a statistically significant decrease in operative time. Three off-pump procedures were converted to on-pump revascularization because of hemodynamic instability. Because the analysis was conducted with an intention-to-treat method, these subjects remained in the OPCAB group. Analysis of the results by treatment received was done in an attempt to identify changes

Table 1. Demographic Data of Patients with Non–Dialysis-Dependent Renal Insufficiency*

	CABG (n = 103)	OPCAB (n = 188)	*P*
Age, mean ± SD (range), y	66.5 ± 11.0 (37-89)	70.3 ± 9.6 (43-87)	.003†
Creatinine clearance, mean ± SD (range), mL/min	46.8 ± 17.2 (12-95)	45.1 ± 15.5 (17-119)	.376
Ejection fraction	43% ± 1.4%	47% ± 1.0%	.017†
>49%, n	42 (41%)	99 (53%)	.034†
30%-49%, n	44 (43%)	73 (39%)	.780
<30%, n	31 (30%)	30 (16%)	.004†
Female patients, n	20 (19%)	34 (18%)	.672
Congestive heart failure, n	55 (53%)	55 (29%)	.083
Chronic obstructive pulmonary disease, n	18 (17%)	27 (14%)	.809
Diabetes, n	61 (59%)	101 (54%)	.218
Family history of CA disease, n	17 (17%)	17 (9%)	.980
Hemodynamic instability, n	9 (9%)	8 (4%)	.099
Hypercholesterolemia, n	57 (55%)	57 (30%)	.783
Hypertension, n	95 (92%)	95 (51%)	.573
Left main stenosis ≥50%, n	26 (25%)	54 (29%)	.311
NYHA class III-IV, n	38 (37%)	84 (45%)	.122
Obesity, n	31 (30%)	45 (24%)	.900
Preoperative use of inotropes, n	5 (5%)	11 (6%)	.475
Previous stroke, n	13 (13%)	13 (7%)	.745
Previous myocardial infarction, n	51 (50%)	65 (35%)	.008†
Smoking history, n			.070
Current	19 (18%)	21 (11%)	
Former	42 (41%)	101 (54%)	
Never	41 (40%)	66 (35%)	
Surgical priority, n			.805
Elective	28 (27%)	58 (31%)	
Urgent	70 (68%)	121 (64%)	
Emergency	5 (5%)	9 (5%)	

*CABG indicates coronary artery bypass grafting; OPCAB, off-pump CABG; NYHA, New York Heart Association.

†Statistically significant.

Table 2. Operative and Perioperative Data*

Variable	CABG (n = 103)	OPCAB (n = 188)	*P*
Conduit, n			
Mammary artery distal	0.9 ± 0.4	0.9 ± 0.5	.595
Radial artery distal	0.5 ± 0.8	0.6 ± 0.8	.225
Total grafts	3.7 ± 1.1	3.6 ± 1.2	.432
Time, h			
Skin-skin time	5.2 ± 1.6	4.1 ± 0.1	<.001†
Total CPB time	2.3 ± 1.0	1.0 ± 0.9‡	.079
Total cross clamp time	1.5 ± 0.5		—
Total intubation time	36.1 ± 65.6	24.0 ± 49.2	.108
Postoperative length of stay, d	10.3 ± 6.4	9.2 ± 6.3	.173

*Data presented as mean ± SD. CABG indicates coronary artery bypass grafting; OPCAB, off-pump CABG; CPB, cardiopulmonary bypass.

†Statistically significant.

‡Three conversions.

in outcome when actual-OPCAB patients were compared with intended-OPCAB patients. With the exception of the development of postoperative atrial fibrillation in 1 patient, there was no morbidity or mortality in the 3 conversions. In addition, there were no late deaths in this group, so the inclusion of the patients in either group did not affect the statistical significance of the analysis.

Clinical outcome is shown in Table 3. The most prevalent adverse outcomes in the combined cohorts were the postoperative development of renal failure (37% of all patients) and atrial fibrillation (31% of patients). Twenty-one percent of the OPCAB group also needed ventilation for more than 24 hours. There was a 22% reduction in mean creatinine clearance from preoperative value to highest postoperative value in the CABG group compared with 7% in the OPCAB group ($P < .001$). Likewise, development of postoperative renal failure and the subsequent need for new dialysis were higher for the on-pump group. Univariate predictors of postoperative renal failure are represented in Table 4. Likely because of the small number of events, multivariate predictors could not be identified. In terms of crude in-hospital mortality there was a significant decrease (7% versus 2%; $P = .049$) when CPB was eliminated. Of the 7 CABG deaths 5 were due to cardiac causes, 1 death was due to multisystem organ failure, and one death was due to pulmonary complications. Two of the 4 OPCAB deaths were due to cardiac causes, 1 patient had postoperative mesenteric ischemia, and the other died of overwhelming sepsis. The mean follow-up time was 20.2 ± 13.4 months (range, 0.3-47.4 months). Kaplan-Meier estimates of survival are depicted in Figure 2. Interestingly, the 1-year (84% versus 92%; $P = .026$) and 2-year (76% versus 85%; $P = .039$) survival rates significantly favored OPCAB, but the log-rank statistic of the entire survival curve did not reveal a significant difference ($P = .143$).

