CONGENITAL HEART

Risk Factors for Semilunar Valve Insufficiency After the Damus-Kaye-Stansel Procedure

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Background. **Cardiac function and survival after the Damus-Kaye-Stansel (DKS) procedure are encouraging, but only limited data exist related to postprocedural semilunar valve function. We investigated postprocedural midterm to long-term outcomes and changes in semilunar valve function and identified risk factors of semilunar valve function deterioration.**

Methods. **Between 1996 and 2012, 63 patients with a single functional ventricle underwent the DKS procedure. Of them, 50 had previously undergone pulmonary artery banding. Cardiac function was measured by catheter examination 5.3 months (interquartile range, 2.6 to 9.7) preoperatively and 1.2 years (interquartile range, 1.0 to 1.4) postoperatively. Echocardiographic examination of the semilunar valve was performed concurrently with the catheter examination and at the last follow-up (5.3 years [interquartile range, 3.1 to 9.2] postoperatively).**

Results. **The overall survival rate at 1, 5, and 10 years postoperatively was 0.97, 0.92, and 0.89, respectively. Aortic and pulmonary valve regurgitation grade 1 year postoperatively and at the last follow-up increased compared with the preoperative grade. There was no significant difference between regurgitation at 1 year and the last follow-up. The duration from pulmonary artery banding to the DKS procedure was longer in the group with at least mild regurgitation (n = 6) than in the group with less than mild regurgitation (n = 54).**

Conclusions. **Although the duration from pulmonary artery banding to the DKS procedure was associated with postoperative regurgitation, neither postprocedural aortic nor pulmonary valve regurgitation increased over time, and there were no deleterious effects on the clinical conditions.**

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The efficacy of the Damus-Kaye-Stansel (DKS) procedure for a functional single ventricle with systemic ventricle outflow obstruction has been described in many reports [1–5]. We previously reported that it avoided cardiac function deterioration and improved long-term results after the Fontan operation not only for patients with subaortic stenosis or a restrictive bulboventricular foramen but also for patients without smooth blood flow between the main ventricle and aorta [6]. However, the function of the semilunar valve, especially the pulmonary valve, is expected to deteriorate because of exposure to systemic pressure or annular distortion. Some reports noted postoperative pulmonary regurgitation (PR) in patients who underwent the DKS procedure [2, 5, 7, 8], but few reports have described semilunar valve functional changes and deterioration-related factors. Outcomes for cardiac function and survival after the DKS procedure are encouraging, but only limited data exist regarding outcomes related to semilunar valve function. We therefore investigated these postprocedural midterm to long-term outcomes and changes in semilunar valve function and identified risk factors for semilunar valve function deterioration.

Patients and Methods

Patients

We retrospectively reviewed data from 63 patients who underwent the DKS procedure at our hospital between January 1996 and December 2012. Any patients who underwent a Norwood-type operation were excluded. Our Institutional Review Board approved this study and waived the requirement for informed consent.

Surgical Procedures

The DKS operation was performed using conventional continuous-flow cardiopulmonary bypass with mild hypothermia (32°C to 34°C) without circulatory arrest. The end-to-side anastomosis between the main pulmonary artery and the ascending aorta was performed in 3 patients before 1997. In the remaining 60 patients, both the ascending aorta and pulmonary trunk were divided above the sinus and sutured together in a side-to-side

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Table 1. Patient Characteristics

Characteristics	Values
Age at DKS operation, months	35.4 (12.2–55.4)
Weight at DKS operation, kg	12.2 (8.3–14.9)
Clinical diagnosis	
Single left ventricle	7 (11.1)
TA + TGA	4 (6.3)
Single right ventricle	8 (12.7)
MS + hypoplastic left ventricle	10 (15.9)
Double outlet right ventricle	18 (28.6)
Unbalanced AVSD	2 (3.2)
TGA + VSD + PS	5 (7.9)
CCTGA + VSD + PS	6 (9.5)
Other	3 (4.8)
Presence of transposed great vessels	32 (50.8)
Previous PAB	50 (79.4)
Duration PAB to DKS, months	27.3 (11.3–46.2)
Timing of DKS	
Concomitantly with BT or RV-PA shunt	3 (4.8)
Concomitantly with BDG	37 (58.7)
Concomitantly with Fontan	22 (34.9)
After Fontan	1 (1.6)
Type of DKS	
End-to-side DKS	3 (4.8)
Double-barrel DKS	60 (95.2)

Values are median (interquartile range) or n (%).

