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Title
Comparing palliation strategies for single ventricle anatomy with transposed great arteries and systemic outflow obstruction

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Informed Consent: This study was approved by the Baylor College of Medicine Institutional Review Board with waiver of informed consent for participation given the retrospective chart-review outcome analysis with minimal risks to participants, no patient contact, no treatment intent, and anonymized publication data.
Glossary of Abbreviations

BCPC: bidirectional cavopulmonary connection

BVF: bulboventricular foramen

BSA: body surface area

CPB: cardiopulmonary bypass

DKS: Damus-Kaye-Stansel

ECMO: extracorporeal membrane oxygenation

LPA: left pulmonary artery

PA: pulmonary artery

PAB: pulmonary arterial band

pASO: palliative arterial switch operation

PBF: pulmonary blood flow

RPA: right pulmonary artery

SPS: systemic-to-pulmonary artery shunt

SV-TGA-SOO: functional single ventricle, transposed great arteries, and systemic outflow tract obstruction
Central Message:
Fontan completion and survival are comparable for palliative arterial switch, pulmonary artery band and modified Norwood for neonates with single ventricle, transposition and systemic obstruction.

Perspective Statement:
Choice of initial surgical palliation for single ventricle with transposition and systemic outflow obstruction is challenging and has long-reaching implications for successful Fontan. We review a diverse longitudinal experience, including the largest published series of the controversial palliative arterial switch operation, to highlight long-term outcomes and salient factors in decision-making.

Central Picture Legend:
Representative pre- and post-operative anatomy after palliative arterial switch operation.
Abstract

Objective: Patients with complex single ventricle anatomy with transposed great arteries and systemic outflow obstruction (SV-TGA-SOO) undergo varied initial palliation with ultimate goal of Fontan circulation. We examine a longitudinal experience with multiple techniques, including the largest published cohort following palliative arterial switch operation (pASO), to describe outcomes and decision-making factors.

Methods: Neonates with SV-TGA-SOO who underwent initial surgical palliation from 1995 to 2022 at a single institution were retrospectively reviewed.

Results: 71 neonates with SV-TGA-SOO underwent index surgical palliation at a median age of 7 days (IQR 6 – 10) by pASO (n=23), pulmonary artery band (PAB) with or without arch repair (n=25), or modified Norwood with Damus-Kaye-Stansel aortopulmonary amalgamation (n=23). Single ventricle pathology included double inlet left ventricle (n=37, 52%), tricuspid atresia (n=27, 38%), and others (n=7, 10%). All mortalities (n=5, 7%) occurred in the first interstage period after PAB (n=3) and Norwood (n=2). Subaortic obstruction in the PAB group was addressed by operative resection (n=10 total, 7 at index operation) and/or delayed aortopulmonary amalgamation (n=13, 52%). 2 pASO patients (9%) had early postoperative coronary complications, 1 requiring operative revision. Median follow-up for survivors was 10.4 years (IQR 4.5 – 16.6 years). Comparing patients by their initial palliation type, notable significant differences included size of bulboventricular foramen, weight at initial operation, operation duration, postoperative length of stay, time to second stage palliation, multiple pulmonary artery reinterventions, and left pulmonary artery interventions. There were no significant differences in overall survival, Fontan completion, reintervention-free survival in the first interstage period, pulmonary artery reintervention-free survival, long-term systemic valve
Conclusions: Excellent mid- to long-term outcomes are achievable following neonatal palliation for SV-TGA-SOO via pASO, PAB, and modified Norwood, with comparable survival and Fontan completion. Initial palliation strategy should be individualized to optimize anatomy and physiology for successful Fontan by ensuring an unobstructed subaortic pathway and accessible pulmonary arteries. pASO is a reasonable strategy to consider for these heterogeneous lesions.

Abstract word count: 319

Keywords: palliative arterial switch, complex single ventricle, single ventricle management, double inlet left ventricle, tricuspid atresia, transposition
Introduction

For the rare subset of patients with single ventricle, transposed great arteries, and systemic outflow obstruction (SV-TGA-SOO), successful Fontan palliation is dependent upon controlling pulmonary blood flow (PBF), relieving obstruction in the systemic pathway, preserving ventricular and semilunar valve function, ensuring a stable rhythm, and allowing pulmonary arterial development. Difficulty in objectively assessing and predicting progression of subaortic obstruction in these heterogeneous lesions further complicates operative decision-making.

Typical palliation strategies in the neonatal period include pulmonary artery banding (PAB) with arch augmentation$^1$ or subaortic resection$^2$ as needed and modified Norwood procedure with Damus-Kaye-Stansel (DKS) aortopulmonary amalgamation and systemic-to-pulmonary shunt (SPS).$^3$ The palliative arterial switch operation (pASO) is an alternative approach that aligns the systemic ventricle with an unobstructed outflow tract, preserves antegrade pulmonary blood flow, and avoids left pulmonary artery (LPA) entrapment.$^4$ Critiques of this operation include its technical complexity and concern for coronary artery complications.

In this study, we describe nearly three decades of experience caring for neonates with SV-TGA-SOO at a high-volume center, including the largest published experience with pASO. By comparing patient characteristics and outcomes in this population, we aim to provide historical and contemporary context for early operative management in this challenging population.

Patients and Methods

Study Design

Following Institutional Review Board approval (protocol H-38659, approved 9/8/2021 with waiver of informed consent), we queried the Texas Children’s Hospital patient database for
patients with diagnoses of single ventricle and transposition who underwent index surgical repair at age ≤ 30 days between July 1995 and July 2022. Medical records were retrospectively reviewed. Anatomic inclusion criteria were preoperative diagnoses consistent with single ventricle cardiac configuration, transposition, and at least one level of systemic outflow obstruction (aortic arch hypoplasia, coarctation, or interruption; aortic valve hypoplasia or stenosis; or presence/substrate for subaortic obstruction due to hypoplastic subaortic chamber, restrictive/potentially restrictive BVF, or prominent subaortic conus). The latter criteria were deliberately broad given lack of consensus on objective criteria for subaortic adequacy in the preoperative setting. Exclusion criteria were index operation at outside institution or bi-ventricular repair.

