

Outcome of Patients Requiring Valve Surgery During Active Infective Endocarditis

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Background. The optimal timing of cardiac operations in patients with infective endocarditis continues to be debated. This observational study analyzed the profile and outcome of patients with active infective endocarditis undergoing operations.

Methods. Between June 2000 and June 2006, 95 surgically treated patients with definite infective endocarditis by the modified Duke criteria were included.

Results. Fifty-eight patients were operated on within the first 7 days after diagnosis of infective endocarditis and 37 at more than 7 days after diagnosis up to immediately after completion of antibiotic treatment. Staphylococci predominated and were significantly associated with embolism, abscess, and septic shock. The most frequent indication for operation was severe regurgitation with heart failure. The 6-month mortality was 15%. Early operation showed a trend towards increased mortality vs late operation. In univariable analysis, factors associated with 6-month mortality included staphylo-

cocci and septic shock. Multivariable analysis revealed that septic shock predicted 6-month mortality. Despite early operation in patients experiencing septic shock, 57% died. No patients without heart failure died after undergoing (early or late) procedures for severe regurgitation.

Conclusions. The prognosis in surgically treated patients was determined by the occurrence of septic shock. The outcome in patients who underwent late operations was favorable compared with the early group. This difference was probably not due to the timing of the surgical intervention but to the severity of infective endocarditis. In patients with severe regurgitation without heart failure, early operation may offer benefit in length of hospitalization and prevention of development of new heart failure.

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The percentage of surgical intervention in patients with infective endocarditis (IE) in previous series varied from 18% to 63%, depending of the hospital setting. Increasingly, clinicians tend to proceed to operation [1–7]. The favorable outcome of valve surgery for IE in previous series has contributed considerably to this evolving trend [1, 2], although this was recently challenged [8].

The timing of operation is still a matter of debate. Surgical intervention is optimally performed before severe hemodynamic disability or spread of the infection to perivalvular tissue [9]. Previous studies have shown that patients for whom early operation would be associated with a better outcome included patients with staphylococcal prosthetic valve endocarditis (PVE) [10–12]; however, other studies did not confirm that early valve replacement was associated with improved overall outcome in patients with *Staphylococcus aureus* PVE [13].

Most previous studies defined early or urgent cardiac operation as a procedure performed before termination

of antibiotic treatment [14, 15]. In this study we wanted to differentiate more in this nonhomogenous patient group. We therefore defined early operation as surgical intervention within 7 days after diagnosis of IE and late operation as an intervention occurring more than 7 days after diagnosis of IE up to immediately after completion of antibiotic therapy. This 6-year observational cohort study aimed to investigate the profile and outcome of patients undergoing valvular operation for active IE.

Patients and Methods

Patient Selection

Between June 2000 and June 2006, we prospectively collected 256 consecutive patients, aged older than 16 years, with definite IE according to the modified Duke's criteria [16], in a tertiary referral center. The present report studied 95 surgically treated patients with left-sided IE. These patients underwent cardiac operation according to predefined criteria for surgical intervention [17]. All patients were treated according to the American Heart Association guidelines [18] and were seen by a cardiologist, cardiac surgeon, and infectious diseases physician. When the microorganism had not been iden-

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Table 1. Preoperatively Diagnosed Complications

Complication	No (%)
Patient total	95 (100)
Embolism	22 (23)
Congestive heart failure	51 (54)
Septic shock	7 (7)
Cardiogenic shock	8 (8)
Severe regurgitation $\geq 3/4$	65 (68)

tified at admission, patients with native valve IE received antimicrobial therapy with flucloxacillin, ampicillin, and gentamicin, and patients with prosthetic valve IE (PVE) received antimicrobial therapy with vancomycin, gentamicin, and rifampicin. The Ethics Committee approved this study and waived the need for individual patient consent.

We excluded 2 patients with postponed cardiac operation due to cerebral bleeding and 3 patients with perioperatively detected IE. One patient who initially decided to refuse operation was excluded. The study excluded 26 patients who were referred to our center more than 7 days after initiation of adequate antibiotic therapy.