DISCUSSION

It is undeniable that end-stage renal failure adversely affects early and long-term outcome of cardiac surgery [Herzog 1999, Liu 2000, Dacey 2002, Szczech 2002]. Results of studies with patients with renal insufficiency not supported by dialysis also have shown an adverse influence of renal dysfunction on CABG outcome [Rao 1997, Penta de Peppo 2002, Nakayama 2003].

In the presence or absence of preexisting renal disease, CPB itself seems to repeatedly emerge as a risk factor for postoperative renal failure. While the popularity of off-pump coronary revascularization has been increasing in recent years,

Table 3. Postoperative Clinical Outcome*

	CABG (n = 103)	OPCAB (n = 188)	*P*
Atrial fibrillation, n	32 (31%)	58 (31%)	.570
Cerebrovascular accident, n	1 (1%)	1 (1%)	.876
Multisystem organ failure, n	2 (2%)	3 (2%)	.760
Pneumonia, n	3 (3%)	4 (2%)	.796
Postoperative myocardial infarction, n	3 (3%)	2 (1%)	.240
Pulmonary edema, n	2 (2%)	4 (2%)	.523
Reoperation for bleeding, n	5 (5%)	8 (4%)	.709
Septicemia, n	2 (2%)	4 (2%)	.640
Sternal wound infection, n	0 (0%)	6 (3%)	.071
Ventilated >24 h, n	29 (28%)	34 (18%)	.983
Postoperative renal failure, n	18 (17%)	16 (9%)	.020†
Postoperative hemodialysis, n	10 (10%)	6 (3%)	.022†
Any complications, n	72 (70%)	103 (55%)	.008†
Readmission within 30 d, n	5 (5%)	15 (8%)	.225
In-hospital mortality, n	7 (7%)	4 (2%)	.049†

*CABG indicates coronary artery bypass grafting; OPCAB, off-pump CABG.

†Statistically significant.

Table 4. Univariate Predictors of Postoperative Renal Failure*

Variable	χ^2	*P*
Hemodynamic instability	21.896	<.001
Cardiogenic shock	17.808	<.001
Age ≥80 y	12.208	<.001
Intraoperative/postoperative IABP	9.660	.002
Anticoagulant use	7.685	.006
Reoperation	6.982	.008
Use of β-blockers	5.514	.019
Preoperative IABP	5.514	.019
Previous cardiovascular intervention†	5.239	.022
Creatinine clearance <45 mL/min	5.080	.024
Cardiopulmonary bypass	4.744	.029
Emergent operation	4.065	.044
Use of angiotensin-converting enzyme inhibitor	3.848	.050
Left main disease ≥50%	3.617	.057
Inotrope use	2.909	.088
History of myocardial infarction	2.688	.101

*IABP indicates intraaortic balloon pump.

†Includes percutaneous and operative intervention.

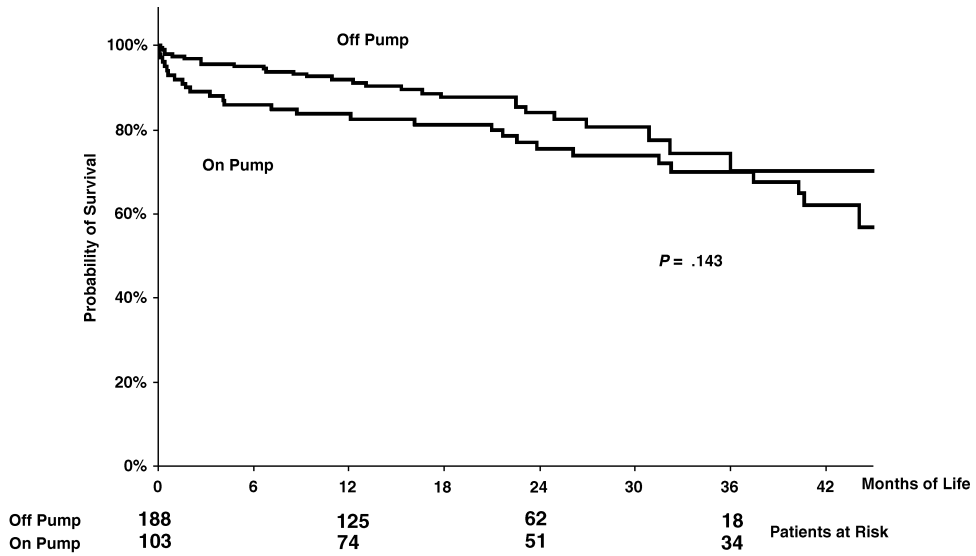

Figure 2. Kaplan-Meier survival curves for patients with non–dialysis-dependent renal insufficiency.