A single cardiologist blinded to palliation strategy systematically reviewed preoperative echocardiograms, focusing on semilunar valves and subaortic region. Parameters were preferentially obtained by direct review of images and extrapolated from existing reports when images were unavailable (studies prior to 2010). Qualitative follow-up echocardiographic parameters (ventricular function, systemic valve insufficiency) were retrospectively obtained from existing reports.

Patients were primarily categorized and compared by their initial intervention (PAB, pASO, or Norwood), unless otherwise stated. Primary outcomes were Fontan completion and survival. Secondary outcomes were unplanned cardiothoracic interventions in the first interstage period, pulmonary artery (PA) interventions, postoperative coronary artery pathology, interventions for subaortic obstruction, transplant, ventricular function, and systemic valve regurgitation.
Strategy Selection

Choice of initial palliation technique was individualized to each patient’s anatomy and hemodynamics, informed by preoperative multidisciplinary discussion, intraoperative transesophageal echocardiography, and direct anatomic inspection. Arrangement of the great vessels, coronary pattern, presence/degree of subaortic obstruction, and semilunar valve function were major determinants of the decision. The aggregate balance of risks, benefits, and feasibility of each option were interpreted subjectively by the performing surgeon, often finalizing the decision intraoperatively. Further details regarding the decision-making process are subsequently discussed, and current practices are summarized in Figure 1.

Operative Technique: Palliative Arterial Switch

Following median sternotomy, institution of cardiopulmonary bypass (CPB), and cardioplegic arrest, the ascending aorta was transected several millimeters distal to the aortic valve commissures. If necessary to obtain adequate coronary buttons, native aortic valve commissures were taken down and reapproximated. Neo-pulmonary sinuses were reconstructed with autologous pericardial patches. Coronary transfer was typically accomplished via medially-based trapdoor incisions. Two of the three surgeons adjusted their approach during the study period to reconstruct the neo-aorta prior to performing coronary transfer. A Lecompte maneuver was performed in all patients. Arch reconstruction was performed when indicated, typically by arch advancement with or without patch augmentation. After weaning from bypass, relative PBF was assessed and restricted (PAB) or augmented (SPS) to maintain saturations between 75% and 85% and distal PA pressures approximately half systemic. Sternal closure was delayed for hemodynamic instability or anticipated need for early PAB adjustment.
**Operative Technique: PAB**

PAB were placed distally on the main PA to minimize distortion of native pulmonary valve and sized by Trusler’s rule, tailored based on systemic oxygen saturation and echocardiographic gradient across the band. Concurrent repair of arch obstruction and other cardiac lesions were performed as indicated. Strategies for dealing with preoperative presence or threat of subaortic obstruction shifted during the study period, with subaortic resection (BVF enlargement, septal myectomy, or resection of accessory valve tissue) to enlarge the subaortic area at index PAB not performed since 2015.

**Operative Technique: Modified Norwood**

End-to-side or side-to-side (“double-barrel”) DKS aortopulmonary amalgamation was performed, depending on great vessel arrangement, to create the neo-aortic root. Patch augmentation was performed as needed to avoid semilunar valve distortion and address arch obstruction. The distal PA bifurcation was either closed primarily or patch augmented. SPS were modified Blalock-Thomas-Taussig shunts except one case with central shunt. Lecompte maneuver was performed in one case.

**Statistical Analysis**

Continuous variables were summarized as medians and interquartile ranges and compared with Kruskal-Wallis or Wilcoxon Rank-Sum tests. Categorical variables were described as absolute and relative frequencies within the group of interest and compared using Fisher’s exact test. Differences in Kaplan-Meier survival curves for time-to-event outcomes were evaluated by log-rank testing. Post-hoc pairwise analyses were performed for statistically significant multi-group
comparisons, without adjustment. P-values are reported using a significance level of 0.05. Analyses were conducted with STATA version 17.0 (StataCorp LLC, College Station, Texas).

Results

Preoperative Characteristics
Selected preoperative characteristics are summarized in Table 1 and Data Supplement Part A. Demographics, fundamental cardiac diagnosis, great vessel looping and orientation, and arch pathology were similarly distributed between groups. Primary single ventricle lesions were double inlet left ventricle (n=37, 52%), tricuspid atresia (n=27, 38%), and other complex arrangements (n=7, 10%) involving double outlet right ventricle or other complex congenitally-corrected transposition.

On preoperative echocardiography (Table 1, Supplement Part B), there was a nearly-statistically-significant trend (p=0.052) toward higher prevalence of pulmonary valve pathology, defined as greater than mild insufficiency and/or leaflet thickening, in the PAB group. Prevalence of subaortic conus and BVF were similar between groups. While a similar proportion of patients had potentially restrictive BVF by size criteria (BVF/BSA < 2 cm$^2$/m$^2$)5, minimum BVF diameter, absolute BVF area, and indexed BVF area to body surface area (BSA) significantly differed, largest in the PAB group, particularly for those without initial subaortic resection.

Index Operation and Interstage Period
Operative data are summarized by cohort in Table 2 and Supplement Part C. Though operative age was similar, operative weight was heavier for Norwood compared to PAB. CPB and cross-clamp times were longest in pASO followed by Norwood then PAB. Delayed sternal closure was
more common after pASO and Norwood compared with PAB. 2 patients (1 pASO, 1 Norwood) had ECMO cannulation at initial palliation for ventricular dysfunction. Both required 4 days of support and were alive at follow-up.

Postoperative events in the first interstage period between initial palliation and bidirectional cavopulmonary connection (BCPC) are detailed in Supplement Part D.

Postoperative length of hospital stay was shortest for PAB but similar for pASO and Norwood (Table 2). Freedom from any unplanned intervention (related to cardiovascular pathology or post-surgical complications) or death prior to BCPC was statistically similar between groups (p=0.08, Figure 2a), though tended to be superior for PAB.

