

“Kidney Support in Children using an Ultrafiltration Device”

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Investor Update hosted by CHF Solutions, Inc

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Aquadex FlexFlow® System – Indication and Regulatory Status in Pediatrics:

The Aquadex FlexFlow system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.

The Aquadex FlexFlow system is not yet cleared by FDA for use in pediatric patients.

CHF Solutions expects to submit an application to the FDA requesting a modification to the 510(k) clearance for the Aquadex FlexFlow system to include pediatric patients above 20kg in the near future.

Moderator:

Jeffrey S. Cohen, Managing Director, Equity Research
Healthcare & Medical Technologies
Ladenburg Thalmann & Co. Inc.

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Speakers Biographies

Stuart L. Goldstein, MD, FAAP, FNKF

Pediatric nephrologist at Cincinnati Children's Hospital Medical Center
Director of the Center for Acute Care Nephrology
Medical Director of the Pheresis Service
Co-Director of the Heart Institute Research Core
Professor of Pediatrics - University of Cincinnati Department of Pediatrics
Medical degree from Columbia University College of Physicians & Surgeons



David Askenazi, MD, MSPH

Pediatric nephrologist at Children's of Alabama
Director of the Pediatric and Infant Center for Acute Nephrology
Professor of Pediatrics at the University of Alabama at Birmingham (UAB)
Medical degree from University of Texas Medical Branch
Masters in Public Health from University of Alabama at Birmingham (UAB)



Dr. Shina Menon, MD

Pediatric nephrologist at Seattle Children's Hospital
Director – Acute Dialysis Program – Seattle Children's Hospital
Assistant Professor – Department of Pediatrics – University of Washington
Medical degree from Maulana Azad Medical College in Delhi, India



Objectives

- Challenges in Neonatal Renal Replacement Therapy (RRT)
- Use of Ultrafiltration to perform Continuous Venovenous Hemofiltration (CVVH) and the Future of Neonatal Continuous Renal Replacement Therapy (CRRT)
- Review of Data from Multi-Center Retrospective Study titled “Kidney Support in Children using an Ultrafiltration Device”

Challenges in Neonatal Renal Replacement Therapy

Stuart L. Goldstein, MD

Clark D West Endowed Chair
Director, The Center for Acute Care Nephrology
Nephrology and Hypertension
The Heart Institute
Cincinnati Children's Hospital Medical Center
Professor of Pediatrics
University of Cincinnati College of Medicine
Cincinnati, Ohio

Disclosures

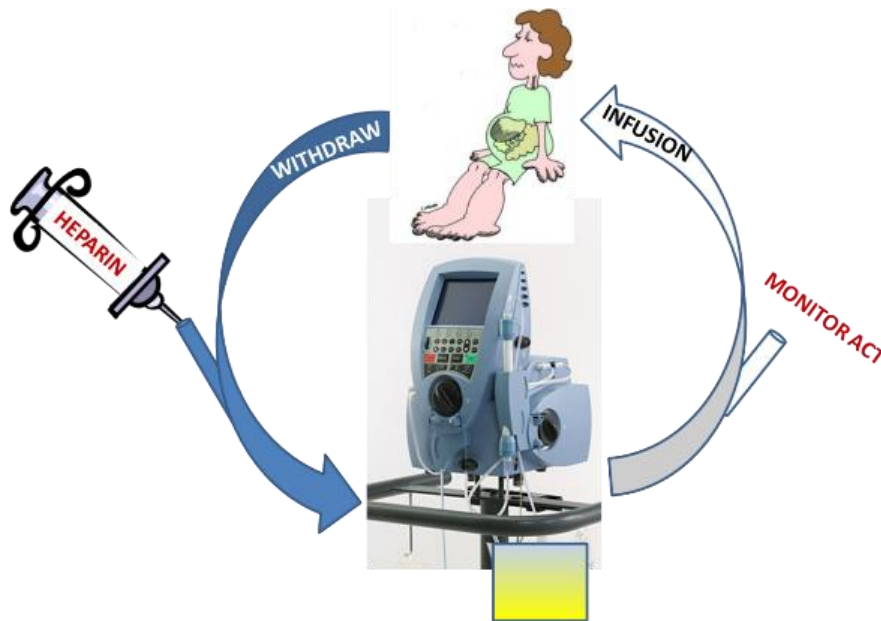
- Baxter Healthcare
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- MediBeacon
 - Consultant, Director of Clinical Development, Shareholder
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- La Jolla Pharmaceuticals, Akebia, Medtronic, Reata, **CHF Solutions**, Fresenius
 - Consultant

