Can we get back to the Transcatheter Fontan?

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Disclosures

- None
- Off label use of FDA approved devices will be discussed
Ideal Fontan Circuit

• unobstructed, laminar flow from IVC+SVC to PAs
• no energy loss through circuit
• ?pulsatility or valved forward motion
• stable flow dynamics over time
• growth potential to match somatic growth
• created with minimal impact
  – does not increase arrhythmia risk
  – does increase injury to ventricle
  – does not increase risk to patient
Lateral Tunnel Fontan

• Advantages
  – widespread experience with procedure
  – applicable to most anatomic variations
  – ease of creation
  – growth potential

• Disadvantages
  – potential increased arrhythmias
    • long atrial suture lines & increased atrial pressure
  – loss of laminar flow overtime with dilatation of circuit
  – myocardial ischemia to create circuit
Fontan Technique

B. Lateral tunnel (intra-atrial baffle)

Anastomosis of enlarged cardiac end of SVC to RPA

Placement of baffle inside right atrium, forming a channel with a decreased diameter
ExtraCardiac Fontan-(tube graft)

• Advantages
  – stable laminar flow
  – no intra-cardiac suture lines or increased pressure
  – can be created without myocardial ischemia

• Disadvantages
  – no growth potential
  – use of adult sized conduit can create distortion at either entrance from IVC or exit into PAs
  – potential thromboembolism of conduit
NCH Fontan technique

- Modified extra-cardiac pericardial “well”
- On bypass, no x-clamp, no circulatory arrest
- Growth potential, no intra-cardiac suture lines
- Possible respiratory & cardiac “pulsation”
Fontan Technique
Fontan Technique
Holy Grail

• A growing replacement material
• Versatile in possible applications
  – Sizes
  – Patches vs tubes vs valves
• Easy to handle and suture yet flexible and strong
• Hemostatic
• In-expensive
Tissue Engineered Heart Valves: Autologous Cell Seeding on Biodegradable Polymer Scaffold

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Evolving Technology

The tissue-engineered vascular graft using bone marrow without culture

Narutoshi Hibino, MD, Toshiharu Shin’oka, MD, PhD, Goki Matsumura, MD, PhD, Yoshihito Ikada, PhD, and Hiromi Kurosawa, MD, PhD

Figure 1. Macroscopic finding of biodegradable scaffolds and scanning electronmicroscopic findings of polymer scaffolds. Upper left, Macroscopic finding; 18 mm in diameter. Copolymer of L-lactide and ε-caprolactone synthesized by ring-opening polymerization, with weight composition ratio of L-lactide and ε-caprolactone at 50:50. Polymeric woven scaffold composed of polyethylene and polylactic acid reinforced with PGA mesh.

Figure 2. Hempathologic findings on explanted patch in patient with regression. Arrows indicate endothelium-like cells. A. Hematoxylin-eosin stain, original magnification x400. B. Masson stain, original magnification x400. C. Victoria blue, original magnification x400. D. Hematoxylin-eosin stain, original magnification x400.

Figure 5. Measurements of major and minor axes of tissue-engineered grafts in patients 2 (A), 4 (B), and 12 (C). Upper row, Anteroposterior view; lower row, lateral view.
Back to the Future
Our Original Hybrid Concept of HLHS Repair

• One comprehensive open heart procedure (combined stage 1, 2 and part of 3), flanked by two less invasive procedures

• Need a way to initially stabilize patient to an age appropriate for the “big operation”
  – Control & protect PBF (LPA/RPA bands)
  – Provide reliable systemic cardiac output (PDA stent)
  – Create unobstructed flow from LA (BAS/stent IAS)

• Develop a way to less invasively complete the Fontan circuit (covered stent)

Presented at the Society for Thoracic Surgeons Meeting, January 2003
Amplatzer PA Flow Restrictor
All Transcatheter Stage 1
Comprehensive Stage 2

Blind pouch
Radio-opaque marker
Radio-opaque band
Fontan completion without surgery.
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Abstract
An ideal Fontan procedure would minimize complications while maximizing flow dynamics through the circuit. We report our early experience with a new combined surgical/transcatheter approach which enables a nonoperative, transcatheter Fontan completion. The conceptual rationale of this management strategy, as well as surgical and catheterization techniques, are discussed.