Interventions to adjust relative pulmonary and systemic blood flow are summarized in Figure 3. Of the 14 pASO patients with PAB placed at index procedure, 3 required PAB adjustment postoperatively (2 prior to chest closure) and 2 required SPS for increasing BVF restriction and PAB. A total of 4 pASO patients had SPS placed at a median of 40 days (range 3 – 77 days) postoperatively.

**Mortality**

There were 5 total mortalities (3 PAB, 2 Norwood) all occurring in the first interstage period at a median of 68 days postoperatively (range 22 – 245 days). Mortality rates were statistically similar between cohorts (Table 2). One PAB patient developed increasing BVF restriction and pulmonary hypertension and underwent conversion to DKS with SPS 4 months postoperatively (BCPC was attempted but aborted due to profound hypoxia). Although PA pressures improved, multifactorial chronic respiratory failure and ventricular dysfunction persisted until their death 8 months following initial palliation. Another patient developed complete heart block following PAB and subaortic resection requiring pacemaker placement; they died from a sudden
respiratory arrest 2 months postoperatively. At 2-month follow-up for the third PAB patient, significant ventricular dysfunction with wall motion abnormalities, ST changes, and elevated troponin were discovered. Workup revealed patent coronaries but multiple venous thrombi. They developed complete heart block and suffered cardiac arrest, followed by acute ischemic stroke with hemorrhagic conversion and persistent poor ventricular function. Ultimately they were withdrawn from transplant listing and expired 8 months postoperatively. A patient who initially presented in extremis with severe ventricular dysfunction prior to Norwood died less than 1 month postoperatively. The second Norwood patient had intrauterine drug exposure and an accessory anomalous coronary artery branch from the PA; their postoperative course was complicated by recurrent severe sepsis, renal failure, and hemodynamic lability despite good cardiac function, and they died 1 month postoperatively.

**Fate of the Coronary Arteries**

Clinical details of patients with any coronary artery pathology following initial palliation (4 pASO, 3 Norwood) are summarized in Supplement Part F (Table S13). 2 patients had coronary complications related to the pASO: one patient required revision of right coronary anastomosis 38 days following pASO for symptomatic proximal stenosis. During initial operation, another patient with abnormal coronary anatomy underwent revision of left coronary anastomosis and ECMO cannulation due to concern for coronary insufficiency. Postoperative catheterization showed preserved distal flow with possible proximal left circumflex dissection (medically managed with therapeutic anticoagulation without intervention). On latest assessment, all 7 patients with coronary pathology were alive with patent coronaries and 6 had normal ventricular function.
21 pASO patients (91%) had postoperative angiographic assessment of their coronaries (catheterization, CT, or MRI), most recently performed at a median of 3.4 years (1.3 – 10.7 years) postoperatively; all studies showed patent coronaries.

**Subaortic Obstruction After PAB**

Management of subaortic obstruction in the PAB group is summarized in Figure 4. 10 patients (40%) had at least one subaortic resection during the study period, of whom 4 had multiple resections. Resections were performed at initial palliation (7/25, 28%), BCPC (4/23, 17% - 3 without prior resection), and Fontan (3/18, 17% - all with prior resections). 13 (52%) of PAB patients underwent subsequent DKS: 5 due to persistent/recurrent subaortic obstruction after resection. DKS was generally performed at BCPC (n=11), though 1 was performed post-Fontan after multiple prior resections and 1 was the interstage conversion to DKS/SPS (deceased).

7 PAB patients (28%) had no subaortic interventions during the study: 1 patient died in the first interstage period secondary to ventricular dysfunction of unclear etiology, 1 is planned to undergo DKS at upcoming Fontan, 2 are monitored for stable mild obstruction, and 3 were unobstructed at follow-up.

**Pulmonary Artery Interventions**

48 patients (68%) had at least one PA intervention during the study period (operative patch augmentation, catheter-based balloon angioplasty, or stent placement), and 21 had multiple PA interventions (Table 3, Supplement Part E). Median time to first intervention was 5.9 months following initial palliation (4 – 11.2 months). Freedom from any PA angioplasty or death was similar for all cohorts (p=0.34, Figure 2b). Compared to PAB, a higher proportion of pASO patients had LPA intervention(s) and multiple PA interventions.
PA augmentation as part of planned staged palliation was performed at 39/66 BCPC (59%) and 22/55 Fontan (40%). Rates of any PA augmentation and rates of LPA augmentation at BCPC were statistically similar between groups, though tended to be more common for pASO (Supplement Part E, Table S7). Rates of PA augmentation at Fontan differed (p=0.04), significantly higher for pASO than PAB (p=0.02).

On pre-BCPC imaging (catheterization, CT, or MRI), minimum right PA (RPA) and LPA diameters (absolute and indexed to BSA) were similar by cohort (Supplement Part E, Table S7). Those who underwent RPA patch augmentation at BCPC had significantly smaller RPA diameters than those who did not (p=0.03, Supplement Part E, Table S8), indicating a correlation between RPA size and the decision to intervene it at BCPC. However, LPA diameters were similar whether or not patients had BCPC LPA augmentation.

Comparing pASO patients with anterior-posterior great vessels and Norwood patients with anterior-posterior great vessels, no significant differences in pre-BCPC PA dimensions or rates of PA interventions (though the latter were higher for pASO, Supplement Part E, Table S9).

A total of 36 patients had a DKS during the study period (23 Norwood, 13 PAB), of whom 21 (58%) had any subsequent PA intervention and 8 (22%) had LPA intervention. Among the 35 patients without DKS, 25 (71%) had any PA intervention and 21 (60%) had an LPA intervention. Comparing those with and without a DKS, there were similar rates of PA intervention (p=0.32), but fewer LPA interventions in those with a DKS (p=0.002).

