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# Interstage outcomes in single ventricle patients undergoing hybrid stage 1 palliation

Janet M. Simsic MD | Christina Phelps MD | Kristin Kirchner RD | Kirby-Rose Carpenito RD | Robin Allen RN | Holly Miller-Tate RN | Karen Texter MD | Mark Galantowicz MD

The Heart Center at Nationwide Children's Hospital, Columbus, Ohio

**Correspondence**
Janet M Simsic, MD, The Heart Center T2292, Nationwide Children's Hospital, 700 Children's Drive, Columbus, OH 43205, USA.
Email: janet.simsic@nationwidechildrens.org

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## Abstract

**Objective**: Interstage readmissions are common in infants with single ventricle congenital heart disease undergoing staged surgical palliation. We retrospectively examined readmissions during the interstage period.

**Design**: Retrospective analysis.

**Setting**: The Heart Center at Nationwide Children's Hospital, Columbus, Ohio.

**Patients**: Newborns undergoing hybrid stage 1 palliation from January 2012 to December 2016 who survived to hospital discharge and were followed at our institution.

**Interventions**: All patients underwent hybrid stage 1 palliation.

**Outcome Measures**: Outcomes included (1) reason for interstage readmission; (2) feeding modality during interstage period; (3) major interstage adverse events; and (4) interstage mortality.

**Results**: Study group comprised 57 patients. Five patients only admitted once during the interstage period for scheduled cardiac catheterization were included in the no readmission group. Therefore, 43 patients (75%) had a total of 87 interstage readmissions. Fourteen patients had 15 major interstage adverse events accounting for 17% of total readmissions. Stroke (n = 1); sepsis (n = 1); pericardial effusion requiring drainage (n = 1); mesenteric ischemia (n = 1); shock (n = 1); and cardiac catheterization requiring intervention (n = 11)—ductal stent balloon angioplasty (n = 3), enlargement of atrial septal defect/stent placement (n = 3), retrograde aortic arch stenosis (n = 4). Thirty-three readmissions were secondary to gastrointestinal/feeding issues; 15 cyanosis; 15 work of breathing; and 9 asymptomatic patients. Four patients suffered interstage deaths (7%). Five patients (9%) spent >30 days in the hospital during the interstage period. Of the 47 newborns (82%) discharged exclusively orally feeding, 74% remained all orally feeding throughout interstage period. No patient discharged with tube feedings learned to eat during the interstage period.

**Conclusion**: Interstage readmissions are common in the hybrid patient population. Seventeen percent were secondary to major adverse events. Interstage mortality was 7%. Future studies to identify interventions aimed at decreasing feeding issues and viral bronchiolitis in this tenuous patient population will hopefully improve quality outcomes, reduce readmissions, and lessen health care costs.

KEYWORDS

feeding, hybrid palliation, interstage, outcomes, readmissions, single ventricle

  

## 1 | INTRODUCTION

Time frame between first and second stages of surgical palliations for single ventricle congenital heart disease is referred to as the interstage period. This time frame continues to be a period of potential hemodynamic instability, with interstage mortality ranging from 0% to 15% for stage 1 palliation survivors.[1–8] In an effort to reduce interstage mortality many programs have adopted the home monitoring strategy which consists of home oxygen saturation monitoring, home weight checks, and frequent follow-ups either by phone or clinic appointments.[4–6] Multiple studies have shown a decrease in interstage mortality with the use of home monitoring.[4–6]

Readmissions during this interstage period are also common.[9–12] The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) reviewed outcomes for interstage readmissions for a large multicenter population of newborns with hypoplastic left heart syndrome undergoing staged palliation.[10] Hanke et al reported unplanned readmissions in 66% of the patients from 50 centers.[10] However, the majority of their patients underwent Norwood operation (92%).[10] Our center philosophy is one of hybrid stage 1 palliation rather than Norwood operation. Hybrid stage 1 palliation consists of bilateral pulmonary artery banding, placement of a stent in the patent ductus arteriosus without cardiopulmonary bypass, and then a balloon atrial septostomy several days following initial palliation. Comprehensive stage II is done at approximately 4–6 months of age and consists of a Norwood arch reconstruction combined with a bidirectional Glenn procedure. The purpose of this study was to retrospectively examine readmissions during the interstage period in patients undergoing single ventricle-staged palliation with the hybrid stage 1 approach rather than Norwood operation.