Data Collection

All data were prospectively collected in a database following a predefined protocol and independently reviewed by 3 experts [7].

Cardiac Operation

Cardiac surgical interventions were performed according to predefined criteria [17]. Indications included severe valvular regurgitation with and without heart failure, abscess or perivalvular extension, failure of conservative medical treatment, and large vegetations exceeding 10 mm with high risk of embolization or (recurrent) embolization during antibiotic treatment.

Complications before and after surgical intervention and IE-related outcome up to 6 months follow-up were registered.

Definitions

Nosocomial IE was defined as IE occurring more than 72 hours after admission to the hospital or IE acquired in association with a significant invasive procedure performed during a recent hospitalization within 8 weeks before this hospitalization [2].

Prosthetic valve endocarditis was classified as early PVE within 12 months after cardiac operation and late PVE after 12 months [11].

Early cardiac operation was defined as surgical intervention within the first 7 days after diagnosis of IE and late cardiac operation as a procedure more than 7 days after diagnosis of IE up to immediately after completion of antibiotic treatment. The definition of “early” operation in most published studies was “valve replacement during the course of antimicrobial therapy.” However,

the early operation groups consisted of patients who were operated on within the first week of antimicrobial therapy up to the end of antibiotic therapy. The clinical profile of patients requiring cardiac operation within the first week of antimicrobial therapy might have differed from patients in whom intervention was performed in the last week before the end of antimicrobial therapy. Therefore, we aimed to divide this heterogeneous group and decided to choose a cutoff of 7 days. If IE is associated with destructive and aggressive microorganisms, complications occur mainly early during the course of IE compared with low-virulent pathogens.

Statistical Analysis

Continuous data are presented as medians and interquartile ranges (IQR), unless stated otherwise. Continuous variables were compared with the Mann-Whitney *U* test and categorical variables with the χ^2 test or the Fisher exact test. To assess linearity, the quadratic age effect was introduced in the model and was not statistically significant. Variables that tended to be significantly associated with early operation or death in univariable analysis were included in the multivariable logistic regression analysis. Multivariable logistic regression analysis was performed to identify independent factors for early operation and death. The significance level used in univariable and multivariable analysis was $p < 0.05$. All the reported *p* values were two-sided. Statistical analysis was performed with the SPSS 12.0 software (SPSS Inc, Chicago, IL).

Results

Clinical Characteristics

The study included 95 IE patients, with a median age of 65 years (IQR, 54 to 73 years) and a male/female ratio of nearly 3/2. Of the 95 patients, 59 were referred to our hospital. Prosthetic valves were involved in 23 patients, of whom 11 underwent early operation and 12 late procedures. Nosocomial IE was present in 18 patients. The most frequent comorbid conditions were chronic obstructive pulmonary disease (COPD) in 11 patients and diabetes mellitus in 8 patients.

Staphylococci predominated and were the causative microorganisms in 35 patients. Methicillin-resistant *Staphylococcus aureus* (MRSA) was present in 4 patients. Streptococci were reported in 23 patients, followed by

Table 2. Postoperatively Diagnosed Complications

Complication	No (%)
Patients, total	95 (100)
Embolism	6 (6)
Congestive heart failure	6 (6)
Septic shock	5 (5)
Cardiogenic shock	2 (2)
Relapse	4 (4)
Surgical reintervention	13 (14)

Table 3. Complications According to the Causative Microorganism

Complication	Staphylococci, No. (%)	Streptococci, No. (%)	Enterococci, No. (%)	Culture-negative, No. (%)	Other, ^a No. (%)
Patient, total	35 (100)	23 (100)	20 (100)	15 (100)	2 (100)
Embolism	15 (43)	4 (17)	6 (30)	0	0
Heart failure	13 (37)	14 (61)	9 (45)	13 (87)	2 (100)
Abscess	22 (63)	5 (22)	2 (10)	5 (33)	2 (100)
Prosthetic valve dehiscence	6 (17)	2 (9)	1 (5)	4 (27)	1 (50)
Cardiogenic shock	2 (6)	1 (4)	4 (20)	2 (13)	1 (50)
Septic shock	10 (29)	0	1 (5)	0	0