Continued Palliation and Follow-Up

All 66 surviving patients completed BCPC (Table 2). Age at BCPC was older for the PAB cohort compared to pASO and Norwood. 55 patients (83% of survivors) completed Fontan, with similar rates by cohort. Of the 11 patients awaiting Fontan, 3 had pre-Fontan cardiac
catheterization (2/4 pASO, 1/4 PAB, and 0/3 Norwood), all with appropriate hemodynamics (Supplement Part D). The remainder were awaiting catheterization or following at other institutions. More PAB than Norwood patients had other concomitant procedures at Fontan (Table 2).

There was an association between arrhythmia requiring pacemaker or anti-arrhythmic medication at most recent follow-up and having had subaortic resection or BVF enlargement (p=0.03): 6/11 patients (55%) with prior resection had arrhythmias compared to 12/60 patients (20%) without.

Median follow-up time for survivors was 10.4 years (4.5 – 16.6 years). 7 patients were lost to follow-up with no documented visits in the last 5 years. 9 patients (13%) required any coarctation reintervention (balloon angioplasty or operation) following index palliation, with a non-significant trend toward higher rates after Norwood (Table 3). Ventricular function and systemic valve competency were uniformly well-preserved between groups (Table 3, Supplement Part F). At most recent echocardiography, 85% of survivors had normal ventricular function and 95% survivors had at most qualitatively mild systemic valve insufficiency. 3 patients had moderate neo-aortic valve insufficiency after pASO, all stable without indication for intervention at recent follow-up. One patient required cardiac transplant due to ventricular dysfunction and failing Fontan physiology (9 years post-Fontan, 12 years after pASO).

Comment

For complex single ventricle patients with malposed great arteries and systemic outflow obstruction, selecting the optimal strategy for initial palliation is challenging and carries far-
reach implications for Fontan success. With such a heterogeneous population, no single strategy can address the needs of every patient: a given anatomic configuration may be comprised of certain factors advantageous to one strategy but disadvantageous to others. Based on our long-term experience with this population, we aim to summarize the advantages, drawbacks, and ideal patient for each management strategy (Figure 5). By comparing preoperative characteristics of patients selected for each strategy, we highlight the salient objective and subjective features that impact early operative decision-making. While outcome comparisons between these groups are fraught with inherent limitations, they are meant to contextualize our center’s continued utilization of pASO and inform those considering including it in current practice.

**Challenges and Changes in Approach to Subaortic Obstruction**

Substrates for subaortic obstruction in SV-TGA-SOO include hypoplastic subaortic outflow chamber, BVF, and subaortic conus. Multiple sites of obstruction and/or accompanying shunts limit the use of gradient or flow acceleration across the subaortic region or BVF to quantify the degree of preoperative obstruction. Size of the interventricular communication indexed to body surface area or aortic valve diameter has been proposed as a potential predictor of current or future restriction,\(^5\)\(^-\)\(^7\) but this does not take into account other obstructive configurations. Indeed, prevalence of subaortic conus and potentially restrictive BVF by size criteria were similar between groups, but BVF size was significantly larger in the PAB group, particularly those who did not have initial subaortic resection. Rather than a single parameter, an aggregate judgement regarding the risk for subaortic obstruction is made based on objective size parameters coupled with subjective anatomic assessment. In addition to traditional echocardiography and direct
operative inspection, advanced imaging modalities including three-dimensional echocardiography and MRI may be a useful adjunct for delineating subaortic anatomy.

For patients with existing or high-risk for early postoperative subaortic obstruction, the index procedure must provide adequate systemic outflow in order to prevent the catastrophic effects of increased ventricular pressure load (hypertrophy) and low cardiac output state (coronary insufficiency, systemic malperfusion). In current practice, we feel this is best accomplished with modified Norwood or pASO. Historically, subaortic resection with PAB was considered a reasonable strategy, though it has fallen out of favor due to risk for conduction system injury and recurrent obstruction. Of the 10 PAB patients who underwent subaortic resection in our study, 4 required multiple resection procedures (1 of whom underwent DKS post-Fontan for recurrent obstruction despite several prior resections) and 5 had arrhythmia requiring pacemaker or anti-arrhythmic medication at last follow-up. Additionally, these procedures may be technically difficult in those with tricuspid atresia, necessitating ventriculotomy to perform the resection, which adds risk to the procedure.

Even if the subaortic area is adequate at initial palliation, the trajectory remains difficult to predict, with time to development of obstruction ranging from 10 days to 15 years postoperatively. In our cohort of 25 PAB patients with SV-TGA-SOO, only 3 had no intervention to relieve the threat or presence of subaortic obstruction and remained unobstructed at last follow-up. Proposed mechanisms for BVF restriction after PAB are altered ventricular geometry following acute volume unloading and hypertrophy due to increased afterload, effects which may be compounded by pre-existing arch obstruction. Delayed DKS (typically at BCPC) is an effective solution, but vigilant monitoring
with reliable follow-up is critical to ensure intervention is performed before subaortic obstruction progresses to ventricular hypertrophy, heart failure, or coronary insufficiency. Individual surgeons may differ in their subjective judgement assessment and tolerance of risk for future subaortic obstruction. Some may prefer to eliminate any possibility of future obstruction by performing DKS at second stage palliation more routinely after initial PAB, while others may be comfortable continuing to observe if there is no subaortic obstruction at time of second stage palliation. Similar biases also affect the choice of initial palliation, balancing the relative simplicity of initial PAB with the risks associated with unpredictable subaortic obstruction.

**Pulmonary Artery Banding**

Pulmonary artery banding with arch augmentation when necessary is the least complex operative technique, boasting shorter bypass times and length of stay in our study. In addition to the aforementioned complexity of managing evolving subaortic obstruction with resection or subsequent DKS, there is potential for encroachment of the band on the branch PAs or native pulmonary valve.

Patients with unobstructed or low-risk subaortic areas are the best candidates for initial PAB. Other factors that make Norwood or pASO more technically challenging or suboptimal may favor PAB, including pulmonary valve pathology, coronary anatomy that would be compromised by DKS or not amenable to switch, or inability to tolerate long operations or shunted physiology.