AVSD = atrioventricular septal defect; BDG = bidirectional Glenn procedure; BT = Blalock-Taussig; CCTGA = congenitally corrected transposition of the great arteries; DKS = Damus-Kaye-Stansel procedure; MS = mitral stenosis; PA = pulmonary artery; PAB = pulmonary artery banding; PS = pulmonary stenosis; RV = right ventricle; TA = tricuspid atresia; TGA = transposition of the great arteries; VSD = ventricular septal defect.

fashion involving approximately half of the pulmonary trunk's circumference. The common orifice of both great arteries was then anastomosed to the divided ascending aorta using polypropylene running sutures. No patch materials were used. The same DKS technique was used throughout the study, although three primary surgeons performed the operations.

For patients having undergone pulmonary artery banding (PAB), the wall contacting the band was dissected to avoid leaving a weakened wall after band removal. Then, each orifice of the pulmonary and aortic arteries were sutured in a side-to-side fashion. Pulmonary arterioplasty with any patch was not performed.

Study Method

Data were collected from medical records involving catheter and echocardiography reports. Pressure gradient across the systemic ventricular outflow tract, systemic ventricular end-diastolic volume index, systemic end-systolic volume index, and cardiac index were measured by catheter examination 5.3 months (interquartile range [IQR]: 2.6 to 9.7) before the procedure and 1.2 years (IQR: 1.0 to 1.4) after. Echocardiographic examination of the semilunar valve was performed concurrently with the catheter examination and at the last follow-up (5.3 years [IQR: 3.1 to 9.2] postoperatively). Pediatric cardiologists evaluated semilunar valve function. Semilunar valve regurgitation was graded as none, trivial, mild, moderate, or severe. Thereafter, the patients, except 3 who died early, were divided into two groups according to PR grade (equal to neoaortic valve regurgitation) at the last follow-up examination (the mild-or-higher group and the lower-than-mild group).

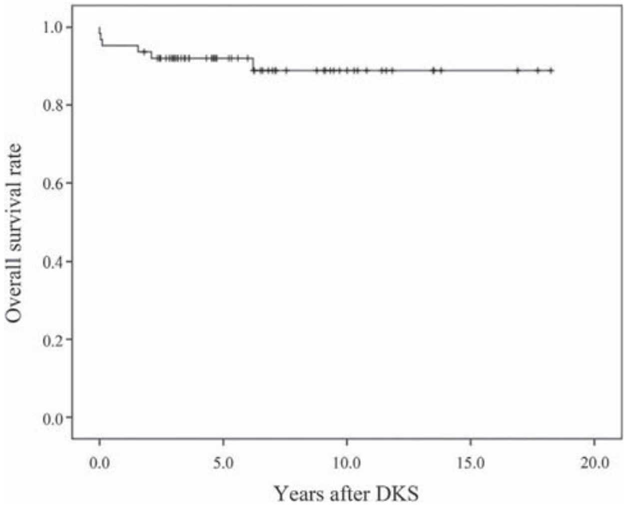

Fig 1. Overall survival after the Damus-Kaye-Stansel (DKS) procedure (determined with the Kaplan-Meier method). Hatch marks designate censored observations.

Statistical Analysis

Data are expressed as median (IQR). Survival rates were estimated using the Kaplan-Meier method. Serial changes in semilunar valve function were compared preoperatively, 1 year postoperatively, and at the last follow-up by the Wilcoxon matched pairs test. Comparisons of categoric data and continuous variables between the mild-or-higher and lower-than-mild PR groups were performed using the χ^2 test and the Mann-Whitney *U* test, respectively. Analyses were performed using SPSS software, version 8.0 (SPSS, Inc, Chicago, IL). A *p* value less than 0.05 was considered significant. To compare serial changes, a *p* value less than 0.017 was considered significant based on Bonferroni's inequality test for avoiding multiplicity.