^a Includes 1 *Pseudomonas aeruginosa* and 1 *Escherichia coli*.

enterococci in 20 patients. Fifteen patients had culture-negative IE, and 2 patients had other microorganisms, namely, 1 with *Pseudomonas aeruginosa* and 1 with *Escherichia coli*. The mitral valve was affected in 56 patients and the aortic valve in 46 patients. Seven patients had multiple valve involvement (aortic and mitral).

Surgical Characteristics

Operations were done in 36 patients because of severe regurgitation with heart failure, in 26 because of severe regurgitation without heart failure, in 13 because of abscess or perivalvular extension, in 11 due to large vegetations exceeding 10 mm with high risk of embolization or (recurrent) embolization during antibiotic treatment, and in 9 due to failure of conservative medical treatment. The median time from diagnosis to operation was 5 days (IQR, 2 to 14 days). Early operations were done in 58 patients, late operations in 37, and emergency operations (≤ 24 hours after diagnosis) in 16.

Twenty-two aortic root repairs were performed. In 17 patients, a Bentall procedure was done with the proximal suture line often low in the outflow tract to exclude all abscesses; and in 5 patients, the aortic root was reconstructed with pericardial patches. During operation, 52 mechanical valves, 42 biologic valves, and 14 homografts were inserted. Three tricuspid and 14 mitral valve repairs were performed. The biologic valves included 20 CE-Pericardial (Carpentier-Edwards, Irvine, CA), 9 Mosaic (Medtronic, Minneapolis, MN), 7 St. Jude Epic (St. Jude Medical, St. Paul, MN), 3 Mitroflow (Sorin Group, Burnaby, BC, Canada), 1 Freestyle (Medtronic), 1 Labcor (Labcor Laboratories, Belo Horizonte-MG, Brazil) and 1 Shelhigh prosthetic valve (Shelhigh Inc, Union, NJ). The mechanical valves included 39 St. Jude HP or Regent (St. Jude Medical), 11 CarboMedics Reduced (Sorin), and 2 Omnicarbon (MedicalCV, Grove Heights, MN). Rings used during valve repair included 14 CarboMedics Annuloflo and 1 Classic Carpentier. For mechanical valves and stented bioprosthesis, we used mattress sutures with pledgets and for Shelhigh conduits and homografts we used single nonpledget sutures.

The median aortic cross-clamp time was 96 minutes (IQR, 71 to 120 minutes). The median cardiopulmonary bypass time was 135 minutes (IQR, 97 to 168 minutes). A significant association was found between the presence

of an abscess and the aortic cross-clamp time ($p < 0.001$) as well with the cardiopulmonary bypass time ($p < 0.001$). There was no significant association between preoperative septic shock and the aortic cross-clamp time ($p = 0.1$) or with the cardiopulmonary bypass time ($p = 0.2$). Two patients required a balloon pump.

Table 4. Mortality According to Clinical Characteristics

Variables	Mortality (%)
Epidemiology	
Referred to the hospital	8/59 (14)
Immediately admitted to the hospital	6/36 (17)
Female sex	8/39 (21)
Male sex	6/56 (11)
Community-acquired IE	10/77 (13)
Nosocomial IE	4/18 (22)
Nidus of infection	
NVE	8/72 (11)
PVE	6/23 (26)
Microorganism	
Staphylococci	10/35 (29)
Streptococci	1/23 (4)
Enterococci	3/20 (15)
Culture-negative IE	0/15 (0)
Other microorganisms	0/2 (0)
Indication	
Severe regurgitation	
With heart failure	8/36 (22)
Without heart failure	0/26 (0)
Failure of conservative medical treatment	2/9 (22)
Large vegetations ^a	2/11 (18)
Complication	
Heart failure	6/51 (12)
Embolism	6/25 (24)
Abscess	7/36 (19)
Cardiogenic shock	2/10 (20)
Septic shock	7/11 (64)
Severe regurgitation $\geq 3/4$	9/65 (14)
Prosthetic valve dehiscence	2/14 (14)

^a With high risk of embolization or recurrent embolization.

