Factors affecting Fontan length of stay: Results from the Single Ventricle Reconstruction trial

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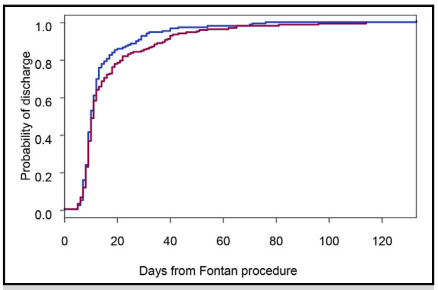
ABSTRACT

Background: In the Single Ventricle Reconstruction trial, infants with hypoplastic left heart syndrome (HLHS) who received a right-ventricle-to-pulmonary-artery shunt (RVPAS) versus a modified Blalock-Taussig shunt (MBTS) had lower early postoperative mortality, but more complications at 14 months. We explored the effect of shunt type and other patient, medical, and surgical factors on postoperative length of stay (LOS) after the Fontan operation.

Methods: Fontan postoperative course was ascertained from medical record review. Cox proportional hazards modeling was used to identify factors associated with LOS.

Results: Of 327 subjects who underwent Fontan, 323 were analyzed (1 death, 1 biventricular repair, 2 with missing data). Median age and weight at Fontan were 2.8 years (interquartile range [IQR]: 2.3, 3.4) and 12.7 kg (IQR: 11.4, 14.1), respectively. Fontan type was extracardiac in 55% and lateral tunnel in 45%; 87% were fenestrated. The RVPAS and MBTS subjects had similar LOS (median 11 days [IQR: 9, 18] vs 10 days [IQR: 9, 13]; $P = .23$). Independent risk factors for longer LOS were treatment center ($P < .01$), LOS at stage II (hazard ratio [HR] 1.02 for each additional day; $P < .01$), and pre-Fontan complications (HR 1.03 for each additional complication; $P = .04$). Use of deep hypothermic circulatory arrest at Fontan (HR 0.64; $P = .02$) was independently associated with shorter LOS. When center was excluded from the model, pre-Fontan complications and use of circulatory arrest were no longer significant; instead, older age at stage II (HR 1.08 for each additional month; $P = .01$) predicted longer LOS. In 254 subjects who had a pre-Fontan echocardiogram, at least moderate tricuspid regurgitation was independently associated with longer LOS,



Kaplan-Meier curves comparing the time to hospital discharge after a Fontan operation for the 2 shunt groups (*blue* = modified Blalock-Taussig shunt; *red* = right-ventricle-to-pulmonary-artery shunt) in transplant-free survivors (logrank $P = .24$).

Central Message

Longer length of stay after a Fontan procedure was associated with greater overall earlier medical complexity, and not with the shunt type used in a Norwood operation.

Perspective

In this follow-up analysis of the multicenter, prospective Single Ventricle Reconstruction trial cohort, survival after a Fontan operation was 99.7%. Length of stay after the Fontan procedure was not associated with shunt type. Rather, global measures of earlier medical morbidity predicted longer LOS. Future studies are needed to assess the impact of early postoperative morbidity on late Fontan outcomes.

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Abbreviations and Acronyms

DHCA = deep hypothermic circulatory arrest
HLHS = hypoplastic left heart syndrome
HR = hazard ratio
IQR = interquartile range
LOS = length of stay
MBTS = modified Blalock-Taussig shunt
RVPAS = right-ventricle-to-pulmonary-artery shunt
SVR = Single Ventricle Reconstruction trial

both with center (HR 1.72; $P < .01$) and without center in the model (HR 1.49; $P = .02$).

Conclusions: In this multicenter prospective cohort of subjects with HLHS, Norwood shunt type was not associated with Fontan LOS. Rather, global measures of earlier medical complexity indicate greater likelihood of longer LOS after the Fontan operation. (J Thorac Cardiovasc Surg 2015;■:1-7)

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Supplemental material is available online.