**Modified Norwood**

The modified Norwood procedure has been advocated by multiple centers\textsuperscript{11,14-16} as a solution that effectively addresses any existing or potential subaortic obstruction at the index
operation. Progress is evident with reduction in neo-aortic regurgitation with the adoption of the Lamberti (“double-barrel”) modification of DKS.14 Era-related advances in experience and critical care are credited with improving the once substantial interstage morbidity and mortality associated with this technique.8,18 Regardless, early commitment to completely shunt-dependent pulmonary blood flow carries substantial complication risk and often requires prolonged and complex postoperative care. In our study, one patient required shunt upsizing and PA augmentation for insufficient pulmonary blood flow and another was found to have shunt thrombosis at BCPC. Patients in the Norwood cohort were heavier at initial operation, reflecting our preference to avoid SPS physiology in smaller neonates.

An additional concern regarding early SPS and DKS is potential compromise to PA growth3,19-20 and accessibility. Particularly in the setting of anterior-posteriorly oriented great vessels, the LPA is trapped between the neo-aorta and left mainstem bronchus. This configuration provides substrate for compression and growth limitation and complicates options for intervention, should significant stenosis develop. Operative LPA augmentation may require DKS transection and reconstruction, and it cannot address space constraints. Catheter-based intervention is possible, though balloon angioplasty often provides incomplete or temporary relief and stents are at risk for erosion into neo-aorta, bronchial compression, or stent fracture due to external compression.

Overall, we feel the modified Norwood approach is best suited to patients with existing or higher risk of subaortic obstruction (as DKS is preferable to resection), side-by-side great arteries (preserves more space for LPA development), and coronary
anatomy unfavorable to translocation. Drawbacks to this technique include commitment to
shunt-dependent PBF and its associated risks, as well as entrapment of the LPA (which has
potential to limit Fontan candidacy and require extensive and higher risk intervention, should
stenosis develop).

**Palliative Arterial Switch**
The palliative arterial switch operation was first proposed as an alternative strategy for patients
with SV-TGA-SOO in the 1980s.\(^1\) It has subsequently been successfully applied as initial
palliation in the neonate and infant population\(^1\) with successful promotion to Fontan.\(^4\)\(^,\)\(^23\)\(^-\)\(^25\)
Critiques of this approach include longer operative times, intraoperative complexity, and concern
for coronary artery complications. Proposed benefits include alignment of the dominant
semilunar valve with the systemic circulation, eliminating the need for BVF enlargement,
postponement or avoidance of shunt-dependent physiology, and preserved LPA accessibility.

Direct alignment of the functional single ventricle with the systemic circulation creates an
unobstructed, laminar outflow tract and physiologically “auto-banded” circulation by converting
subaortic obstruction to subpulmonary obstruction. Of our 23 pASO patients, 14 (60%) had
initial PAB and 8 were “auto-banded” (6 remained well-balanced without requiring PAB or
SPS). Shunt physiology was avoided or postponed past the vulnerable immediate postoperative
setting for most patients (of 5 pASO patients with SPS, only 1 was placed at index operation).
Even when SPS is required, it avoids completely shunt-dependent circulation by preserving
antegrade PBF, which may allow for improved symmetric PA growth. Achieving balanced
systemic and pulmonary blood flow may be challenging, and the potential need for postoperative
adjustment of PAB or placement of SPS should be anticipated. Delayed chest closure allows
opportunities to intervene once pulmonary congestion has improved. However, the now-
subpulmonary obstruction may continue to evolve beyond the immediate postoperative period.

Our previously published favorable short-term experience with the pASO\(^4\) has
been sustained at longer-term follow-up with 100% survival. Overall, patients with
coronary anatomy not amenable to translocation, morphologically abnormal native
pulmonary valve, or side-by-side great vessels may be better served by other palliation
strategies. However, for patients with subaortic obstruction (or at significant risk) and
antero-posterior great vessels, pASO can safely and effectively palliate these complex
patients with superior accessibility of the branch PAs for ease of augmentation at staged
operations. Drawbacks to the pASO include the potential for coronary complications,
unpredictable PBF, and a lengthy, complex operation. While our findings confirm that
indeed, cardiopulmonary bypass and aortic cross-clamp times are longest in the pASO
group, postoperative length of stay was similar to the Norwood group. Furthermore,
coronary complications were rare and did not impact long-term coronary patency or
survival. Among these complex single ventricle patients, coronary artery anomalies are
common, and may require intervention or monitoring regardless of palliation strategy.

**Pulmonary Artery Interventions: Accessibility or Pathology?**

Given the selection bias inherent in the study, our data do not definitively answer the debate
regarding the true impact of LPA entrapment by DKS on PA growth. Future imaging studies in
expanded cohorts of patients may shed further light on PA growth following DKS vs Lecompte.
LPA diameters were not significantly different between pASO and Norwood prior to BCPC,
even comparing the subgroup of patients with anterior-posterior great vessels.
Of the 23 pASO patients, 18 (78%) underwent at least one PA angioplasty and 11 had multiple. 17 had at least one operative augmentation, including 16 at BCPS and 12 at Fontan. 17 patients had at least one intervention that included the LPA. Significant differences between the cohorts in rates of LPA intervention, multiple PA interventions, and PA angioplasty at Fontan reached pairwise significance only between PAB and pASO, with similar rates between pASO and Norwood (though pASO was observed to have the highest rates in these categories). Patients with DKS had similar any-side PA interventions but fewer subsequent LPA interventions compared to those without DKS.