IE = infective endocarditis; NVE = native valve endocarditis; PVE = prosthetic valve endocarditis.

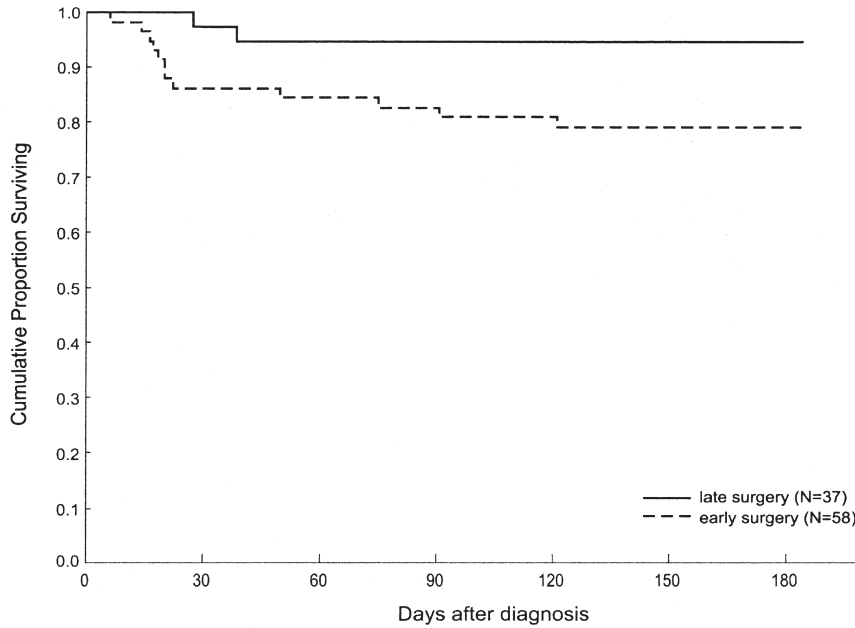


Fig 1. Six-month survival in patients with early (dashed line) and late operation (solid line).

Patients at risk							
Days	0	30	60	90	120	150	180
Early surgery	58	50	49	48	47	46	46
Late surgery	37	36	35	35	35	35	35

Complications

One or more major preoperative complication, including congestive heart failure, septic shock, or cardiogenic shock, was present in 40 patients; and one or more major postoperative complication, including congestive heart failure, septic shock, cardiogenic shock, or surgical reoperation, was observed in 23 patients. An abscess was present in 36 patients. Tables 1 and 2 summarize preoperatively and postoperatively diagnosed complications, respectively. Some complications were significantly associated with the causative pathogen. These data are presented in Table 3. In particular, the rate of embolism was highest in staphylococcal IE ($p = 0.007$). Abscess formation was also significantly associated with staphylococcal IE ($p < 0.001$), as was an association with septic shock ($p = 0.001$). Congestive heart failure was most frequently present in the group of other microorganisms ($p = 0.004$).

Outcome

The 6-month mortality rate was 15% (14 of 95). Table 4 presents mortality rates according to clinical characteristics. Mortality was significantly higher in IE caused by staphylococci than from the other pathogens ($p = 0.02$). No patients with culture-negative IE died. The mortality rate did not differ significantly between the 8 of 59 patients (14%) who were referred to this hospital and the 6 of 36 patients (17%) who were immediately admitted to this hospital ($p = 0.7$). There was no significant difference in mortality rate between the indications for cardiac operation ($p = 0.2$); notably, no patients with severe regurgitation without heart failure died. Both patients who required a balloon pump died. A significant associ-

ation was found between death and the aortic cross-clamp time ($p = 0.049$) and a nearly significant association with the cardiopulmonary bypass time ($p = 0.051$).