## 2 | METHODS

This retrospective study was approved by the Institutional Review Board at our institution with waiver of informed consent. All neonates (aged <30 days at time of surgery) with single ventricle physiology with arch obstruction undergoing hybrid stage 1 palliation (S1P) from January 2012 to December 2016 who survived to hospital discharge and were followed interstage at our institution were retrospectively reviewed. Fifty-seven patients comprised the study group. End points for analysis were completion of a second stage palliation or death before the second surgery. Our center philosophy is one of hybrid stage 1 palliation rather than Norwood operation.

### 2.1 | Home monitoring

All of the patients undergoing S1P are home monitored. Home monitoring at our institution began in 2009. However, it was not until April 2014 when our institution developed a comprehensive single ventricle team that included designated single ventricle cardiologists, standardized protocols for patient management including medications and timing of tests/interventions, as well as standardized responses to breeches of home monitoring. Prior to this the home monitoring nurses referred issues to the primary cardiologist without standardization in management. Our current home monitoring begins with parental/family education prior to discharge on (1) the diagnosis, surgery, and projected future plan; (2) discharge medications; (3) how to use the infant scale and pulse oximeter; (4) when to call the pediatrician; when to call the cardiologist; and (5) conference call transfer of care handoffs to the pediatrician and single ventricle team cardiologist. The parents are also encouraged to participate in these conference calls.

Home monitoring for patients following S1P include the parents obtaining Monday, Wednesday, and Friday weight checks, daily systemic saturation checks by pulse oximeter, weekly telephone call by the single ventricle nurse clinician to assess weight gain, enteral intake, systemic saturations, red flags, or other parental concerns. Patients are seen in multidisciplinary single ventricle clinic every 2 weeks. Multidisciplinary single ventricle clinic includes the single ventricle cardiologist, dietician, and home monitor nurse clinician. Echocardiograms are performed at each of these clinic visits. Parents are instructed to call the home monitoring team if (1) the baby loses weight, (2) the baby's oxygen saturations drop below 75% or 10 below baseline, (3) the baby is breathing harder or faster, (4) the baby vomits more than twice in 24 hours, not counting spit-ups, (5) the baby has more than three loose or watery bowel movements, (6) the baby has a temperature >100.5, (7) the baby is sleeping more than usual, (8) the baby is unable to be comforted, or (9) for any other question or concern. There are standardized responses for each breech of home monitoring.

### 2.2 | Outcomes

Outcomes included (1) reason for interstage readmission; (2) feeding modality during the interstage period; (3) major interstage adverse events included cardiac arrest, shunt occlusion, cardiac catheterization with intervention, arrhythmia, seizure, stroke, aspiration, and infection requiring antibiotics; and (4) interstage mortality defined as death after hospital discharge following S1P but before second-staged palliation. Mesenteric ischemia was conservatively defined as clinical concerns resulting in NPO and antibiotics × 7 days. Reason for interstage readmission was admittedly difficult to classify as most were multifactorial. Classification was based on the chief complaint and symptoms that led to hospital admission.

## 3 | RESULTS

The study group comprised 57 patients. Five patients who were only admitted once during the interstage period for a scheduled cardiac catheterization were included in the no readmission group. Data for these 5 patients are not included in the readmission group. Therefore, 43 patients (75%) had a total of 87 interstage readmissions.

Twenty-two patients (51%) had more than one readmission; 8 patients (18%) had more than 3 readmissions. Total readmission days during the interstage time frame were average 16.5 ± 22 days (median 9.5; range 1–100 days).

Readmission occurred on average 43 ± 40 days after hospital discharge following S1P (median 25; range 5–167 days). Three patients (7%) were readmitted within 7 days of hospital discharge following S1P. One of these patients was readmitted for decreased systemic saturations; one for inadequate oral feeding; and one for blood in the stool. Five patients (12%) were readmitted greater than 100 days after hospital discharge following S1P. One for unplanned catheterization requiring balloon dilation of the PDA stent; one for new right-sided weakness; one for poor weight gain; one for cyanosis; and one for increased work of breathing with decreased oral intake. Five patients (12%) spent >30 days in the hospital during the interstage period. Patients in the no readmission group had longer, though not statistically significant, lengths of stay following S1P compared to the readmission group (average 32 ± 21 days; median 27; range 11–78 days vs 27 ± 16 days; median 23; range 10–92 days) Table 1.