Objectives

- Ultrafiltration (UF) for pediatric patients < 20 kg
- Why heart failure is not just an adult problem
- Approach and Challenges to CRRT in Neonates prior 2014
- Future of neonatal CRRT
- Enhancement of the current device will optimize our ability to support babies

Traditional Use of Aquadex FlexFlow®

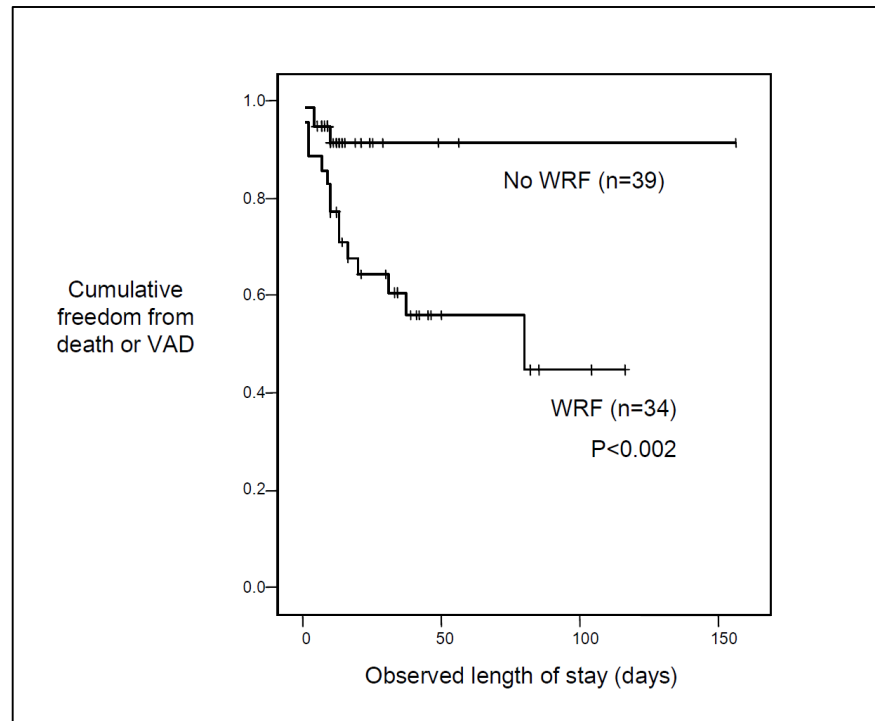
- Slow Continuous UF for Adults with Diuretic Resistant Heart Failure



- FDA approved for ultrafiltration in 2007
- 33 cc circuit volume
- 4 kg = 10 % ECV

Children and the Rational for Ultrafiltration

- Children with the cardiorenal syndrome have similar risks of morbidity and mortality compared to adults