The underlying explanations for these differences are likely multifactorial. Our institution has a liberal policy toward PA augmentation (68% of patients had any PA intervention and PA augmentation was performed at 59% of BCPC and 40% of Fontan operations). The accessibility of the PAs after Lecompte may confer a lower threshold to intervene at planned palliation and the LPA may be compressed as it drapes over the neo-aorta. Conversely, there may be a higher threshold to intervene for those with impaired accessibility due to DKS, requiring relatively more severe stenosis or hypoplasia to justify the intervention. Our pre-BCPC imaging data showed that while RPA size correlated with RPA intervention at BCPC, the same was not true for the LPA, indicating that factors other than vessel size likely influence the decision to intervene upon the LPA.

**Weighing the Options**

Overall, meaningful mid- to long-term outcomes for all three palliation strategies were comparable (Figure 6). Mortality rates were similar, with no late deaths. All surviving patients progressed to BCPC and either completed or are awaiting Fontan. On pre-Fontan evaluation, all
groups had effective protection of their pulmonary vasculature with low pulmonary artery pressures, low trans-pulmonary gradient, and low pulmonary arteriolar resistance as well as preserved ventricular function with normal end diastolic pressures. Only one patient required late post-Fontan transplant.

Our outcomes demonstrate that pASO facilitates safe, effective palliation to a Fontan circulation, making it a valuable addition to the surgeon’s armamentarium in approaching these complex patients. While not appropriate for every patient, we believe the pASO is a reasonable option to consider for patients with subaortic obstruction, anterior-posterior great vessels, and transferrable coronary arteries. In these challenging situations, no single technique has proven superior, and patient selection criteria for each palliation strategy remain ill-defined. We therefore recommend individualized assessment of each patient’s anatomy and hemodynamics pre- and intra-operatively in order to select an approach to create a favorable circulation for successful Fontan.

Limitations

This study is subject to the limitations of a retrospective single-center design as well as the heterogeneity of the complex cardiac lesions. Data were obtained from the medical chart, operative notes, echocardiographic reports, and catheterization reports which vary in reporting standardization and completeness. The limited number of neonatal patients with SV-TGA-SOO palliated at our institution during this time period could bias the results toward finding no difference between groups when there actually is a difference. Low number of events such as death and transplantation precluded multivariable regression analysis. The long duration of the study in order to characterize the historical and contemporary experience does add complexity
with changing practices over time. Additionally, there is significant inherent selection bias among the groups, with subtle and often competing anatomic factors influencing subjective decision-making. Results and comparisons should be interpreted within the context of these limitations as a descriptive longitudinal experience rather than a rigorously matched comparison.

**Conclusions**

The palliative arterial switch is a valuable addition to the surgical armamentarium for neonates with single ventricle, transposition, and systemic outflow obstruction. While not appropriate for every patient, pASO is a reasonable option to consider for safe and effective palliation of patients, especially those with subaortic obstruction, anterior-posterior great vessels, and transferrable coronary arteries. Excellent survival and Fontan completion were comparable to modified Norwood and PAB, and pASO confers PA accessibility for ease of augmentation without substantial risk of coronary artery complications.


### Table 1: Preoperative Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=71)</th>
<th>pASO (n=23)</th>
<th>Norwood (n=23)</th>
<th>PAB (n=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary cardiac diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DILV</td>
<td>37 (52%)</td>
<td>12 (52%)</td>
<td>10 (43%)</td>
<td>15 (60%)</td>
<td>0.57</td>
</tr>
<tr>
<td>TA</td>
<td>27 (38%)</td>
<td>10 (43%)</td>
<td>9 (39%)</td>
<td>8 (32%)</td>
<td></td>
</tr>
<tr>
<td>Other (DORV, cc-TGA)</td>
<td>7 (10%)</td>
<td>1 (4%)</td>
<td>4 (17%)</td>
<td>2 (8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Great vessel looping</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D-TGA</td>
<td>43 (61%)</td>
<td>12 (52%)</td>
<td>13 (57%)</td>
<td>18 (72%)</td>
<td>0.40</td>
</tr>
<tr>
<td>L-TGA</td>
<td>28 (39%)</td>
<td>11 (48%)</td>
<td>10 (43%)</td>
<td>7 (28%)</td>
<td></td>
</tr>
<tr>
<td><strong>Great vessel orientation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior-Posterior</td>
<td>59 (83%)</td>
<td>20 (87%)</td>
<td>19 (83%)</td>
<td>20 (80%)</td>
<td>0.92</td>
</tr>
<tr>
<td>Side-Side</td>
<td>12 (17%)</td>
<td>3 (13%)</td>
<td>4 (17%)</td>
<td>5 (20%)</td>
<td></td>
</tr>
<tr>
<td><strong>Interrupted Aortic Arch</strong></td>
<td>12 (17%)</td>
<td>5 (22%)</td>
<td>5 (22%)</td>
<td>2 (8%)</td>
<td>0.49</td>
</tr>
<tr>
<td><strong>Coarctation</strong></td>
<td>46 (65%)</td>
<td>14 (61%)</td>
<td>17 (74%)</td>
<td>15 (60%)</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>Pulmonary valve pathology</strong></td>
<td>12 (17%)</td>
<td>2/23 (9%)</td>
<td>2/23 (9%)</td>
<td>8/25 (32%)</td>
<td>0.052</td>
</tr>
<tr>
<td>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjective subaortic obstruction</td>
<td>15 (21%)</td>
<td>4 (17%)</td>
<td>8 (35%)</td>
<td>3 (12%)</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Subaortic conus</strong></td>
<td>51 (72%)</td>
<td>19 (83%)</td>
<td>15 (65%)</td>
<td>17 (68%)</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>BVF</strong></td>
<td>64 (90%)</td>
<td>21 (91%)</td>
<td>20 (87%)</td>
<td>23 (92%)</td>
<td>0.89</td>
</tr>
<tr>
<td><strong>BVF/BSA (cm^2/m^2)</strong></td>
<td>0.87 (0.54-1.36)</td>
<td>0.66 (0.37-1.14)</td>
<td>0.69 (0.53-1.11)</td>
<td>1.37 (1.07-1.96)</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Potentially restrictive BVF</strong></td>
<td>35 (49%)</td>
<td>12 (50%)</td>
<td>13 (57%)</td>
<td>10 (40%)</td>
<td>0.58</td>
</tr>
</tbody>
</table>

