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Early Results of the “Clamp and Sew” Fontan Procedure Without the Use of Circulatory Support

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Abstract

Background—A modification of the Fontan operation was recently applied, which includes anastomoses of the extra-cardiac conduit to the right pulmonary artery and inferior vena cava using simple clamping with no additional circulatory support, venous shunting, pulmonary artery preparation, or prior maintenance of azygos vein patency. The objective of this study is to assess the outcomes of this novel off-pump “clamp and sew” Fontan procedure.

Methods—This is a retrospective review of all patients having a Fontan procedure between January 2009 and October 2010 at a single institution.

Results—Twelve patients had a Fontan procedure with the use of cardiopulmonary bypass (CPB group), and 12 had an off-pump Fontan procedure (off-pump group). Preoperative demographic and hemodynamic data were similar except for higher mean pulmonary artery pressure in the CPB group (12.2 ± 1.6 mm Hg versus 9.9 ± 2.4 mm Hg; $p = 0.02$). No patients in the off-pump group required conversion to CPB. The mean inferior vena cava clamp time in the off-pump group patients was 10 ± 3 minutes. There were no early or midterm deaths. No patients exhibited postoperative hepatic or renal dysfunction. Postoperative maximal serum creatinine and aspartate transaminase were significantly lower in the off-pump group compared with the CPB group (0.59 ± 0.12 versus 0.77 ± 0.22 mg/dL; $p = 0.03$ and 35.5 ± 8.3 versus 53.1 ± 19.0 U/L; $p = 0.02$, respectively). At median follow-up of 13 months (range, 1 to 20 months), all but 1 patient in the CPB group are in New York Heart Association class I with unobstructed Fontan circulation.

Conclusions—The clamp and sew technique for completion of an extracardiac conduit Fontan procedure appears safe and feasible for selected patients.

The Fontan procedure, introduced in 1971 [1], has been used in the palliation of patients with single-ventricle physiology. During the last four decades, it has been modified numerous times to improve the early and long-term outcomes [2–4]. One of these modifications is the off-pump Fontan procedure, which theoretically avoids volume overload, activation of the inflammatory cascades, and the coagulopathy associated with the use of cardiopulmonary bypass (CPB) [5, 6]. To ensure blood return from the inferior vena cava (IVC) to the heart during the IVC cross-clamp, some groups have used cavoatrial

venous shunts [7]. Shiraishi and associates [8] relied on the collateral flow through the azygos system, which was intentionally kept patent, and preparation of the pulmonary artery (PA) for Fontan completion during stage II reconstruction by augmenting the central part of the PA with a cuff constructed by autologous pericardial patch or extended polytetrafluoroethylene. To avoid thrombosis, a systemic-pulmonary shunt was constructed in this blind-ended pouch [8].

A modification of the extracardiac Fontan procedure was recently applied, with anastomoses of the extracardiac conduit to the right PA and to the IVC using simple clamping with no additional circulatory support, venous shunt, PA preparation, or prior maintenance of azygos vein patency. The objective of this study was to assess the outcomes of this novel off-pump “clamp and sew” technique.

Material and Methods

Study Design

Between January 2009 and October 2010, all consecutive patients who had the Fontan procedure were identified using the pediatric cardiothoracic surgery database at the University of California, San Francisco. The study was approved and monitored by the Institutional Review Board, and because of its retrospective nature, need for patient consent was waived.

Medical records were reviewed, and the following data were retrieved and analyzed: basic demographic data, anatomic information, surgical history, preoperative catheterization data, intraoperative data, and postoperative outcomes including immediate and midterm complications. Follow-up data were obtained from the last clinic visit.

Statistical Analysis

Data are expressed as frequencies, as mean plus or minus one standard deviation, and as median with ranges. For subgroup analyses, the χ^2 test was used for the analysis of contingency tables, Student's *t* test was used to compare parametric values, and the Mann–Whitney *U* test was used to compare nonparametric values. Stat Mate III software (ATMS Co, Tokyo, Japan) was used for statistical analysis. A probability value less than 0.05 was considered significant for all analyses.