Continuous Renal Replacement Therapy for Neonates

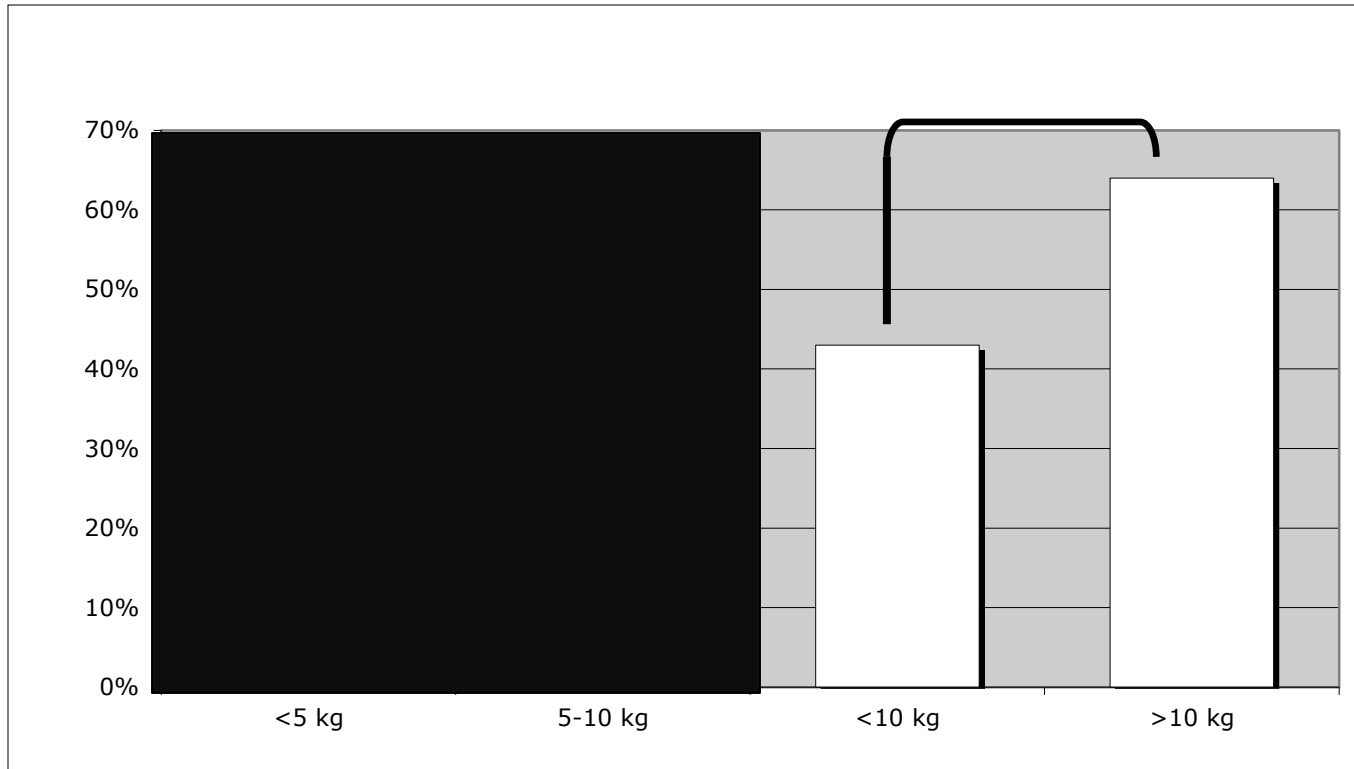
BACKGROUND

- Acute Kidney Injury (AKI) and volume overload are common and are associated with morbidity and mortality in critically ill neonates and children
- In recent years, CRRT has emerged as the preferred modality to provide kidney support to such children
- CRRT is used sparingly in neonates and is associated with worse outcomes compared with larger children as they are designed/approved for adult-sized patients and require larger catheters, tubing, and filters, which result in a high extracorporeal volume relative to patient size
 - A recent single study evaluation of hemodynamic stability in neonates (eight patients, 70 sessions) after CRRT initiation showed that 55% of sessions had intradialytic hypotension, most of which occurred shortly after CRRT initiation

Fluid Overload is Bad for Those < 10 kg

Variable	Adjusted OR	<i>p-value</i>
PRISM II score at CRRT	1.1 (1.0 – 1.2)	0.02
Fluid Overload Groups		
< 10 % vs. 10-20 %	0.9 (0.17 – 4.67)	0.25
< 10 % vs. > 20 %	4.8 (1.3-17.7)	0.01
UOP (ml/kg/hr) @ CRRT start	0.72 (0.53-0.97)	0.04
*66/84 observations used for analysis (40 death vs 26 Survival).		
variables used in the model include: PRISM 2 score, mean airway pressure (P_{aw}) and urine output at CRRT, % fluid overload (categorically divided by 10% intervals), MODS and Inborn error of metabolism.		

Smaller Children in ppCRRT Have Lower Survival



My Neonatologists Used to HATE CRRT

- The machines don't run very well
 - Alarms going up all night
 - Circuits clot all the time
- Nurses very confused about the therapy: high risk low volume procedure
 - Often need to transfer patients to PICU where CRRT is performed more often
- They always 'crash' when we start CRRT
- Catheters are a pain to put in and manage
- Used as a "last resort" --- sometimes
- Too 'RISKY'

Medical Decision Making

- All medical decision-making is about weighing the potential risks and benefits of options
 - Therapy A
 - Therapy B
 - Nothing



- Up until 2013, the risks were so high, that we rarely provided Kidney Support Therapy to babies