N (% total) or median (IQR) with n=non-missing data when applicable. Multi-group comparison p-value reported, with bold denoting statistical significance. Subaortic and pulmonary valve parameters reported based on preoperative echocardiography. * Pulmonary valve pathology defined as greater than mild insufficiency or leaflet thickening. Additional echocardiographic data and pairwise comparisons are reported in the supplement part B.
Table 2: Single Ventricle Palliation

<table>
<thead>
<tr>
<th></th>
<th>pASO (n=23)</th>
<th>Norwood (n=23)</th>
<th>PAB (n=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Palliation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative age (days)</td>
<td>7 (5 – 9)</td>
<td>7 (6 – 9)</td>
<td>8 (7 – 13)</td>
<td>0.19</td>
</tr>
<tr>
<td>Operative weight (kg)</td>
<td>3.3 (2.9 – 3.6)</td>
<td>3.5 (3.3 – 3.9)</td>
<td>3.1 (2.9 – 3.5)</td>
<td><strong>0.03</strong> * 0.4 § 0.053 # 0.02</td>
</tr>
<tr>
<td>CPB time, if used (mins)</td>
<td>272 (221 – 292)</td>
<td>198 (173 – 211)</td>
<td>118.5 (95 – 153)</td>
<td><strong>0.0001</strong> * § &lt; 0.0001</td>
</tr>
<tr>
<td>Postoperative LOS (days)</td>
<td>23 (19 – 49)</td>
<td>26 (15 – 38)</td>
<td>19 (10 – 25)</td>
<td><strong>0.015</strong> * 0.01 § 0.50 # 0.02</td>
</tr>
<tr>
<td>Interstage Mortality</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% total)</td>
<td>0 (0%)</td>
<td>2 (9%)</td>
<td>3 (12%)</td>
<td>0.36</td>
</tr>
<tr>
<td>Any Unplanned Interstage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention (% total)</td>
<td>10 (43%)</td>
<td>8 (35%)</td>
<td>5 (20%)</td>
<td>0.23</td>
</tr>
<tr>
<td>BCPC (% total)</td>
<td>23 (100%)</td>
<td>21 (91%)</td>
<td>22 (88%)</td>
<td>0.36</td>
</tr>
<tr>
<td>BCPC age (months)</td>
<td>4.3 (3.7-5.9)</td>
<td>4.5 (3.9-5.6)</td>
<td>7.4 (6.6-9.3)</td>
<td><strong>0.0002</strong> * 0.0001 § 0.31 # 0.0005</td>
</tr>
<tr>
<td>BCPC PA plasty (% BCPCs)</td>
<td>16 (70%)</td>
<td>12 (57%)</td>
<td>11 (50%)</td>
<td>0.45</td>
</tr>
<tr>
<td>Fontan (% total)</td>
<td>19 (83%)</td>
<td>18 (78%)</td>
<td>18 (72%)</td>
<td>0.73</td>
</tr>
<tr>
<td>Fontan age (years)</td>
<td>4 (3.5-4.6)</td>
<td>4.2 (3.6-4.7)</td>
<td>4.4 (3.8-5.0)</td>
<td>0.79</td>
</tr>
<tr>
<td>Fontan PA plasty (% Fontans)</td>
<td>12 (63%)</td>
<td>6 (33%)</td>
<td>4 (22%)</td>
<td><strong>0.04</strong> * 0.02 § 0.10 # 0.71</td>
</tr>
<tr>
<td>Fontan co-operation</td>
<td>6 (33%)</td>
<td>2 (11%)</td>
<td>10 (56%)</td>
<td><strong>0.02</strong> * 0.19 § 0.23 # 0.01</td>
</tr>
</tbody>
</table>

Number of patients (% total or at risk, as noted) or median (IQR), p-value for difference in proportion or median among the 3 cohorts (bold p-values indicating statistical significance < 0.05). Post-hoc pairwise comparisons with their respective p-values denoted as follows: * pASO vs PAB, § pASO vs Norwood, # PAB vs Norwood.
### Table 3: Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=71)</th>
<th>pASO (n=23)</th>
<th>Norwood (n=23)</th>
<th>PAB: all (n=25)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Follow-up time</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(years, survivors)</td>
<td>10.4 (4.5-16.6)</td>
<td>7.9 (4.0-16.2)</td>
<td>9.8 (4.5-16.6)</td>
<td>13.0 (6.0-17.8)</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Any PA intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% total)</td>
<td>48 (68%)</td>
<td>18 (78%)</td>
<td>15 (65%)</td>
<td>15 (60%)</td>
<td>0.40</td>
</tr>
<tr>
<td><strong>Any LPA intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% total)</td>
<td>39 (55%)</td>
<td>17 (74%)</td>
<td>13 (57%)</td>
<td>9 (36%)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Multiple PA interventions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>(% total)</td>
<td>21 (30%)</td>
<td>11 (48%)</td>
<td>7 (30%)</td>
<td>3 (12%)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Arrhythmia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>(% total)</td>
<td>18 (25%)</td>
<td>3 (13%)</td>
<td>4 (17%)</td>
<td>11 (44%)</td>
<td>0.03</td>
</tr>
<tr>
<td>(% survivors)</td>
<td>16 (24%)</td>
<td>3 (13%)</td>
<td>4 (19%)</td>
<td>9 (41%)</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>Any coarctation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.37</td>
</tr>
<tr>
<td>reintervention (%)</td>
<td>9 (13%)</td>
<td>2 (9%)</td>
<td>5 (22%)</td>
<td>2 (8%)</td>
<td></td>
</tr>
<tr>
<td><strong>Ventricular dysfunction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>(≥ mild, % survivors)</td>
<td>10 (15%)</td>
<td>4 (17%)</td>
<td>3 (14%)</td>
<td>3 (14%)</td>
<td></td>
</tr>
<tr>
<td><strong>Systemic valve</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.37</td>
</tr>
<tr>
<td>insufficiency (%)</td>
<td>35 (53%)</td>
<td>13 (57%)</td>
<td>13 (62%)</td>
<td>9 (41%)</td>
<td></td>
</tr>
<tr>
<td>(≥ mild, % survivors)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None-trivial</td>
<td>31 (47%)</td>
<td>10 (43%)</td>
<td>8 (38%)</td>
<td>13 (59%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Mild</td>
<td>32 (48%)</td>
<td>10 (43%)</td>
<td>13 (62%)</td>
<td>9 (41%)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>3 (5%)</td>
<td>3 (13%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Number of patients (% total or at risk, as noted) or median (IQR), p-value for difference in proportion or median among the 3 cohorts (bold p-values indicating statistical significance < 0.05). Post-hoc pairwise comparisons with their respective p-values denoted as follows: * pASO vs PAB, § pASO vs Norwood, # PAB vs Norwood.