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Technique

• Transcatheter Fontan Completion
  – Previous “modified” cavo-pulmonary connection
  – Transseptal needle puncture/RF perforation from jugular vein thru “sweet spot” into RA
  – Snare guidewire to form veno-veno “rail”
  – Custom-made covered stent
    • Delivered from groin through 13 or 14 Fr sheath
  – Goal: No interference with PA or IVC/hepatic vein flow & limit residual R→L shunt
  – Be ready to “bail-out” by converting back to BDG using CREBO (Cheatham Rapid Exchange Bail Out)
    • a 12-16mm x 1cm long balloon on multi-track design delivered from neck
PICS VI, Sept 25th, 2002: 2 y/o HLHS Undergoing Transcatheter Fontan Completion
Transseptal Perforation Along Radio-Opaque Marker (Sweet Spot)
Snare Of Guidewire To Allow CCPS Delivery
8Zig-60mm CCPS With 1 Row Uncovered @ Each End On 16mm BIB Catheter
Post Implant: IVC Angiogram... ↑ O2 Sats 95%
Post Implant: SVC Angiogram... ↑ O2 Sats 95%
Transcatheter Fontan Completion
After 24 hours, ready for discharge!
Results

• 5 patients (22-24 months old, 10-12.4 Kg)
• All successful transcatheter Fontan circuit
  – ↑ Sats 95%
  – PAp increased 1 mmHg
  – Unobstructed flow from IVC & hepatic veins into PA
• No deaths, effusions, or blood transfusions
• All discharged home within 24 hours

Presented to The American Association of Thoracic Surgeons
International Symposium, May 2003
Results - late

• 4 pts developed R>L shunts with decreased O2 sats
  – 1 btw interlocking stents
  – 3 at the IVC-RA junction

• All successfully treated with additional transcatheter covered stent
4 mo after implant, O2 sats decreased to 72% secondary to “fenestration”

O2 sats increased to 96% after covering “fenestration”
Other Past Attempts

- “Hausdorf G; Schneider M; Konertz W. Surgical preconditioning and completion of total cavopulmonary connection by interventional cardiac catheterisation: a new concept. Heart. 1996; 75(4): 403-9”

- First Stage: modified Hemi Fontan
  - Subtotal banding of SVC-RA post Glenn
  - Multiperforated baffle 5-7 (5 mm each) in RA

- Second Stage: Percutaneous completion
  - Technique-1: Non-covered stent at surgically banded SVC-RA + Septal Occlusion devices at each fenestration
  - Technique-2: Angioplasty of surgically banded SVC-RA + Covered stent from IVC to dilated SVC-RA

8 patients with no mortality
The “Set Up” For Transcatheter Completion Of Fontan
Gerd Hausdorf

Interventional completion of Fontan Technique 1

Interventional completion of Fontan Technique 2
Fontan Completion in the Cath Lab
Lessons Learned
for Surgeons & Interventionalists

Lee Benson & Christopher Caldarone
The Hospital for Sick Children
Toronto, Ontario
A Simple Surgical Technique For Interventional Transcatheter Completion Of The Total Cavopulmonary Connection

Igor E. Konstantinov, MD, Lee N. Benson, MD, FRCPC, Christopher Caldarone, MD, Jia Li, MD, PhD, Mikiko Shimizu, MD, John G. Coles, MD, FRCSC, Glen S. Van Arsdell, MD, FRCSC and William G. Williams, MD, FRCSC

♥ Performed transcatheter Fontan completion successfully in 4 Yorkshire pigs
Surgical Setup at BCPS

Hemi-Fontan

BCPC
Outcomes

Procedure performed in 7 children.

Sat’s: 77 ± 3% before intervention
69 ± 4% @ case completion
90 ± 8% @ hospital DC (n=4)
95 ± 3% 2 weeks after DC’ (n=4)

3/4 children had PAVM’s detected @ cath.

A pleural effusion occurred in 6 children, 1 requiring pleurocentesis.
Outcomes

Morbidity & mortality: due to stent migration.

IVC dislodgement was noted at cath and a 2\textsuperscript{nd} stent placed uneventfully, the child DC' home.