Fourteen patients had 15 major interstage adverse events, accounting for 17% of total readmissions. Major interstage adverse events included: stroke (n = 1); sepsis (n = 1); pericardial effusion requiring drainage (n = 1); mesenteric ischemia (n = 1); shock (n = 1); and cardiac catheterization requiring intervention (n = 11)—ductal stent balloon angioplasty (n = 3), enlargement of atrial septal defect/stent placement (n = 3), retrograde aortic arch stenosis (n = 4). One patient had 2 interventions during the same cardiac catheterization Figure 1. Four patients died during the interstage period—these patients were not included in the major adverse events. Five major adverse events occurred before April 2104 (institution of the comprehensive single ventricle team and formalized home monitoring management protocols); 10 occurred after April 2014.

In addition to the 15 readmissions for major adverse events Figure 1, 33 readmissions were secondary to feeding issues including poor enteral intake and/or inadequate weight gain n = 21; diarrhea or emesis and dehydration n = 7, and blood in stool n = 5. Fifteen readmissions were secondary to increasing cyanosis. Fifteen were secondary to increased work of breathing associated with viral bronchiolitis. Nine readmissions occurred in asymptomatic patients—three for scheduled cardiac catheterizations no interventions occurred during procedure; six for changes on echocardiogram either decreased function or increased retrograde aortic arch gradient which did not required intervention. Figure 2.

Four patients for the total cohort of 57 patients suffered interstage deaths (7%). There was one interstage death per year between 2012 and 2015. One patient from the readmission group (2%) and three patients from the no readmission group (21%) $P = .04^{*}$. The interstage death in the readmission group was in early 2014. Unfortunately, autopsies were not obtained for all patients who suffered interstage deaths. Details regarding interstage mortality as follows.

Patient 1 (2012) died at primary care physician's office during a routine visit 6 days after hospital discharge following S1P. Hospital course was complicated by ectopic atrial tachycardia treated with sotalol. There were no anatomic concerns on discharge echocardiogram. Home monitoring call the day prior to death was without parental concerns. This patient did not have an autopsy due to religious beliefs.

Patient 2 (2013) died at an outside emergency department 2 weeks after hospital discharge following S1P. This patient was exclusively orally feeding. Hospital course was complicated by atrial flutter that was attributed to central line placement and was not treated. There were no anatomical concerns on discharge echocardiogram. Home monitoring call 6 days prior was without parental

**TABLE 1** Variables between the readmission and no readmission groups

| | Readmission | No readmission | *P* value |
|---|---|---|---|
| N | 43 | 14 | |
| Mean birth weight kg (median, range) | 3.05 ± 0.45 (3.07; 1.6–3.7) | 3.3 ± 0.4 (3.3; 2.7–3.9) | .5 |
| Birth weight <3 kg | 13 (30%) | 4 (28%) | .7 |
| HLHS | 31 (72%) | 9 (64%) | .5 |
| Single ventricle variant | 12 (28%) | 5 (36%) | .5 |
| Preop feeding | 22 (51%) | 9 (64%) | .8 |
| All po at S1P discharge | 36 (84%) | 11 (78%) | .7 |
| Tube feeds at S1P discharge | 7 (16%) | 3 (22%) | .7 |
| Mean S1P hospital LOS (days) (median, range) | 27 ± 16 (23; 10–92) | 32 ± 21 (27; 11–78) | .1 |
| S1P hospital LOS >30 days | 10 (23%) | 4(31%) | .7 |
| Total # of readmissions | 87 | 0 | |
| 1 | 21 (49%) | | |
| >1 | 22 (51%) | | |

Abbreviations: HLHS, hypoplastic left heart syndrome; LOS, length of stay; 1, stage 1 hybrid palliation.