Accuracy Issues with Current Devices

- Even the most accurate CRRT devices have limitations that create challenges for neonatal/infant CRRT
- Lower limit of blood flows not necessarily accurate and/or refined (increments of 10 ml/minute)
- Fluid balance errors/safety parameters still not geared for small babies
 - 70 ml error over 3 hours could lead to hypotension or volume overload in a small infant
 - Necessitates more strict manual processes to ensure safe volume balance
 - No NIVM of hematocrit monitor to assess intravascular volume changes

Clinical Summary

David Askenazi MD, MSPH
Professor of Pediatrics
Director – Pediatric and Infant Center for
Acute Nephrology (PICAN)



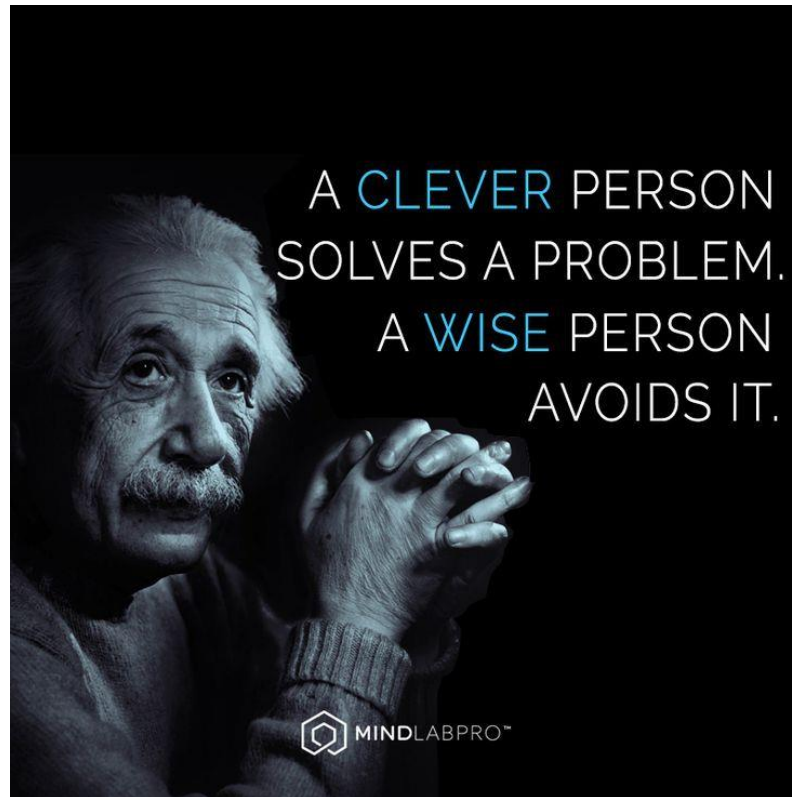
Disclosures

- Speaker for Baxter, and the AKI Foundation
- Consultant for CHF solutions
- Research/ Education funding from the NIH, FDA, Octapharma, Bioporto, Baxter and CHF solutions