Results

Patient Characteristics

Twelve patients had CPB (CPB group) and 12 patients had the Fontan procedure without the use of CPB (off-pump group). Three patients in the off-pump group had a cavoatrial shunt during IVC cross-clamp, and 9 patients had the off-pump clamp and sew technique. Choice of technique was at the surgeon's discretion. Inclusion criteria for the clamp and sew technique were (1) unobstructed PAs with no necessity for patch arterioplasty, (2) adequate length of the right PA to allow vascular clamp placement with unobstructed flow through the bidirectional cavopulmonary shunt anastomosis to either lung, (3) no need for intracardiac

repairs or arch reconstruction, and (4) normal IVC return into the right atrium with no separate hepatic vein return.

The demographic and pre-Fontan hemodynamic data are summarized in Table 1. More patients had a modified Norwood procedure as stage I palliation in the CPB group compared with the off-pump group (7 of 12 versus 2 of 12; $p = 0.03$). The mean pre-Fontan PA pressure in the CPB group was significantly higher compared with the off-pump group (12.2 ± 1.6 versus 9.9 ± 2.4 mm Hg; $p = 0.02$). The azygos vein was ligated, and all additional sources of pulmonary blood flow (ie, antegrade flow through the PA or systemic to PA shunts) were also removed at the time of the Glenn operation in all patients. All patients were in sinus rhythm with the exception of 1 patient with heterotaxy syndrome who had a dual-chamber epicardial pacemaker placement for sinus node dysfunction.

Operative Intervention

The extracardiac Fontan procedure using a Gore-Tex conduit is the surgical technique of choice and is exclusively used for all patients. After redo median sternotomy, the heart, superior vena cava, bidirectional cavo-pulmonary shunt anastomosis, right PA, and IVC were dissected and mobilized. The patient was fully heparinized (300 U/kg). A Gore-Tex (W.L. Gore and Associates, Flagstaff, AZ) tube graft was beveled to construct a PA to conduit anastomosis.

In the CPB group, a standard extracardiac Fontan was performed as previously described [3]. In the off-pump group, a test occlusion of a branch PA allowing blood flow to one lung was performed. The patient's hemoglobin-oxygen saturation, cerebral and somatic near-infrared spectroscopy, and hemodynamics were monitored to ensure tolerance of the clamping. It is institutional practice to avoid placement of central venous catheters in the neck and upper extremity veins for fear of thrombotic complications, and therefore the superior vena cava pressure was not monitored. The vascular clamp was placed again after choosing an optimal anastomotic site, which was directed to the right or left of the cavopulmonary connection with the goal to offset the two anastomoses. The PA was opened, and an extracardiac conduit was sutured to the opening with continuous polypropylene suture (Fig 1). During anastomosis, the cerebral near-infrared spectroscopy was stable at approximately 75% (range, 69% to 81%) in all off-pump group patients. The vascular clamp was removed, and the conduit was clamped at the midpoint after thorough removal of air. The conduit was trimmed to the appropriate length and configuration.

When a venous shunt was used, the IVC and the right atrium were cannulated and a passive venous flow was initiated. The IVC was snared, and a vascular clamp was placed adjacent to the cavoatrial junction. The IVC was divided, and the atrial side was oversewn with continuous polypropylene suture in two layers. The conduit was then anastomosed to the distal IVC stump in end-to-end fashion using continuous polypropylene suture [7]. Of the 3 patients who had a venous shunt, 2 were early in our off-pump experience, and the clamp and sew technique was not attempted. One patient (a 32-year-old woman with tricuspid atresia and ventricular septal defect who had a classic Blalock-Taussig shunt at 1 year of age and worsening exercise intolerance) required the shunt owing to hypotension during IVC test clamping.

In the clamp and sew off-pump Fontan group, the patient was placed in Trendelenburg position. A bolus infusion of 5% albumin or lactated Ringer's solution was administered to volume load the patient, and dopamine infusion was started at $5 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ to prepare the IVC cross-clamp. No patient had monitoring of the IVC pressure during clamping. A test clamp was applied on the IVC to assess the safety of the clamp and sew technique. After a brief recovery, two straight vascular clamps were placed adjacent to the cavoatrial junction and at the distal intrathoracic IVC. The IVC was divided adjacent to the upper clamp, and the atrial side was oversewn with continuous polypropylene suture in two layers. The conduit was then sutured to the distal IVC stump in end-to-end fashion using continuous polypropylene suture. Air was removed from the conduit, and the lower clamp was removed to allow blood flow through the conduit (Fig 2). During anastomosis, the somatic near-infrared spectroscopy was stable at approximately 70% (range, 64% to 78%) in all clamp and sew group patients.