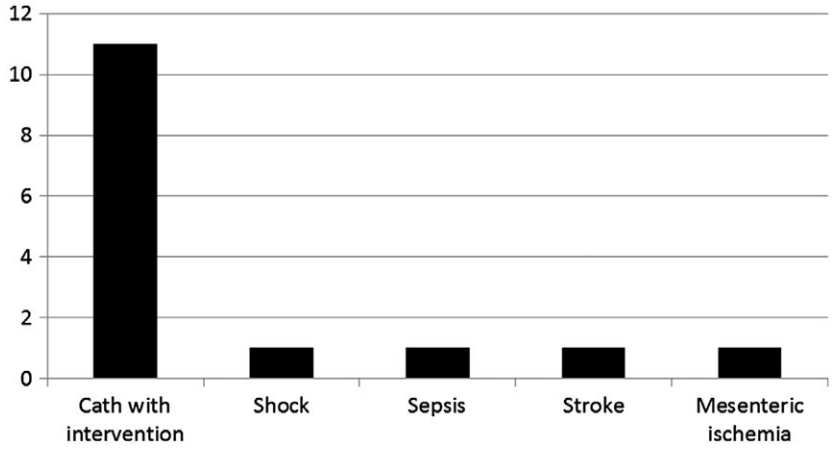


**FIGURE 1** Major interstage adverse events

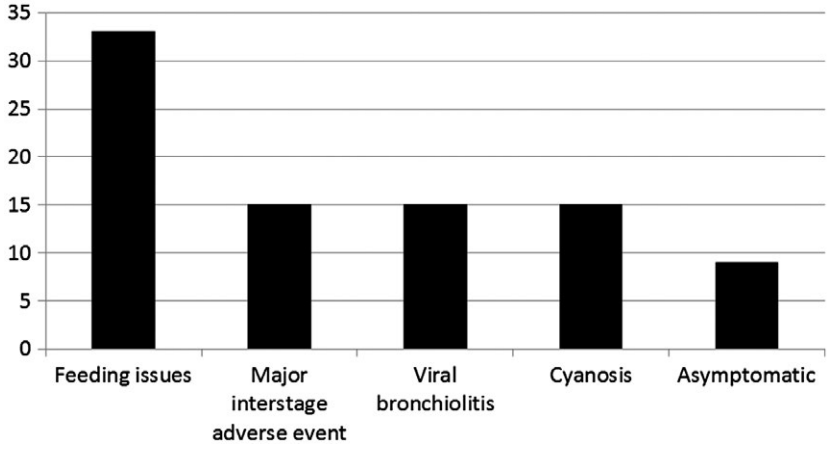


**FIGURE 2** Reason for interstage readmission

concerns. Patient had routine cardiology follow-up appointment scheduled for the day of interstage death.

Patient 3 (2014) presented to outside emergency department 129 days after hospital discharge following S1P mottled with desaturation and arrested in route to our cardiothoracic intensive care unit; expired 4 days later. Patient was positive for human rhinovirus. There were four previous interstage readmissions. Outpatient echocardiogram 2 days prior to arrest revealed mildly increased gradient across the PDA stent and mild retrograde aortic arch obstruction, function was normal. This patient expired in early 2014 prior to the formation of our comprehensive single ventricle team.

Patient 4 (2015) died at outside emergency department 17 days after hospital discharge following S1P. Hospitalization was complicated by mesenteric ischemia post-S1P. Patient presented to the primary care physician day prior to death with irritability, fever 100.7. Saturations were 73%; RSV and influenza were negative. This patient was fed via gastrostomy tube. Patient expired the following day at an outside emergency department—autopsy revealed recurrent mesenteric ischemia.

Of the 47 newborns (82%) discharged following S1P exclusively orally feeding; 74% remained all orally feeding throughout the interstage period. No patient discharged with a feeding tube or gastrostomy tube learned to eat during the interstage period.

## 4 | DISCUSSION

Readmissions during the time between staged surgical palliations for single ventricle congenital heart disease are common.[9–12] However, the majority of the current literature is regarding patients who underwent Norwood operation. This retrospective review is unique in that our center philosophy is one of hybrid stage 1 palliation rather than Norwood operation. Hybrid stage 1 palliation consists of bilateral pulmonary artery banding, placement of a stent in the patent ductus arteriosus without cardiopulmonary bypass, and then a balloon atrial septostomy several days following initial palliation. Comprehensive stage II is done at approximately 4–6 months of age and consists of a Norwood arch reconstruction combined with a bidirectional Glenn procedure. Hybrid patients comprised 100% of this study's patient population.