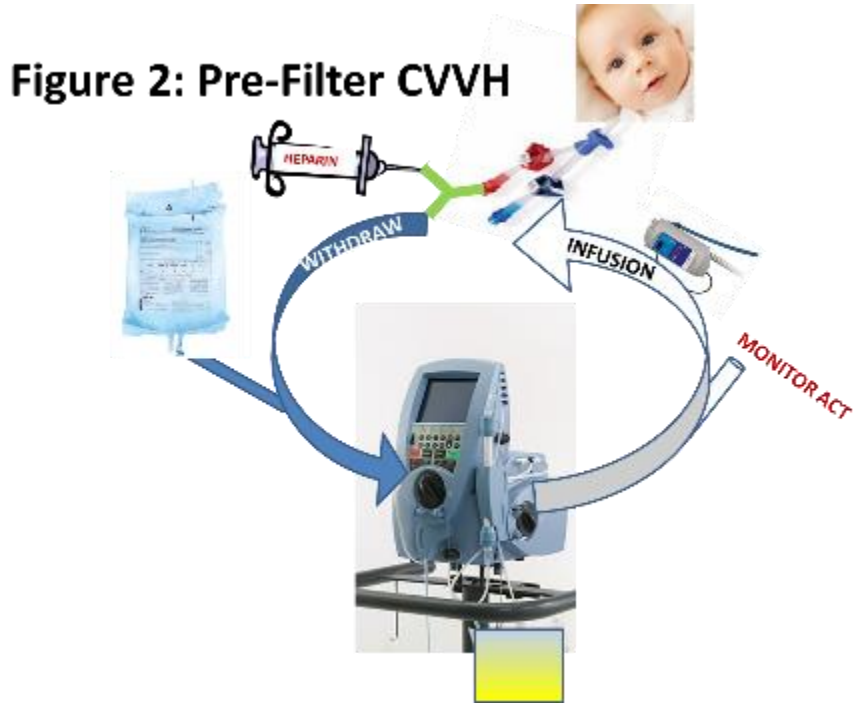
Objectives

- How we used the Aquadex FlexFlow to perform CVVH
- Our experience in the Neonatal Intensive Care Unit (NICU)
- The future of neonatal CRRT
 - All big programs need a neonatal device

What if we had a smaller circuit?



Aquadex FlexFlow[®] for Renal Support In Babies



The Aquadex FlexFlow system is not cleared by FDA for use in pediatric patients.

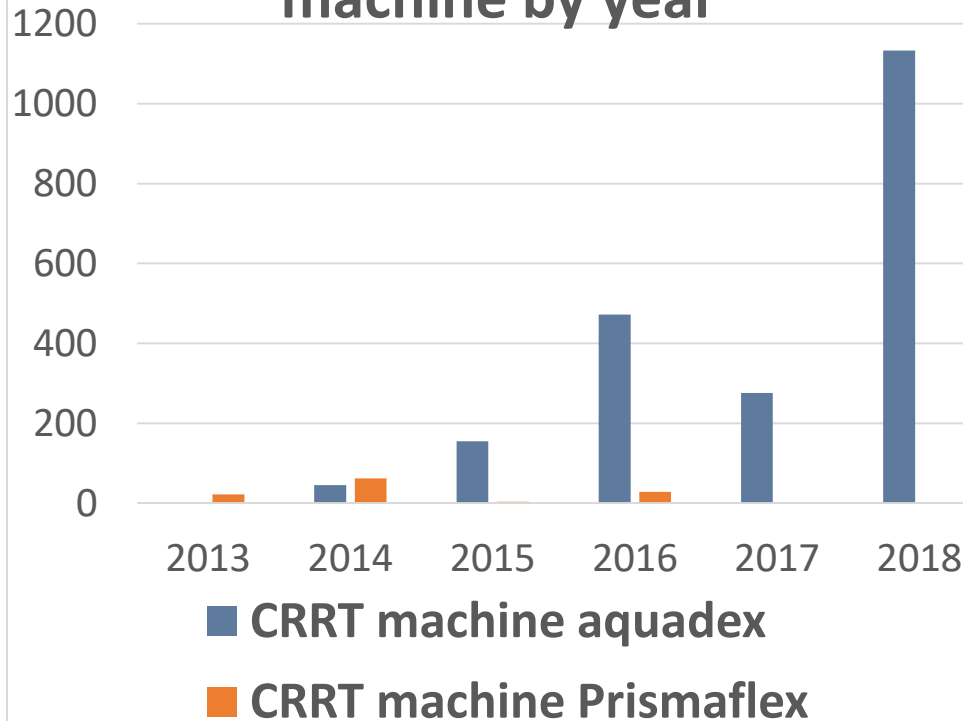
What if we had a smaller circuit?

- We could use smaller access....
- We could use smaller blood flows as the resistance of the tubing would be smaller
- We could avoid blood prime
- If you needed to blood prime...
 - A 12% blood prime is not as dangerous as a 50% blood prime

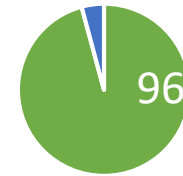


NICU – Specific QI data

NICU - CRRT days by machine by year

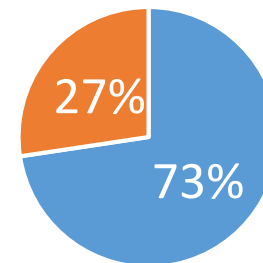


Hypotension Requiring Intervention at Initiation



■ no ■ yes

Non-Patient Issue Circuit Survival (>60 hrs)