many investigators have sought to prove whether the absence of CPB would attenuate risk. The earliest randomized study addressing this hypothesis was conducted by Ascione and colleagues [1999]. These investigators concluded that OPCAB clearly offered better protection of renal function than CABG with CPB and cardioplegic arrest in 50 low-risk patients. Subsequent studies had contrary findings. Tang and colleagues [2002] randomized 45 low-risk patients to either conventional CABG or OPCAB. These investigators found that postoperative renal injury after cardiac surgery was transient. The authors ultimately concluded that, at least in low-risk patients, avoidance of CPB does not offer a significant benefit. Results of other investigations tended to agree that the renal damage was subclinical and the benefit of avoiding CPB was trivial [Gamosos 2000, Gerritsen 2001, Loef 2002].

Similar to studies of renal injury in conventional coronary revascularization, most off-pump investigations tended to exclude patients with preoperative renal injury. Accordingly, a review of the literature reveals only 1 study addressing off-pump revascularization in patients with NDDRI. Ascione and colleagues [2001] retrospectively reviewed the cases of 51 OPCAB and 202 CABG patients with preoperative renal insufficiency. Except for a lower number of grafts per patient in the OPCAB group (2.3 versus 2.9; $P < .001$), the groups were very well matched. The on-pump group had a significantly higher incidence of stroke and acute renal failure requiring dialysis. Furthermore, the authors stated that the significant differences in postoperative serum creatinine concentration between CABG and OPCAB patients were only transient.

In an effort to enhance the limited experience with patients with preoperative NDDRI, we describe our institutional experience in these patients. The level of 1.5 mg/dL of serum creatinine chosen as a cutoff for defining preoperative NDDRI was used in this study in accordance with previously published data [Szczech 2002, Nakayama 2003]. Moreover, a review of risk factors for postoperative renal dysfunction after conventional CABG in 38,874 isolated CABG patients [Chertow 1997] confirmed the strong predictive power of preoperative creatinine concentration in excess of 1.5 mg/dL. In the current study, the mean preoperative creatinine value was 1.85 mg/dL in OPCAB patients and 1.92 mg/dL in CABG patients ($P = .373$). Similarly, the mean creatinine clearance values were not statistically different (45.1 versus 46.9 mL/min; $P = .376$). Despite similar preoperative values in the current study, the postoperative creatinine clearance values were markedly lower in the CABG group (42.0 versus 36.9 mL/min; $P = .037$). The mean change in creatinine clearance was equally as significant (3.4 ± 13 mL/min [OPCAB] versus 9.9 ± 13 mL/min [CABG]; $P < .001$). Furthermore, the need for new dialysis in the OPCAB group was significantly less (3% versus 10%; $P = .022$). As may authors report, postoperative need for new dialysis is an independent predictor of mortality in cardiac surgery patients [Chertow 1998, Mangano 1998, Durmaz 1999]. Of the 16 patients (10 CABG, 6 OPCAB) who needed postoperative dialysis, 4 remained on dialysis, and only 1 no longer needed this support. The other patients died (n = 10) or could not be reached (n = 1).

The mean STS-predicted risk of mortality was 4.3% (0.5%-39.6%) in the OPCAB patients and 4.7% (0.6%-37.9%) in the CABG patients. This value resulted in observed to expected ratios of 0.5 and 1.5, respectively. Because this finding proved noteworthy, we tried to determine whether the value translated into longer-term benefit for OPCAB patients. The 1-, 2-, and 3-year survival rates showed a significant survival benefit in the early outcome analysis. However, as we approached longer-term follow-up, fewer patients were available for comparison, and the statistical significance diminished.

Although the results of the current study were encouraging, several limitations existed. First was the retrospective design of the study. The second and probably the most profound limitation was the potential introduction of selection bias. The decision to proceed with OPCAB or conventional CABG was the

sole decision of the operating surgeon at the time of operation and usually was based on anatomic or clinical findings. Over the past 3 years, however, we have approached all revascularization patients as potential off-pump candidates and have tended to select patients for OPCAB preferentially when we believe the patient would benefit most from elimination of CPB. These patients tend to be the sicker patients with greater comorbid conditions. Last, renal insufficiency was defined on the basis of 1 creatinine measurement; therefore some values may have represented variability outside the normal range caused by fluctuations in hemodynamics and may not represent true parenchymal disease.

In conclusion, the results of this study suggest that patients with preoperative NDDRI have more favorable outcome when revascularization is done off pump. Avoidance of CPB results in (1) a reduction in the incidence of postoperative renal failure; (2) a reduction in the need for new dialysis; and (3) improved in-hospital and midterm survival. We believe that randomized trials and longer-term follow-up are needed to confirm these encouraging findings.

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