SVC dislodgement in 1, IVC dislodgement in 2 resulting in the need for ECMO support, & ultimately stent removal & surgical Fontan's.

One of these children suffered a neurological injury & was withdrawn from ventilatory support, despite an intact CCF circuit.
The concept of a CCF has been supported.

Stent stability in the superior (SVC) & inferior (IVS) ends, is not completely solved.

The IVC-RA junction undergoes dynamic changes in its topology during respiration and retching.

The fixed SVC end exacerbates the problem.
Fontan completion without surgery.
Sallehuddin A, Mesned A, Barakati M, Fayyadh MA, Fadley F, Al-Halees Z.
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Abstract

OBJECTIVE: There are several modifications introduced in the preparation for a subsequent non-surgical transcatheter completion of the Fontan procedure. We report our experience with one type of the modification and the short-term results following its implementation.

Ten months later (range 5–16 months), nine patients underwent transcatheter Fontan completion (mean age 20 months, mean weight 10.6 kg). Demographics of these patients are shown in Table 2. The mean diameter of the aperture had decreased from 11.8 mm to 7.4 mm; $p \ll 0.001$ (Fig. 2). The mean fluoroscopy time was 41 min (range 27–81 min). The stents across the RF perforated pericardial patch were dilated to 14.4 mm average diameter (range 12–16 mm). Except in one patient, all apertures were closed with Amplatzer devices (sizes 6–8 mm). Average oxygen saturations increased from 85 to 94% ($p = 0.001$) but the pulmonary artery pressures were not significantly altered (16 vs. 19 mmHg, $p = 0.12$). These findings were similar to those reported by Galantowicz and Cheatham [6]. During the catheterization procedure, no patient had hemodynamic compromise and none required inotropic support. There were no early or late deaths. No patient required blood transfusions. No patient required mechanical ventilation and none developed significant pleural effusions or arrhythmias. This is in contrast to an incidence of 15–16% pleural effusions and 7–8% of dysrhythmias in patients following the modified Fontan operation previously reported from our institution [9]. All were discharged from hospital within 6 days of the non-surgical Fontan completion. On average, our surgical patients remain for 14–15 days in hospital after the modified Fontan operation.
Aperture creation in the PTFE medial wall of the lateral tunnel.


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Angiogram following stent and ASD device placements within the lateral atrial tunnel.
Ideas in the Works

- Novel surgical set-ups
- "Docking stations"
- Different covered stents
  - Self-expanding vs balloon
- Tapered balloons
- Novel membrane materials
- Cavo-pulmonary Assist Device
Lateral Tunnel Docking Port

Courtesy of Evan Zahn, M.D.
Miami Children’s Hospital

The Heart Center At Nationwide Children’s Hospital
Creating the Docking Port

Courtesy of Evan Zahn, M.D.
Miami Children’s Hospital

The Heart Center At Nationwide Children’s Hospital
The Future

Total cavopulmonary connection
The experimental model

PATENT OF INVENTION
For a term of 20 years for an invention for a title
FENESTRATION WITH INTRINSIC MEANS OF SELECTIVE CLOSURE
INCORPORATED TO A TUBULAR BODY AND USED IN INTERVENTIONAL
CARDIOVASCULAR PROCEDURES
Applied by RICARDO GAMBOA MD
Argentinian
Address: Calle 8 Nº 823
Postal code: 1900
Tolosa, La Plata
Buenos Aires Province
Argentina
Inventor: Ricardo Gamboa MD
Total cavopulmonary connection
The experimental model

FIGURE 1

FIGURE 7
FENESTRATION

Closed

Open
Total cavopulmonary connection
The experimental model

PROTOTYPE

right branch

left branch

fenestration

Anatomic View
Total cavopulmonary connection
The experimental model

Anatomic View

PROTOTYPE IN NITINOL

right branch

left branch

principal body
Fontan rescue
Neonatal Fontan!
Conclusions

• Yes, there has been and will be again a transcatheter Fontan option

• Merging forces of influence
  – Surgical efforts to limit exposure to cross-clamping and development of techniques for off-bypass Fontan completion
  – Hybrid collaboration yielding new combined surgical-cath procedures
  – Rapidly emerging transcatheter technologies
THANK YOU