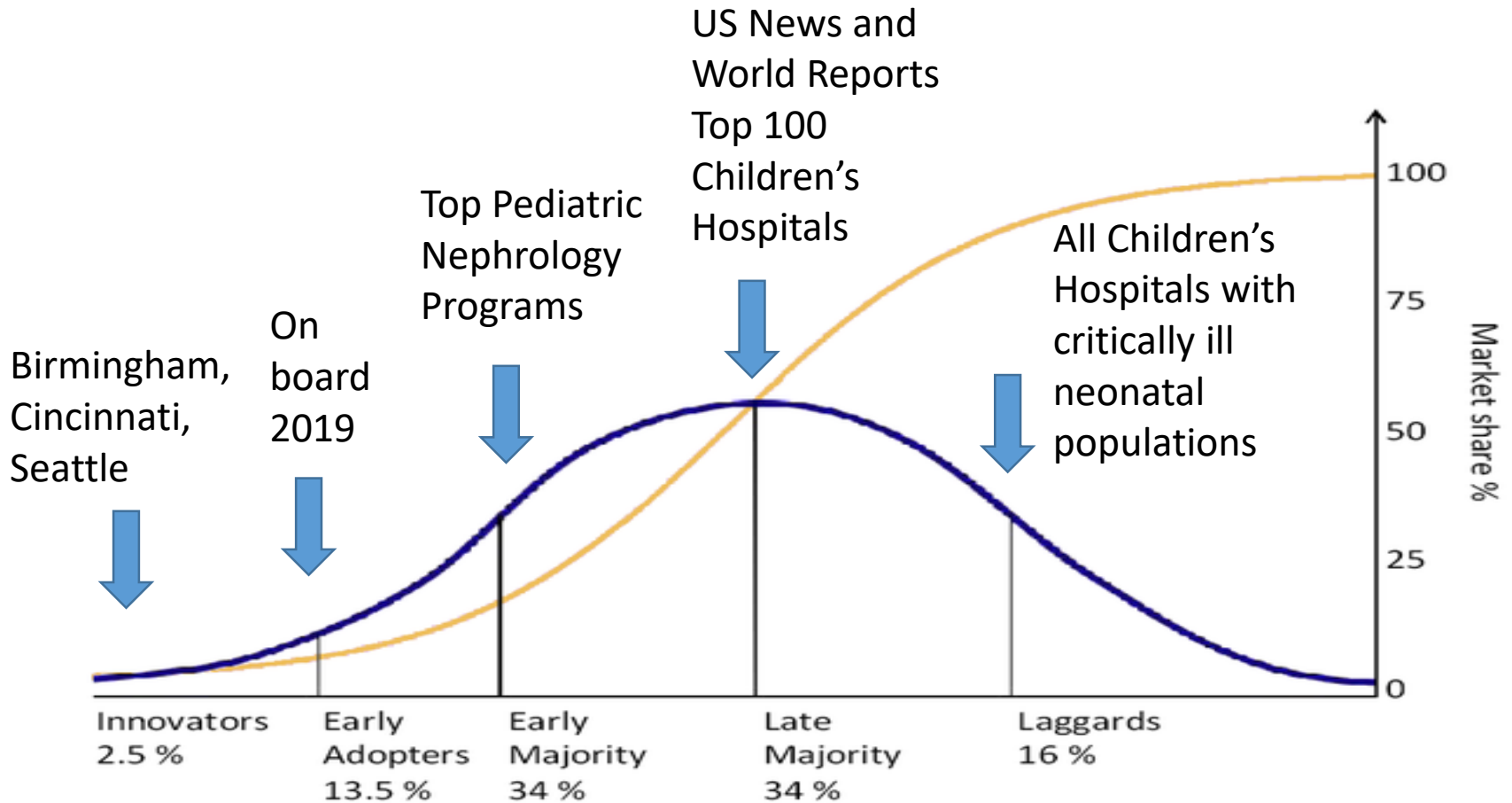


■ goal met

What has changed at our Hospital between 2013 to 2019?