A fenestration was used selectively and, if necessary, was constructed by side-to-side anastomosis between the right atrial free wall and a corresponding site on the extracardiac conduit. The decision to fenestrate was made intraoperatively, when the Fontan pressures were elevated (Fontan pressure greater than 17 mm Hg or transpulmonary gradient more than 10 mm Hg), or the patient experienced hypotension or acidosis, or required significant fluid resuscitation. More recently we extended the use of fenestration in patients who had higher pulmonary vascular resistance, significant regurgitation of the common atrioventricular valve, higher end diastolic pressure of the common ventricle, ventricular dysfunction, or small PAs. After creation of the fenestration, the heparin effect was reversed, hemostasis was ensured, atrial and ventricular pacing wires were placed, the mediastinum and both pleural spaces were drained, and the chest was closed in routine fashion.

Operative technique and early operative outcomes are summarized in Table 2. One patient in the CPB group had an 18-mm extracardiac conduit, one patient in the off-pump group had a 22-mm extracardiac conduit, and the remaining 22 patients had a 20-mm extracardiac conduit. All tolerated the procedure well. The mean IVC cross-clamp time in the clamp and sew group was 10 ± 3 minutes. Recently the IVC clamp time was reduced to as low as 6 minutes by performing the IVC to conduit anastomosis before closure of the cavoatrial stump. No patient in the off-pump group required conversion to CPB because of hemodynamic instability or bleeding. The mean CPB time was 63 ± 27 minutes. Seven patients having CPB also had concomitant intracardiac procedures ($n = 1$) or PA patch arterioplasty ($n = 6$). The mean intraoperative Fontan pressure was significantly lower in the off-pump group compared with the CPB group (10.3 ± 3.0 versus 15.2 ± 3.1 mmHg; $p = 0.002$). There was a trend toward less blood and blood product use in the off-pump group, but the difference did not reach statistical significance (30.3 ± 30.8 versus 68.3 ± 84.4 mL/kg; $p = 0.16$). The incidence of platelet and fresh-frozen plasma transfusion was significantly less in the off-pump group patients compared with the CPB group patients (3 of 12 versus 11 of 12; $p = 0.001$). One patient in the clamp and sew group required no blood transfusion.

Early Operative Outcomes

There were no early or late deaths in both groups. No patients required extracorporeal membrane oxygenation, and there was no Fontan takedown. In the CPB group, 1 patient required delayed chest closure, and 1 patient required emergent fenestration on the day of surgery owing to hemodynamic instability.

Two patients in the off-pump group were extubated in the operating room. All other patients were weaned off mechanical ventilation in the intensive care unit after confirming complete hemostasis and stable hemodynamics. The median mechanical ventilation time was shorter in the off-pump group compared with the CPB group (4 hours [range, 0 to 10 hours] versus 10 hours [range, 4 to 138 hours]; $p = 0.02$).

No patient exhibited postoperative hepatic, renal, or neurologic deficiency in either group. In the clamp and sew group, the mean maximal postoperative serum aspartate transaminase, alanine transaminase, alkaline phosphatase, international normalized ratio of prothrombin time, and creatinine level were 33.6 ± 6.0 U/L, 15.4 ± 8.8 U/L, 85.8 ± 7.1 U/L, 1.73 ± 0.18 , and 0.56 ± 0.11 mg/dL, respectively. The maximal postoperative serum creatinine level and the maximal postoperative aspartate transaminase level were significantly lower in the off-pump group compared with the CPB group (0.59 ± 0.12 versus 0.77 ± 0.22 mg/dL; $p = 0.03$ and 35.5 ± 8.3 versus 53.1 ± 19.0 U/L; $p = 0.02$). The maximal postoperative international normalized ratio of prothrombin time was not significantly different between groups (1.73 ± 0.18 versus 1.99 ± 0.70 ; $p = 0.22$).