Results

Patient Characteristics

Patient characteristics are summarized in Table 1. Median age at the time of DKS was 35.4 months (IQR: 12.2 to 55.4) and median body weight was 12.2 kg (IQR: 8.3 to 14.9 kg). Of the 63 patients, 50 had previously undergone PAB—43 as the first palliation and 7 concomitantly with a bidirectional Glenn procedure. The median duration from PAB to the DKS procedure was 27.3 months (IQR: 11.3 to 46.2). The DKS procedure was performed concomitantly with the bidirectional Glenn procedure in 37 patients, the

Fontan operation in 22, the modified Blalock-Taussig shunt in 2, and a right ventricle-to-pulmonary artery shunt in 1. One patient underwent the DKS procedure independently after the Fontan procedure because a subaortic stenosis became apparent. The end-to-side DKS procedure was performed in only 3 patients before 1997. The 60 most recent patients underwent the double-barrel DKS procedure. All patients who completed the bidirectional Glenn procedure are receiving the angiotensin-converting enzyme inhibitor enalapril.

Overall Outcomes

The median postprocedural follow-up period was 5.3 years (IQR: 3.1 to 9.2). Overall survival at 1, 5, and 10 years was 0.97, 0.92, and 0.89, respectively (Fig 1). There were 3 postprocedural hospital deaths: 2 deaths were due to high pulmonary vascular resistance subsequent to common atrioventricular valve regurgitation progression, and 1 death was due to ventricular dysfunction. Three late deaths occurred, 2 due to encephalopathy associated with viral infection (1.6 and 6.2 years after DKS) and another due to sudden death (2.1 years after DKS). Of the 35 survivors among the 40 patients who underwent the DKS procedure before the Fontan operation, 34 reached the Fontan operation or are good candidates awaiting the Fontan operation. The remaining patient had an unbalanced atrioventricular septal defect and trisomy 21 and was not deemed a good candidate for the Fontan operation owing to increased pulmonary vascular resistance. Only 1 patient, who underwent the end-to-side DKS, required reoperation for severe PR; pulmonary valve replacement was performed 17.4 years after DKS.

Semilunar Valve Function

Serial changes in aortic and pulmonary valve regurgitation are shown in Figure 2. Aortic and pulmonary valve regurgitation grades 1 year postprocedurally and at the last follow-up increased compared with preoperatively ($p < 0.001$). There was no significant difference between regurgitation 1 year after DKS and at the last follow-up. At the last follow-up, 5 patients had mild PR, and 1 who underwent end-to-side DKS had severe PR.

Table 2 shows a comparison of the variables between patients with mild or worse PR and patients with better than mild PR at the last follow-up. There was no significant difference in the number of patients with transposed great vessels, age at DKS, number of patients who had undergone PAB preprocedurally, preoperative pressure gradient across the systemic ventricular outflow tract, number of patients who underwent the end-to-side DKS, follow-up period, preoperative aortic regurgitation (AR), or preoperative PR. There were also no significant differences in postoperative cardiac function, including systemic ventricular end-diastolic volume index, systemic end-systolic volume index, and cardiac index. Although PAB was not a significant risk factor for postoperative mild or higher PR ($p = 0.243$), the duration from PAB to DKS for the mild-or-higher PR group was longer than that for the lower-than-mild PR group ($p = 0.029$).

Comment

Although aortic and pulmonary semilunar valve function worsened after DKS compared with preoperatively, most observed deterioration was a decline from "none" to "trivial." Midterm and long-term results showed that only 2 patients had mild AR, and only 6 had mild or higher PR. Additionally, the duration between PAB and DKS was a risk factor for mild or higher PR at midterm and long-term follow-up. Reoperation due to severe PR was required for only 1 patient, and overall outcomes, including cardiac function and survival, were very good.