- We now offer Kidney Support Therapy to many kids who we would not have even considered it
 - We can now give babies a chance to live
- Our Neonatologist and Cardiac ICU intensivists are no longer 'afraid' of this therapy
- Our nurses have become proficient at it
- Babies hardly know they are getting therapy
- GAME - CHANGER

Future of Neonatal CRRT in the US



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Study Results and Summary

Shina Menon, MD

Assistant Professor, Division of Nephrology

Medical Director, Acute Dialysis

Seattle Children's Hospital

Disclosures

- Consultant for CHF solutions

Objectives

- Review the data from our 3 – center study
 - Methods
 - Results
 - Main Conclusions

Overview

Background

- AKI and volume overload are common and are associated with morbidity and mortality in critically ill neonates and children
- Continuous renal replacement therapy (CRRT) is the preferred modality to provide kidney support to such children
- CRRT is used sparingly in neonates and is associated with suboptimal outcomes
 - Use of machines designed/approved for adult-sized patients
 - Need for larger catheters, tubing, and filters, which result in a high extracorporeal volume (ECV) relative to patient size
 - Significant hemodynamic instability seen at CRRT initiation in neonates- 55% of sessions had intradialytic hypotension
- With an ECV of 33 ml, the Aquadex FlexFlow System can mitigate some complications seen at CRRT initiation in smaller infants
- Previously demonstrated by Dr Askenazi in 12 infants and small children, who received continuous venovenous hemofiltration (CVVH) using the Aquadex FlexFlow device
 - CVVH initiated with minimal complications

Methods

Study Design

- Retrospective chart review of all patients who received therapy with Aquadex FlexFlow from January 2012-March 2018 (n=119 admissions, 884 circuits)
- Data on demographics, circuit characteristics, complication, and follow-up outcomes
 - 3 centers: Children's of Alabama, Cincinnati Children's Hospital, and Seattle Children's Hospital

Primary and Secondary Outcomes

- Primary outcome: patient survival to end of treatment course
- Secondary outcomes: patient survival and kidney function at 1 year or last follow-up

Results

Attributes	Group 1: <10 kgs	Group 2: 10-20 kgs	Group 3: >20 kgs
Number of patients	N=72	N=13	N=34
Median age	19 days	26 months	190 months
Median weight at onset of therapy	4.1 kg	15.1 kg	60.1 kg
Primary disease	43% kidney disease 29% cardiac disease	54% kidney disease 31% Other	38% kidney disease 38% cardiac disease
Predominant indication	46% Volume overload	54% Volume overload	91% Volume overload
Common modality	67% CVVH	62% CVVH	92% SCUF
Median blood flow rate, ml/min	40	40	40
Median number of days on UF	9	7	1
Median number of circuit	4	3	2
Cardiorespiratory support at initiation (or with complications at initiation)	3%	7%	0%
Patient survival at the end of treatment	43 (60%)	13 (100%)	33 (97%)
Patient survival at hospital discharge	23 (32%)	11 (85%)	23 (68%)
Patient survival at 1-year	12	8	14
Most prevalent complications	Transient hypotension (30), clot in filter (37)	Transient hypotension (3), clot in filter (9)	Transient hypotension (4), clot in filter (6)

Summary

- Many of the patients who received CVVH in this study were small, young, and critically ill
 - *A majority of these may not have traditionally received KRT due to earlier described issues with adult designed/approved CRRT devices (i.e., larger catheters, tubing, and filters)*
 - More than 50% of patients weighing <10 kg survived therapy
 - Mortality was high in the younger patients, likely related to their underlying disease along with other comorbidities
- In patients weighing >20 kg, who primarily received slow continuous ultrafiltration, 97% survived to end of therapy
- Complications during therapy were infrequent, and mostly related to vascular access (clot or catheter malfunction) or minor bleeding at catheter insertion sites

Key Takeaways

Overall

- This study speaks to the *unmet need* for devices specifically designed for younger patients
- With the use of a machine with small extracorporeal volume, CRRT therapy could be initiated safely without significant cardiovascular decompensation
- Having more size-appropriate machines will shift the benefit–risk equation such that small children can get the benefit of kidney support to a level that is closer to larger children and older patients

Key Takeaways

Aquadex FlexFlow

- Renal support using Aquadex FlexFlow is well tolerated
- The use of a machine with small extracorporeal volume allows for the initiation of therapy with good hemodynamic stability, which is critical to patient care
- Physicians were able to provide kidney support to neonates with Early Stage Kidney Disease (ESKD) who were unable to receive PD (peritoneal dialysis)
- A small group of patients with volume overload were managed in the outpatient dialysis unit

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Thanks