Chest tubes were removed when the total amount of drainage was less than $1 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$. One clamp and sew patient without a fenestration had a prolonged chylous effusion that required pleural drainage for 19 days, and 3 patients in the CPB group without a fenestration had a prolonged pleural effusion that required pleural drainage for 22, 30, and 64 days, respectively. The median duration of mediastinal or pleural drainage was significantly shorter in the off-pump group compared with the CPB group (7 days [range, 3 to 19 days] versus 14 days [range, 6 to 64 days]; $p = 0.02$).

The intensive care unit stay and the hospital stay in the off-pump group were significantly shorter compared with the CPB group (3 days [range, 2 to 6 days] versus 4 days [range, 3 to 31 days]; $p = 0.02$ and 9 days [range, 7 to 60 days] versus 18 days [range, 8 to 67 days]; $p = 0.02$, respectively).

During median follow-up of 13 months (range, 1 to 20 months), all patients are doing well and are in New York Heart Association functional class I, except for one who required fenestration placement 5 months after the Fontan procedure owing to recurrent pleural effusion and ascites. The latest echocardiogram in all off-pump Fontan patients showed unobstructed low-velocity flow in the extracardiac conduit, IVC, and branch PAs. No patient required reintervention. Two patients had follow-up catheterization 14 and 16 months after surgery that showed widely patent Fontan circuit without any stenosis (Fig 3).

Comment

In patients with single-ventricle physiology the Fontan procedure achieves separation between the pulmonary and systemic circulations by directing the total caval blood flow to the PAs. Because the hemodynamics after the Fontan procedure are frequently suboptimal as a result of the absence of a pulmonary ventricle, successful outcomes require the best possible cardiac output with the lowest possible venous and Fontan pressure [7]. In children, the use of CPB produces an inflammatory response that leads to increased capillary leak, decreased pulmonary compliance, impaired gas exchange, and myocardial edema with diastolic dysfunction. Fontan patients, who rely on passive circulation of the venous blood through the lungs, are particularly sensitive to these changes [9]. Prolonged CPB, as a surrogate risk factor for the need for additional procedures to correct associated lesions, may increase the risk and has been associated with poor outcomes after the Fontan operation [4, 10–12]. Some groups have focused on reducing or eliminating the use of CPB during the Fontan operation to minimize the impact of the inflammatory response associated with the use of CPB and to improve post-Fontan hemodynamics [7, 8]. Some reports demonstrated attenuation of the inflammatory response and a decrease in the total amount of mediastinal and pleural drainage after an off-pump Fontan procedure [13, 14]. Others reported no immediate clinical benefit associated with the off-pump Fontan procedure [15]. It is likely that with the contemporary improvement of Fontan outcomes, it will be difficult for single-center series to demonstrate the superiority of one technical modification of the procedure over another.

Petrossian and colleagues [7] reported favorable early and midterm outcomes of the Fontan procedure using techniques that evolved with time, including full and partial CPB, active IVC decompression with a centrifugal pump during the IVC to conduit anastomosis, and passive decompression with a venous shunt. A variety of early outcome measures improved in the no-oxygenator group, but there was no difference between the active and passive IVC decompression groups, suggesting that elimination of the oxygenator might be more important than elimination of the pump. It is known that veno-venous bypass is not immune from activation of the inflammatory cascades [16]. Contact between the patient's blood and the perfusion tubing may result in activation of the complement systems independently from the presence or absence of an oxygenator. Significant benefits from off-pump approaches have not been clinically proven. It may be beneficial to completely avoid the use of an extracorporeal support circuit in the Fontan procedure. This technique may reduce the inflammatory response associated with the bypass circuit and may minimize coagulopathy and bleeding [13]. In this series there was a trend toward less intraoperative blood product use in the off-pump group, although because of small numbers this difference did not reach statistical significance.

A fenestration was used selectively and was constructed after the conduit was opened to restore the pulmonary circulation. Initially the decision to fenestrate was made in the operating room for patients with elevated Fontan pressures, hypotension, or acidosis who required significant fluid resuscitation. One patient required emergent fenestration on the first postoperative night because of hemodynamic instability. More recently the use of fenestration was extended in all the higher risk patients with elevated pulmonary vascular

resistance, significant regurgitation of the common atrioventricular valve, higher end-diastolic pressure, ventricular dysfunction, or small PAs. Although there are reports supporting the selective use of fenestration in the extracardiac conduit Fontan procedure, a prospective randomized trial evaluating the clinical utility of fenestration in standard-risk Fontan patients demonstrated decreased pleural drainage leading to improved hospital length of stay [17, 18]. We intend to follow this cohort of patients and report on their intermediate and long-term outcomes in the future.