When the factor timing of cardiac operation was studied as a continuous variable, there was a nearly significant association with death ($p = 0.09$). When the timing of cardiac surgery was analyzed as a categorical variable with a cutoff of 7 days between early and late surgery, again a nearly significant association with death was found ($p = 0.07$). The highest mortality rate was 21% and was observed in the patients (12 of 58) who had early operations vs 5% in the late group (2 of 37; Fig 1). The mortality rate was 19% (3 of 16) in the true emergencies (≤ 24 hours) and 21% (9 of 42) in the remaining early patients. No patients died during the operation.

Variables that were analyzed for studying predictors of 6-month mortality included age, sex, PVE, nosocomial origin, comorbid conditions (diabetes mellitus, chronic obstructive pulmonary disease, cancer and immunosuppression), the causative microorganism, the timing of cardiac operation, and the complications, including cardiogenic shock, septic shock, embolism, heart failure, the presence of an abscess, severe regurgitation ($\geq 3/4$), and prosthetic valve dehiscence. In univariable analysis, factors associated with 6-month mortality in surgically treated patients were staphylococci ($p = 0.006$) and septic shock ($p < 0.001$, Table 5). Multivariable logistic regression revealed that septic shock (odds ratio, 11.9; 95% confidence interval, 2.4 to 59.1; $p = 0.002$) was independently associated with 6-month mortality. All patients who experienced preoperative septic shock belonged to the early operation group, of whom 4 of 7 (57%) died.

Table 5. Clinical Characteristics Associated With 6-Month Mortality

Variables	Univariate Analysis, <i>p</i> Value	Multivariate, OR (95% CI)	<i>p</i> Value
Age	0.07		
Sex (male)	0.2		
PV endocarditis	0.08		
Nosocomial origin	0.5		
Comorbid conditions			
Immunosuppression	1.0		
Diabetes mellitus	0.3		
Cancer	1.0		
COPD	0.054		
Microorganism			
Staphylococci	0.006	2.5 (0.6–10.7)	0.2
Streptococci	0.2		
Enterococci	1.0		
Culture-negative IE	0.1		
Other microorganisms	1.0		
Timing of operation			
Continuous variable	0.09		
Categoric variable			
Cutoff 7 days (early vs late)	0.07		
Cutoff 24 hours (urgent)	0.7		
Complication			
Heart failure	0.4		
Embolism	0.2		
Abscess	0.3		
Cardiogenic shock	0.6		
Septic shock	< 0.001	11.9 (2.4–59.1)	0.002
Severe regurgitation \geq 3/4	0.7		
PV dehiscence	1.0		

CI = confidence interval; COPD = chronic obstructive pulmonary disease; IE = infective endocarditis; OR = odds ratio; PV = prosthetic valve.

Comment

The principal dilemma is whether to operate early to limit the risk of emboli and of severe cardiac insufficiency, or to delay surgical intervention until resolution of the infection to reduce the risk of operation and of relapse of IE. Previous studies compared early valve replacement vs medical treatment. The definition of “early” operation varied between the studies from “valve replacement during the course of antimicrobial therapy” to “surgery during the initial hospitalization for IE” [5, 10, 13]. Moreover, the early operation group consisted of patients who were operated on within the first week of antimicrobial therapy up to the end of antibiotic therapy. The clinical profile of patients requiring cardiac operation within the first week of antimicrobial therapy probably differed from patients who underwent operations in the last week before the end of antimicrobial therapy. Revilla and colleagues [15] found no significant difference in mortality between urgently (before antibiotic treatment has ended) and electively (at completion of

antibiotic treatment) operated on patients. They stated, however, that patients with IE who needed an operation before antibiotic treatment had ended had a poor clinical course.