Since its original description, the Fontan operation has been performed for various single-ventricle anomalies.[1] The Fontan circuit relies on systemic venous pressure to propel blood through the lungs; it therefore depends on low pulmonary vascular resistance, which in turn is affected by such factors as ventricular function and pulmonary artery distortion. Few studies have explored the role of shunt type during the Norwood procedure for hypoplastic left heart syndrome (HLHS) in modulating these factors and affecting the Fontan postoperative course.[2]

The Single Ventricle Reconstruction (SVR) trial showed better transplant-free survival at 12 months in patients assigned to the right-ventricle-to-pulmonary-artery shunt (RVPAS), compared with the modified Blalock-Taussig shunt (MBTS), at the time of the Norwood operation for HLHS and other, related, single right-ventricular anomalies.[3] However, subjects in the RVPAS group had more pulmonary artery stenosis, smaller pulmonary arteries, greater need for intervention, and more complications. These results raise concern, given that pulmonary artery stenosis has been associated with poor outcomes after the Fontan operation.[4] In addition, the incision in the right ventricle that is required for placement of the RVPAS can lead to scar formation, which has the potential to diminish ventricular function and be a nidus for arrhythmia.[5-7] In the SVR trial cohort, by the time of pre-Fontan echocardiography, survivors who had been randomized to the RVPAS, compared with the group who received the MBTS shunt, showed greater deterioration in right-ventricular ejection fraction.[8,9]

All transplant-free survivors of the SVR trial were eligible for enrollment in the SVR Extension study (SVR II), which compares clinical outcomes and right-ventricular performance through 6 years postrandomization. Annual medical histories were obtained when patients were between 2 and 6 years old, and data were collected during the Fontan procedure hospitalization. This well characterized cohort provides a unique opportunity to describe outcomes after the Fontan operation for HLHS, and related, single right-ventricular anomalies, and to determine factors that affect these outcomes from birth to the time of the Fontan procedure.

We hypothesized that subjects who received an RVPAS would have a longer postoperative length of stay (LOS) after undergoing the Fontan procedure, compared with those who received an MBTS. Postoperative LOS was specifically selected as the primary outcome for this analysis, owing to the anticipated low incidence of death, transplantation, or Fontan takedown in this cohort. In addition, we sought to determine the association of patient characteristics with medical and surgical factors relating to LOS after the Fontan operation.

METHODS

Study Design and Data Collection

In the Pediatric Heart Network's SVR trial,[3] infants with HLHS and related, single right-ventricular anomalies, from 15 centers across North America, were randomized to receive the RVPAS or MBTS during the Norwood operation. Patients who had undergone the Fontan operation as of April 1, 2013 were eligible for inclusion in this analysis. The study was approved by the institutional review board or research ethics board at each participating center, and written informed consent was obtained from parents and/or guardians before enrollment in the trial.

The shunt that was in place at the end of the Norwood operation was used for the current analysis (as opposed to intention to treat). An annual medical history was obtained from transplant-free survivors, via phone interview with parents and/or guardians and review of medical records. Medical factors that were analyzed include the following: LOS, at both Norwood and stage II; the number of serious adverse events in the first 12 months, and the number of complications and interventional catheterizations in the time period from before the Norwood to the Fontan procedure.

Nonfatal serious adverse events that were recorded from the time of randomization in the SVR trial to age 12 months included acute shunt failure, cardiac arrest, use of extracorporeal membrane oxygenation support, unplanned cardiovascular reoperation, and necrotizing enterocolitis. Other potential risk factors, including patient characteristics, are listed in Appendix E1. Only those pre-Fontan echocardiograms that were performed at the study center were reviewed in a core laboratory, and pre-Fontan cardiac catheterization was performed per standard clinical practices at each center. The month in which the Fontan operation was performed was included as a potential seasonal predictor of LOS, with 2 categories: November through March (the peak time of year for viral