Shiraishi and colleagues [8] reported their experience of Fontan procedure by simply cross-clamping the IVC, which provided excellent operative field view and good early outcomes without evidence of abdominal organ congestion. However, their technique required extensive preparation at the time of cavopulmonary connection. For the preparation of the conduit anastomosis, a cuff of either autologous pericardium or prosthetic material was anastomosed to the undersurface of the right PA, and a systemic to pulmonary cuff shunt was constructed to avoid stasis and thrombosis in this blind-end pouch. This negated one of the major advantages of the second-stage operation: the volume unloading of the single ventricle that improves ventricular performance and decreases the risk of sudden death caused by coronary insufficiency [19]. In addition, the azygos vein was intentionally left open to be used as a collateral during IVC cross-clamp at the time of the Fontan procedure. This can result in cyanosis, something that was not observed in their series owing to the addition of the systemic to pulmonary shunt and the short interval between the cavopulmonary connection and the Fontan procedure (median Fontan age, 16 months).

In this series, the clamp and sew technique—simple IVC cross-clamp, division, and anastomosis of the IVC to the conduit without extensive preparations at the time of cavopulmonary connection—was safe and feasible in selected patients with favorable anatomy. The patients tolerated this technique well with inotropic support and volume loading to maintain adequate blood pressure and cardiac output. Only 1 adult patient had to have a venous shunt, as she did not tolerate the IVC cross-clamp. Higashiyama and colleagues [20] suggested that interruption of venous drainage from the lower body by clamping the IVC for longer than 15 minutes without resuscitation can result in low cardiac output, abdominal organ congestion, and liver failure. The incidence of liver injury increased considerably when the IVC pressure exceeded 26 mm Hg. The IVC cross-clamp time in the present series never exceeded 15 minutes. We recently were able to further reduce the clamp time by constructing the IVC to conduit anastomosis before closing the cavoatrial stump. During this modification of the technique, the clamp controlling the cavoatrial junction is left in place while the IVC to conduit anastomosis is performed. The IVC clamp is released, and the atrial closure is then performed in two layers. Lower body venous pressures were not assessed during IVC cross-clamp. The theoretical risk of liver and kidney dysfunction owing to passive congestion was not realized, as no patient experienced postoperative hepatic or renal dysfunction. There were no significant immediate complications and all patients are currently doing well.

Although this initial study of the off-pump clamp and sew Fontan modification has as its primary goal to assess the safety and feasibility of this technique, some of the results raise the question of some possible benefits. Even though no patient in either group experienced

postoperative renal or hepatic dysfunction, the maximal postoperative serum creatinine level and aspartate transaminase level were significantly lower in the off-pump group compared with the CPB group. The overall duration of mechanical ventilation, intensive care unit stay, and hospital stay were comparable with the ones already reported in the literature [4, 7, 21]. The criteria for chest tube removal in this study were quite strict ($<1 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{day}^{-1}$), and the intensive care unit stay and hospital stay are not always entirely dependent on medical practice but reflect utilization of available hospital resources or the patient's background and social support system. Nevertheless, the duration of mediastinal and pleural drainage, intensive care unit stay, and hospital stay were significantly shorter in the off-pump group. It is possible that the use of fenestration may have impacted the chest tube output and hospital length of stay more so than the choice of operative technique [18]. All these differences could also very well be the result of selection bias, as patients with the off-pump technique had lower mean preoperative PA pressure.

The main limitation of this study is that it represents a retrospective nonrandomized review of a single-center experience with a limited patient number and a limited follow-up period.

In summary, the clamp and sew technique for completion of an extracardiac conduit Fontan appears safe and feasible in selected patients with excellent early outcomes. Intraoperative splanchnic, hepatic, and portal venous pressures and flow dynamics are an important future area of evaluation.

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Fig 1.
Pulmonary artery to extracardiac conduit anastomosis with patency of Glenn flow to the left lung.

Fig 2.
Inferior vena cava to extracardiac conduit anastomosis with simple cross-clamp of inferior vena cava.