Interstage readmissions were more common in our patient population compared to those reviewed by Di Maria et al.[13] However, interstage readmissions in this current study were similar to those reported by Uzark et al[14] and Rudd et al.[3] in the Norwood population. Hanke et al in a retrospective review from the NPC-QIC reported increased readmissions for the patients undergoing hybrid stage 1 palliation, although only 8% of the patients in his study has undergone hybrid stage 1 palliation.[10] Lloyd et al also reported

interstage interventions were more common in the hybrid stage 1 palliation group compared to the Norwood group (hybrid, 6 of 18 (33%) vs Norwood, 6 of 80 (8%); $P = .007$*).[15] However, Knirsch et al reported interstage interventions common in both groups (hybrid stage 1 palliation 4 of 6 (67%) vs Norwood 2 of 8 (25%); $P = .3$).[16] Although the numbers in both groups were small making statistical significance difficult to interpret clinically.

The hybrid population has different concerns during the interstage period compared to the Norwood population. Hybrid palliation avoids neonatal exposure to cardiopulmonary bypass, but does not prevent some degree of volume and pressure overload to the systemic ventricle.[17] Unique concerns to hybrid stage 1 palliation include retrograde aortic arch obstruction and ductal in stent stenosis resulting in compromise of the coronary circulation because the systemic outflow obstruction remains untreated at hybrid stage I palliation.[18–20] Progressive narrowing of the aortic isthmus may result in myocardial ischemia and subsequent global ventricular dysfunction.[19,20] Hybrid patients are followed closely for retrograde arch stenosis at the junction of the aorta and the ductal stent, ductal in stent stenosis, restriction at the atrial level (may also be seen with Norwood operation), and pulmonary blood flow secondary to the pulmonary artery bands. We speculate that interstage readmissions for cardiac reasons including catheter interventions are likely to be increased in the hybrid stage 1 population compared to the Norwood population secondary to the unique concerns for retrograde aortic arch stenosis, restrictive atrial septal defect and ductal in stent stenosis. Five of the cohort's interstage major adverse events occurred before April 2104 (institution of the comprehensive single ventricle team and formalized home monitoring management protocols); and 10 occurred after April 2014. Eight of the 10 interstage major adverse events occurring after April 2014 were related to anatomic concerns that were addressed in the cardiac catheterization laboratory. Our patient, who expired in early 2014 prior to the formation of our comprehensive single ventricle team, had increasing PDA stent gradient noted on outpatient echocardiogam. Although the patient was asymptomatic and the ventricle function remained normal. We can only speculate that perhaps the mildly increased gradient through the ductal stent, while not a breech in the home monitoring protocol, may have prompted admission and cardiac catheterization in the current era. We believe that recognizing and promptly addressing issues with catheter interventions while increasing our interstage major adverse events, likely reduced the potential for interstage mortality.

Breakdown of interstage readmissions were somewhat similar between our patient population, hybrid stage 1 palliation, and Hanke et al primarily Norwood stage 1 palliation.[10] Of the readmissions, 38% in the current study were secondary to feeding or gastrointestinal problems compared to 36% in Hanke's study; 30% in the current study were secondary to respiratory problems including increasing cyanosis and viral bronchiolitis compared to 48% in Hanke's study.[10] Major interstage adverse events in the current study (17%) were greater than those reported by Hanke et al 6%.[10] The breakdown of major adverse events was also not similar between the 2 studies. Sixty-five percent of patients in Hanke's review were readmitted for intravenous antibiotics whereas only 1 patient in the current study required intravenous antibiotics.[10] Shock, seizure, and stroke were infrequent in both studies.[10] In the current study, there were 11 cardiac catheterizations with interventions during the interstage period. This highlights one of the differences between the hybrid and Norwood populations. While these are considered major adverse events we believe that these are examples of a successful process. These issues were identified and addressed thus potentially preventing patient harm and interstage mortality. One patient who suffered interstage mortality in our cohort, prior to our comprehensive single ventricle team and standardized patient management, had an echocardiogram prior to their death with increased gradient thru the ductal stent. As stated previously, we can only speculate if the mildly increased ductal stent gradient would have prompted an interstage readmission as the patient did not meet home monitoring breech of protocol, was asymptomatic and the ventricular function remained normal.