$ PA interventions defined as operative PA augmentation or catheter-based balloon angioplasty or stent placement

@ Arrhythmia requiring anti-arrhythmic medication or pacemaker placement at last follow-up

^ neo-aortic valve insufficiency for those with DKS or pASO, native aortic valve for those with PAB and no DKS.
Figure 1
Algorithm summarizing main anatomic factors driving initial palliation strategy selection at Texas Children’s Hospital in the current era, though additional patient factors and surgeon preferences continue to guide the final decision. PAB with subaortic resection is generally avoided as an initial strategy in current practice, given risk for conduction system injury and recurrent obstruction.

Figure 2
Kaplan-Meier survival curves with shaded 95% confidence intervals (CI), truncated at time points when approximately 10% of the starting populations remained at risk.

(2a) Reintervention-free survival in the first interstage period, defined as time from initial palliation to either death or first unplanned intervention for cardiovascular pathology or postoperative complications, censored at second stage palliation with BCPC. There were no statistically significant differences between cohorts (p=0.08).

(2b) Pulmonary-artery reintervention-free survival, defined as time from initial palliation to death or first pulmonary artery angioplasty following initial palliation (catheter-based or operative), censored at last follow-up. There were no significant differences between cohorts (p=0.34).

Figure 3
Schematic flow diagram showing patients’ initial operative palliation (top two rows of boxes) and post-operative interventions for adjustment of relative pulmonary and systemic blood flow (bottom row).

Figure 4
Diagram summarizing interventions for subaortic obstruction in the PAB cohort during the study period. Practices shifted away from performing subaortic resection or BVF enlargement given the associated risks of conduction system injury and recurrent obstruction. In current practice, we prefer either Norwood or pASO as initial palliation if substantial subaortic obstruction is present or felt to be likely to develop in the short term, rather than initial PAB with resection. For those with lower risk or unobstructed subaortic regions, PAB may be performed initially with delayed DKS at time of BCPC if subaortic obstruction develops or there is ongoing concern for future obstruction.

**Figure 5**
Venn diagram summarizing the major advantages and disadvantages of three palliation techniques for SV-TGA-SOO.

**Figure 6**
Outcomes including mortality, Fontan completion, coronary complications and interventions, ventricular function, and neoaortic valve function were similar between the surgical palliation cohorts. A higher proportion of pASO patients had LPA intervention(s) and multiple PA reinterventions compared with PAB, possibly reflecting the easy accessibility for pulmonary artery augmentation following pASO. These results imply that pASO is a reasonable strategy for initial palliation in neonates with SV-TGA-SOO with comparable outcomes to PAB and modified Norwood.
SV-TGA-SOO Anatomy

Subaortic area
- Obstructed or "High-Risk"
  - Unobstructed or "Low-Risk"
    - PAB
      - Consider Stage 2 DKS
  - Side-Side
    - Norwood

Great vessel orientation
- Anterior-Posterior

Coronaries transferable
- Yes, consider
  - pASO
- No
PAB
(+): short, simple operation
(+): short postop LOS
(-): variable timing/degree of subaortic obstruction; close surveillance necessary, likely DKS at Glenn; resection not recommended
(-): slipped band may distort native pulmonary valve

Norwood
(-): Qp completely shunt-dependent
(-): small neonates may have higher mortality, risks
(-): LPA trapped between bronchus/DKS: substrate for hypoplasia/stenosis, difficult to intervene

pASO
(+): predominantly (auto)banded physiology
(-): variable progressive BVF restriction can alter Qp:Qs

(+): If shunt needed, preserves antegrade Qp; often delay shunt beyond neonatal period
(+): Accessible LPA for augmentation
(-): adjusting Qp:Qs may require additional interventions in IS1
(-): technical complexity

(+): early definitive relief of subaortic obstruction
(-): long operation
(-): long postop LOS
DATE: February 21, 2023

TO: The Journal of Thoracic and Cardiovascular Surgery
    American Association for Thoracic Surgery
    500 Cummings Center, Suite 4550
    Beverly, MA 01915

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Corresponding author(s): Alyssa B Kalustian MD, Zachary A Spigel MD, Christopher E Greenleaf MD, Iki Adachi MD, Jeffrey S Heinle MD, Ziyad M Binsalamah MD

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Title: Manager, Multimedia Services
Comparing palliation strategies for single ventricle anatomy with transposed great arteries and systemic outflow obstruction

pASO is a reasonable strategy for neonates with single ventricle, transposed great arteries, and systemic outflow obstruction with similar Fontan completion, survival, and coronary complications to PAB and modified Norwood.

LPA: left pulmonary artery; neo-AI: neo-aortic valve insufficiency; PA: pulmonary artery; PAB: pulmonary artery band; pASO: palliative arterial switch operation; SV-TGA-SOO: single ventricle with transposed great arteries and systemic outflow obstruction
Comparing palliation strategies for single ventricle anatomy with transposed great arteries and systemic outflow obstruction

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