Fig 3. Angiogram of inferior vena cava to pulmonary artery conduit 16 months after off-pump clamp and sew Fontan procedure showed widely patent extracardiac conduit with smooth blood flow to bilateral branch pulmonary arteries.

Table 1**Demographic and Hemodynamic Data**

Variable	Off-Pump Fontan Group (n = 12)	CPB Fontan Group (n = 12)	p Value
Congenital heart disease diagnosis			
Tricuspid atresia	5	1	0.06
Pulmonary atresia/intact ventricular septum	3	2	0.62
Hypoplastic left heart syndrome	2	4	0.35
Heterotaxy syndrome	1	4	0.13
Others	1	1	1.00
Stage I surgery			
Modified Norwood procedure	2	7	0.04
Systemic to pulmonary artery shunt	6	2	0.08
Pulmonary artery banding	2	0	0.14
Other	1	1	1.00
None	1	2	0.54
Stage II surgery			
Age (mo)	6.6 ± 3.1	5.7 ± 2.1	0.40
Bilateral bidirectional Glenn procedure	3	4	0.65
Pre-Fontan catheter intervention			
Pulmonary artery stent placement	2	4	0.34
Coil embolization of collaterals	3	4	0.65
Pre-Fontan evaluation			
Atrioventricular valve regurgitation			
None	3	4	0.65
Trace	7	3	0.10
Mild	2	3	0.62
Moderate	0	2	0.14
Severe	0	0	N/A
Pulmonary artery pressure (mm Hg)	9.9 ± 2.4	12.2 ± 1.6	0.02
Common atrium pressure (mm Hg)	6.3 ± 1.8	7.4 ± 2.4	0.18
Nakata index (mm ² /m ²)	289 ± 165	228 ± 109	0.11
Pulmonary vascular resistance (Wood units)	1.6 ± 0.7	1.5 ± 0.7	0.84
Preoperative PT – INR	1.2 ± 0.1	1.1 ± 0.1	0.64
Preoperative creatinine (mg/dL)	0.4 ± 0.1	0.4 ± 0.1	0.54
Fontan procedure			
Age (y)	7.0 ± 8.2	4.7 ± 1.6	0.36
Time interval from stage II surgery to Fontan (y)	6.4 ± 8.1	4.3 ± 1.6	0.73
Body weight (kg)	18.9 ± 8.2	16.1 ± 3.5	0.29

CPB = cardiopulmonary bypass; INR = international normalized ratio; N/A = not applicable; PT = prothrombin time.

Table 2**Intraoperative and Postoperative Data**

Variable	Off-Pump Fontan Group (n = 12)	CPB Fontan Group (n = 12)	p Value
Fontan procedure			
20-mm extracardiac conduit	11	11	1.00
Fenestration	3	5	0.39
Concomitant intracardiac procedure	0	2	0.14
Concomitant pulmonary patch arterioplasty	1	6	0.02
Post-Fontan central venous pressure (mm Hg)	10.3 ± 3.0	15.2 ± 3.1	0.002
Intraoperative blood product use (mL/kg)	30.3 ± 30.8	68.3 ± 84.4	0.16
Platelet and/or fresh-frozen plasma transfusion	3/12	11/12	0.001
Postoperative end-organ function			
Maximum AST (U/L)	35.5 ± 8.3	53.1 ± 19.0	0.02
Maximum ALT (U/L)	18.2 ± 13.2	21.0 ± 9.0	0.57
Maximum ALP (U/L)	78.5 ± 21.4	68.8 ± 33.0	0.47
Maximum PT – INR	1.73 ± 0.18	1.99 ± 0.70	0.22
Maximum creatinine (mg/dL)	0.59 ± 0.12	0.77 ± 0.22	0.03
Postoperative course			
Mechanical ventilation time (h)	4 (range, 0–10)	10 (range, 4–138)	0.02
Duration of drainage (days)	7 (range, 3–19)	14 (range, 6–64)	0.02
Intensive care unit stay (days)	3 (range, 2–6)	4 (range, 3–31)	0.02
Hospital stay (days)	9 (range, 7–60)	18 (range, 8–67)	0.03

ALP = alkaline phosphatase; ALT = alanine transaminase; AST = aspartate transaminase; CPB = cardiopulmonary bypass; INR = international normalized ratio; PT = prothrombin time.