The present study aimed to investigate the clinical profile and predictors of outcome of patients requiring cardiac operation and studied the impact of timing of cardiac surgical intervention on 6-month mortality. The study included 95 surgically treated IE patients, and their overall 6-month mortality rate was 15%. According to our results, diabetes mellitus did not influence prognosis. In contrast, Chu and colleagues [19] identified diabetes mellitus as an independent risk factor for death; however, their data were from a study that included medically and surgically treated patients. Despite a higher mortality rate of prosthetic than of native valve endocarditis, the presence of a prosthetic valve did not appear to be a predictor of death. Staphylococci were the predominant causative microorganisms and were associated with the highest mortality rate. Only in univariate analysis was there a significant association between staphylococci and death. However, staphylococcal IE was associated with embolism, abscess formation, and septic shock, concluding that staphylococci are indirectly predictors of an unfavorable clinical course and outcome.

When we evaluated the impact of timing of cardiac surgery on mortality, we found a nearly significant association by univariate analysis; however, this difference might have been significant if more patients had been involved in this study. The prognosis in patients who were operated on more than 7 days after diagnosis of IE was relatively favorable because only 5% died. In contrast, in patients in whom the intervention was performed within 7 days of diagnosis of IE, the mortality rate was more than a fourfold higher. Likely, this difference was not due to the timing of the cardiac operation itself but to the severity of the disease.

Congestive heart failure, the most common indication for operation in this study, was not significantly associated with death. As well, Revilla and colleagues [15] found that congestive heart failure, also the main cause of urgent operation, was not significantly associated with death in patients with an early procedure. Their explanation for this finding was that heart failure is caused by a localized problem at the valve that can be treated successfully by surgical intervention.

In studying predictors of death in surgically treated patients, we found that septic shock was an independent predictive factor of 6-month mortality. In contrast to congestive heart failure, septic shock represents uncontrolled systemic and disseminated infection. This unfavorable clinical status cannot be resolved by a local cardiac intervention and may explain why septic shock was associated with a high mortality rate. Patients experiencing preoperative septic shock had a very high mortality rate despite undergoing early cardiac operation.

In this series, no patients with the indication for operation of “severe regurgitation without heart failure” died. These results may suggest that early operation in patients with severe regurgitation without heart failure may be

beneficial: outcome results were similar to the late surgically treated group, and the length of hospitalization may be shorter than in patients with an elective operation later during or at the end of antimicrobial therapy. Moreover, new heart failure developed during antibiotic therapy in more than one-fifth of patients who underwent a late operation, which might have been avoided by an early cardiac intervention.

Limitations of this study are that it lacked a randomized controlled treatment strategy. This study reported findings of a single tertiary-care referral center, resulting in limitations to the generalization of the results. Owing to the relative low number of patients included in this study and the low mortality rate, some risk factors might not have reached statistical significance.

In conclusion, septic shock predicted 6-month mortality, and even by performing early cardiac intervention in patients with a preoperative septic shock, the mortality rate remained considerable. The prognosis in patients who were operated on late was favorable compared with those who had an early operation, but this difference was probably not due to the timing of the intervention but to the severity of IE.

Only in patients without life-threatening complications, such as severe regurgitation without heart failure, is the discussion about early or late operation meaningful. Our results show that the outcome did not differ between early and late operation in patients with severe regurgitation without heart failure. Therefore in these patients, early operation may offer benefit in length of hospitalization and prevention of development of new heart failure. However, future and larger studies are needed to convincingly pass a verdict in this topic.

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INVITED COMMENTARY

Despite many therapeutic efforts, surgery for active infective endocarditis represents a risky situation. The decision-making process is complex; the heterogeneous nature of the disease and its surgical treatment frequently make the choice of appropriate treatment difficult. Regardless of the valve location, the patient's general condition influences the choice of the best treatment option. The extent of the valve and perivalve lesions and the technical challenges of reconstruction define the

problems and affect periprocedural mortality, even in the best hands.

The paper by Hill and colleagues [1] addresses a controversial and unsolved issue: timing an operation in the acute setting of active infective endocarditis. In their experience, surgery performed within 7 days after the diagnosis is associated with higher mortality. Septic shock and *S. aureus* infection are the most important factors affecting mortality. Patients in shock had early