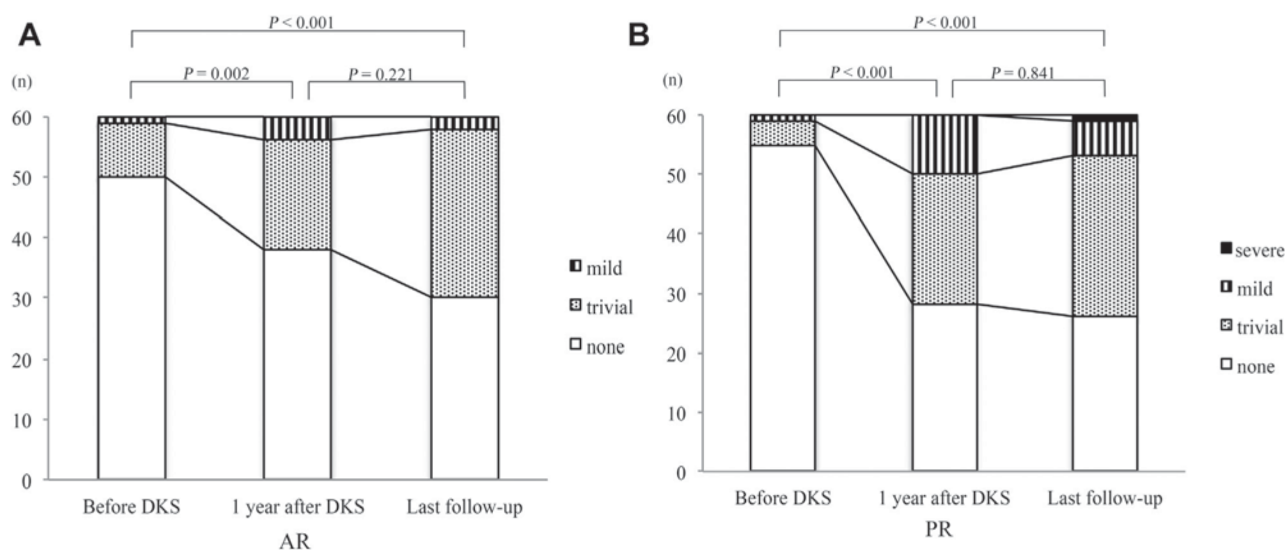

Fig 2. (A) Serial changes in aortic valve regurgitation (AR): mild (striped areas), trivial (dotted areas), and none (open areas). (B) Serial changes in pulmonary valve regurgitation (PR): severe (solid areas), mild (striped areas), trivial (dotted areas), and none (open areas). (DKS = Damus-Kaye-Stansel.)

Table 2. Comparison of Variables Between Mild or Higher Pulmonary Regurgitation Group and Lower Than Mild Pulmonary Regurgitation Group

Variables	Mild or Worse PR (n = 6)	Less Than Mild PR (n = 54)	*p* Value
Age at DKS, months	46.6 (32.7–102.1)	37.6 (13.0–55.6)	0.187
Weight at DKS, kg	13.6 (12.1–20.0)	12.2 (8.5–14.9)	0.147
Transposed great vessels	2 (33.3)	30 (55.6)	0.404
Previous PAB	6 (100.0)	45 (83.3)	0.243
Duration PAB to DKS, months	44.0 (20.0–97.1)	27.7 (13.3–42.8)	0.029
Preoperative catheter data			
SVOT gradient, mm Hg	0 (0–6.8)	0 (0–0)	0.275
SVEDVI, mL/m^2	175.0 (125.0–196.4)	204.7 (160.7–258.7)	0.196
SVESVI, mL/m^2	59.4 (59.2–93.6)	89.1 (68.9–118.3)	0.282
Cardiac index, L · min^{-1} · m^{-2}	3.9 (3.8–4.7)	3.9 (3.2–4.7)	0.957
Preoperative AR			0.917
None	5 (83.3)	45 (83.3)	
Trivial	1 (16.7)	8 (14.8)	
Mild	0 (0.0)	1 (1.9)	
Preoperative PR			0.621
None	5 (83.3)	50 (92.6)	
Trivial	0 (0.0)	4 (7.4)	
Mild	1 (16.7)	0 (0.0)	
End-to-side DKS	1 (16.6)	2 (3.7)	0.108
Follow-up after DKS, years	9.7 (7.2–11.2)	5.3 (3.2–9.0)	0.068
Postoperative catheter data			
SVOT gradient, mm Hg	0.0 (0.0–0.3)	0.0 (0.0–0.0)	0.515
SVEDVI, mL/m^2	151.1 (121.7–153.2)	165.1 (133.3–190.2)	0.914
SVESVI, mL/m^2	70.0 (64.4–83.9)	78.1 (60.0–95.1)	0.688
Cardiac index, L · min^{-1} · m^{-2}	3.4 (3.1–4.5)	3.5 (3.2–4.3)	0.626
Postoperative AR at last follow-up			0.659
None	3 (50.0)	27 (50.0)	
Trivial	3 (50.0)	25 (46.3)	
Mild	0 (0.0)	2 (3.7)	

Values are median (interquartile range) or n (%).

AR = aortic regurgitation; DKS = Damus-Kaye-Stansel; PAB = pulmonary artery banding; PR = pulmonary regurgitation; SVEDVI = systemic ventricular end-diastolic volume index; SVESVI = systemic ventricular end-systolic volume index; SVOT = systemic ventricular outflow tract.