Interstage mortality had been reported ranging from 0% to 15% for stage 1 palliation survivors.[1–8] Several institutions that perform both the Norwood operation and the hybrid stage I palliation have compared outcomes and interstage mortality between the 2 groups.[15,16] Lloyd et al found no difference in interstage mortality despite the hybrid patients having a higher Aristotle score (Norwood patients 10/80 (12.5%) vs hybrid stage 1 palliation 3/18 (16.7%); $P = .7$).[15] Knirsch et al also showed no difference in interstage mortality in their cohort; although admittedly their numbers were small, hybrid stage 1 palliation 0 of 6 (0%) compared to Norwood 1 of 8 (12.5%); $P = 1$).[16] Our hybrid patient population had an overall interstage mortality of 7% (4 of 57 total patients). Interestingly, three of the four of the patients with interstage mortality were either seen by a physician or had a home monitoring phone call within 2 days prior to their death. In this patient cohort, there was no significant change in interstage mortality with the introduction of our comprehensive single ventricle team. There was one interstage death per year.

The majority of our patients discharged exclusively orally feeding following S1P remained all orally feeding throughout the interstage period (73%). However, unlike several previous studies,[13,14,21] our patients discharged with supplemental tube feeds did not "learn to eat" during the interstage period. In the study by Di Maria et al 61% of patients who were NGT fed at S1P discharge transitioned to the 100% orally feeding group during the interstage period.[13] In the study by Uzark et al 58% of patients who were NGT fed at S1P discharge transitioned to the all orally feeding group during the interstage period.[14] In a study from the National Pediatric Cardiology Quality Improvement Collaborative, oral feeding increased from 44% of patient following S1P discharge to 62% at time of second stage palliation.[21] Admittedly, the lack of "learning to eat" in our patient population is multifactorial; however, we speculate that a contributing factor may include the lack of robust outpatient occupational and speech therapy. With the institution of our high-risk feeding clinic in 2016, we are hopeful that this will improve.

### 4.1 | Limitations

The limitations to this study include those inherent to any retrospective review. Limited patient information, specifically cause of death secondary to lack of autopsies, death at home or at another hospital, prevent us from commenting on the cause of interstage mortality in all patients. The 14 patients in the no readmission group spent a longer time in the hospital following S1P, were more frequently discharged with tube feeds and had greater interstage mortality, which might suggest that this was a sicker patient population. Although none of the variables reached statistical significance. Reason for interstage readmission was admittedly difficult to classify as most were multifactorial. Classification was based on the symptoms at time of admission. Our cohort had four total interstage deaths, one per year from 2012 to 2015, thus making it difficult to comment on the impact of our comprehensive single ventricle team and formalized home monitoring started in April 2014. Our center philosophy is one of hybrid stage 1 palliation rather than Norwood operation, hybrid patients comprised 100% of this study's patient population. Comparisons from the literature are mostly from centers primarily performing Norwood operations.

## 5 | CONCLUSION

Interstage readmissions are common in this cohort of patients occurring in 75% of our patients. The majority of the interstage readmissions are unscheduled and 17% were secondary to a major adverse event. The most common reason for readmission was gastrointestinal or feeding issues including poor po intake and inadequate weight gain. Interstage mortality was 7% in this cohort. Future studies to identify interventions aimed at decreasing feeding issues and viral bronchiolitis in this tenuous patient population will hopefully improve quality outcomes, reduce readmissions, and lessen health care costs.

## CONFLICT OF INTEREST

None of the authors have any conflicts of interest.

## AUTHOR CONTRIBUTIONS

Janet M Simsic MD, cardiologist, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper and revising it critically; and has approved the submitted and final versions.

Christina Phelps MD, cardiologist, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Kristen Kirchner RD, registered dietician, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Kirby-Rose Carpenito RD, registered dietician, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Robin Allen RN, nurse clinician, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Holly Miller-Tate RN, nurse clinician, participated in research design, the acquisition, analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Karen Texter MD, cardiologist, participated analysis and interpretation of data; drafting the paper; and has approved the submitted and final versions.

Mark Galantowicz MD, cardiac surgeon, participated in research design, the analysis, and interpretation of data; drafting the paper; and has approved the submitted and final versions.

## ORCID

*Karen Texter* http://orcid.org/0000-0002-7875-9266

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