The DKS procedure was originally developed to treat transposition of the great arteries [9–11]. Because many reports indicate its usefulness in treating a single functional ventricle with ventricular outflow tract obstruction [1–5], we have been proactively performing DKS in such cases [6]. However, postprocedural valve function deterioration is a concern, because semilunar valves, especially the pulmonary valve, are exposed to systemic blood pressure. In the arterial switch operation to treat transposition of the great arteries, the pulmonary valve is exposed to systemic blood pressure; postoperative PR, neo-AR, and aortic root enlargement have been reported to occur over the long term [12–14]. Many reports have demonstrated the occurrence of post-DKS PR, and there are also many reports of regurgitation, especially with the end-to-side DKS procedure [2, 5, 7, 8]. Compared with the double-barrel DKS procedure, the end-to-side DKS procedure may be a risk factor for worsening postoperative semilunar valve regurgitation [15]. Pulmonary valve exposure to systemic blood pressure and regurgitation caused by a distorted pulmonary valve may explain why postoperative PR occurs after the end-to-side DKS procedure. In particular, because this procedure involves anastomosis of the pulmonary artery to the aortic side wall, it can be easily imagined that the pulmonary valve is pulled and the annulus becomes distorted. In the current study, although the end-to-side DKS procedure was not a risk factor for mild or higher PR, the patient who underwent reoperation was the one who had undergone the end-to-side DKS procedure and did not show PR preoperatively. Hence, it is very possible that PR occurred owing to a distorted valve. To prevent such distortion, it may be better to use patch material [16]. However, as there is concern about long-term calcification and stenosis when foreign patch material is used, at the present time the double-barrel DKS procedure described by Waldman and associates [17] is widely used. We switched from an end-to-side technique to a double-barrel approach in 1998, not only to avoid valve distortion but also because the end-to-side technique was difficult, particularly in patients after PAB because the pulmonary arterial wall is short after removing the band portion. However, suturing is easy in a side-to-side fashion regardless of previous PAB. Some recent reports included patients who had undergone the double-barrel DKS procedure [2, 4, 5, 15, 18]. Although mild or higher PR was observed in some of those studies [4, 5, 15], no reports have investigated factors leading to mild or higher PR over the midterm to long-term.

Fujii and colleagues [15] compared 13 end-to-side DKS procedures and 34 double-barrel DKS procedures, and they also found the end-to-side procedure to be a risk factor for PR deterioration. They defined regurgitation that worsened compared with the preoperative condition as “deteriorated,” but since they achieved excellent outcomes—only 4 patients had deteriorated regurgitation and only 3 had mild or higher PR—they did not investigate factors that led to mild or higher PR. In reality, even if valve regurgitation worsened compared with the preoperative state, regurgitation is rarely problematic if the grade is trivial or none. Conversely, mild or higher regurgitation at midterm and long-term follow-up may have a greater effect on cardiac function and reoperation. We therefore focused on mild or higher regurgitation and compared the midterm and long-term outcomes of the 6 patients with mild or higher regurgitation with outcomes from the 54 patients with lower than mild regurgitation. We found that the duration between PAB and the DKS procedure was a risk factor for mild or higher regurgitation.

With regard to PAB, it has been reported that previous PAB is a risk factor for postoperative PR after the arterial switch operation [13, 14, 19]. In the present study, previous PAB itself was not the risk factor. However, a high proportion (50 of 60) of the surviving patients had previously undergone PAB, which may explain why a difference was not observed between the two groups and why PAB was not identified as a risk factor. The duration between the two procedures was a risk factor for postoperative mild or higher PR, so the effect of PAB on valve function cannot be ignored. Although the mechanism for the association between previous PAB and the risk of PR is unclear, previous reports suggested that increased wall tension proximal to the band may predispose the root to abnormal enlargement after the arterial switch operation [20, 21]. Moreover, the pulmonary wall is thinner than the aortic wall and thus more susceptible to passive dilation under a systemic pressure afterload [22]. Prifi and colleagues [19] hypothesized that the mechanism for postoperative PR after the arterial switch operation consisted of two phases: an increase of the neoaortic root diameter preoperatively and mismatched neoaortic anastomosis-induced flow turbulence as a consequence of sinus dilation preventing leaflet coaptation. Meanwhile, McMahon and associates [13] reported that the risk of moderate or more severe postoperative PR was low compared with the significant prevalence of neoaortic root and annulus enlargement, so neoaortic root dilation may not necessarily cause postoperative PR. The association of root dilation with PR was not investigated here because it was difficult to measure the root diameter in the double-barrel DKS procedure. However, significant enlargement of the neoaortic root and pulmonary (neoaortic) annulus was not observed, except for the patient who required pulmonary valve replacement owing to severe PR.

Another mechanism in addition to root and annulus enlargement may affect PR after PAB. Amin and colleagues [16] stated that, to prevent PR deterioration when the DKS procedure is performed after PAB, the operation should be performed as peripherally as possible. However, careful consideration should be taken not to perform it too peripherally to prevent branch stenosis. Depending on the site of the PAB, flow turbulence proximal to the PAB is not thought to be equally applied to each pulmonary leaflet and thereby causes unequal growth of the leaflet. Over time, the diameter of the growing annulus becomes relatively larger than that at the site of the PAB. Prolonged exposure to this situation may cause leaflet degeneration and valvular function deterioration due to flow turbulence proximal to the PAB. Although we did not measure root diameter, it is desirable to clarify associations between changes in overall root measurements and in valve regurgitation. Therefore, we now measure root diameter immediately postoperatively and at midterm to long-term follow up by echocardiogram to determine any change in overall root measurements.

The results from the present study indicate that a long period should not be permitted between PAB and the DKS procedure. Some of the present group of patients had previously undergone PAB, including those who underwent the DKS procedure and bidirectional Glenn procedure after waiting until some growth had occurred, and those who were initially considered to be ineligible for the Fontan procedure but were later determined to be eligible upon reexamination and subsequently underwent both the DKS and the Fontan procedures. This series included some patients treated under an older protocol, when we believed that the appropriate timing for the Fontan procedure was 4 years old, when pulmonary vascular resistance would be lowest and a larger conduit could be placed in an extracardiac Fontan procedure. At that time, we performed the Glenn procedure at approximately 3 years of age, which may have prolonged the duration from PAB to DKS. Therefore, our study included patients who underwent the DKS procedure a long time after PAB, although there are currently very few such cases. Furthermore, we now perform the Glenn procedure at 3 months to 1 year after birth, and DKS is performed concomitantly when possible. The DKS procedure is performed concomitantly with the Fontan procedure only in patients requiring forward pulmonary blood flow for pulmonary arterial growth or to avoid the nonconfluent pulmonary artery after the bilateral, bidirectional Glenn procedure. The Fontan procedure, using an 18-mm to 20-mm diameter extracardiac conduit, is now performed at approximately 2 years of age. Therefore, the duration from PAB to DKS is shorter now than it was for some of the patients in this study. However, careful monitoring for postoperative PR occurrence is necessary for patients who, for one reason or another, had no choice but to wait a long time in a state of PAB, or for patients undergoing DKS who previously underwent PAB and were initially deemed ineligible to receive the Fontan but later became eligible.

Study Limitations

There are some limitations to this study. First, it has a retrospective design and was not randomized. Second, only a small number of patients ($n = 63$) were enrolled. Another limitation is that, whereas factors that led to mild or higher PR in the midterm and long-term were investigated, there were only 6 patients with mild or higher PR. In the present study, the end-to-side DKS procedure was not found to be a risk factor, possibly because there were only 3 patients who had undergone this specific procedure. In addition, although preoperative and postoperative valve regurgitation was assessed with echocardiographic examination by our hospital's pediatric cardiologists, assessments were not necessarily conducted by the same individual, and, consequently, some errors may have occurred. However, because the assessments were conducted by cardiologists who had received thorough training at our hospital and were also confirmed by the supervising physician, we do not believe that a seriously problematic error occurred. The same issue can be discussed regarding catheter examinations.

Conclusion

Outcomes after the DKS procedure were satisfactory. Although AR and PR worsened after the DKS procedure compared with the preoperative state, there were no subsequent changes over time, and most patients maintained lower than mild regurgitation. Reoperation was required for only 1 patient who underwent an end-to-side DKS procedure because severe PR developed. The duration between PAB and the DKS procedure was associated with mild or higher PR. It is not recommended that patients remain in a state of PAB for a long time, and for those who have no choice but to undergo the DKS after a long time has elapsed, careful monitoring with respect to the development of postoperative PR is considered necessary.

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