Comparison of Transfusion Adverse Events in Children with Sickle Cell Disease (SCD) Receiving Simple or Automated Red Blood Cell Exchange (aRBX) Transfusions for Stroke Prevention

Shannon Kelly, M.D.
Disclosure

• Presented analysis part of larger study funded by Terumo BCT
Stroke Prevention in SCD
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- STOP trial randomized 130 children with a Transcranial Doppler MCA velocity > 200 cm/sec to observation or transfusions

| Transfusions (n=63) | Standard care (n=67) |
**Stroke Prevention in SCD**

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92% difference in stroke risk (p<0.001)
Stop II → When Can We Stop Transfusions??

- Patients from STOP I (n=79)
  - Chronic transfusions for 30 months
  - Normal TCD, MRI and MRA
  - Randomized to continue or stop transfusions

| 41 patients randomized to stop transfusions | 38 patients randomized to continue transfusions |
Stop II → When Can We Stop Transfusions??

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41 patients randomized to stop transfusions

2/41 Stroke
14/41 Converted to abnormal TCD

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Study discontinued early

Adams. NEJM 2006 339 (1) 5-11.
Chronic Transfusions in SCD

- SCD patients transfused for stroke prevention → indefinitely committed to chronic transfusions
Chronic Transfusions in SCD

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• UCSF Benioff Children’s Hospital Oakland Policy
  – All patients transfused ~ every 4 weeks to maintain target pre-transfusion HbS < 30%
  – Automated exchange preferred for patients transfused for stroke prevention if appropriate IV access available
    – Two peripheral IVs or 11.4F Double lumen Vortex™ Port
  – Automated RBC exchange on COBE Spectra [Spectra Optia since May 2014] with target post transfusion hematocrit ≈ pre transfusion hematocrit
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• Unique risk / benefit profile for available methods for transfusion (simple vs automated red blood cell exchange, aRBX)
Study Objectives

- Study objective: Compare clinical and adverse outcomes between simple and aRBX

**Clinical Outcomes**
- Control of HbS
- Hemolysis
- Hospitalizations
- Neurologic Events
  - CVD, TCD

**Adverse Outcomes**
- Transfusion
- Adverse Events
- Iron Overload
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Adverse Outcomes

- Transfusion Adverse Events
- Iron Overload
Methods

• Retrospective analysis of data captured for clinical care of chronically transfused patients
• All nursing, physician and blood bank records for all transfusions reviewed to capture potential adverse events (AEs)
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- Retrospective analysis of data captured for clinical care of chronically transfused patients
- All nursing, physician and blood bank records for all transfusions reviewed to capture potential adverse events (AEs)
- CDC Hemovigilance definitions
  - Alloimmunization
  - Febrile non-hemolytic transfusion reactions (FNHTR)
  - Delayed hemolytic transfusion reaction (DHTR)
  - Transfusion associated circulatory overload (TACO)
  - Allergic reactions
  - Transfusion related acute lung injury (TRALI)
  - Transfusion transmitted infections (TTI)
- Gastrointestinal symptoms (GI) – any abdominal pain, nausea/vomiting that required an intervention
- Citrate/hypocalcemia symptoms that required an intervention
Methods

• Iron Overload - average ferritin over 6 months > 1000ng/mL
  – Serum ferritin frequently monitored
  – Other methods to assess iron (MRI, SQUID) only performed if ferritin consistently high
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• Statistical Analysis
  – Generalized estimating equation (GEE) models used to calculate odds ratio (OR) of outcomes with simple compared to exchange
    – GEE models relationship between repeated measures outcomes (adverse events) and predictor (transfusion method of simple or aRBX) allowing for within subject correlation
  – Analysis for transfusion adverse events → analyzed per unit (predictor = simple or aRBX unit)
  – Analysis for iron overload → transfusion time divided into 6 month blocks and each time block classified as simple or aRBX (predictor = simple or aRBX time block)
Eligibility

- SCD patients chronically transfused (at least 8 transfusions in a calendar year) at UCSF Benioff Children’s Hospital Oakland (BCHO)

- Indication for chronic transfusion therapy = stroke prevention
  - Previous stroke
  - Abnormal TCD
  - Abnormal brain MRI/A

- >75% of care at BCHO Pediatric SCD Program

- Underwent at least 1 year of chronic transfusion therapy between 1998 – 2013 (aRBX first available in 1998)
# Study Population

## Study Population Demographics (n=56)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Gender</strong></td>
<td>32 (57.1%) Female</td>
<td>24 (42.9%) Male</td>
</tr>
<tr>
<td><strong>Sickle Genotype</strong></td>
<td>55 (98.2%) SS</td>
<td>1 (1.8%) SC</td>
</tr>
<tr>
<td><strong>Age start CTT</strong></td>
<td>7.5 (2 – 19 years)</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of CTT</strong></td>
<td>7.8 (1 – 23 years)</td>
<td></td>
</tr>
<tr>
<td><strong>Total Units Transfused</strong></td>
<td>13,700 total units</td>
<td>5,238 simple units</td>
</tr>
<tr>
<td></td>
<td>8,462 aRBX units</td>
<td></td>
</tr>
<tr>
<td><strong>Units per Patient</strong></td>
<td>244 (8-933 units)</td>
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* Mean, range
Study Population

- Many patients received a mixture of simple and aRBX transfused units during the time of CTT

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<th>Percent of Total Units via Simple Transfusion</th>
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Intravenous Access

• Types of Intravenous Access in 37 patients with any aRBX

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– 1 AV fistula infected + bacteremia
– 0 catheter associated bacteremia with Vortex Port
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- Complications Associated with IV Access
  - Infections
    - 1 AV fistula infected + bacteremia
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  - Thrombus
    - 1 right atrial thrombus → Port removal
## Results – Iron Overload

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- Odds of developing iron overload over time with simple compared to aRBX comparing “pure” patients
  OR 5.1 [2.8-9.0] p<0.0005
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- Odds of developing iron overload over time with simple compared to aRBX including all patients
  
  OR 2.7 [1.9-4.0] p<0.0005
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<th>aRBX 8462 U</th>
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<td>N events</td>
<td>AE/100 U</td>
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</tr>
<tr>
<td>Allo-antibodies</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>FNHTR</td>
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</tr>
<tr>
<td>Citrate</td>
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</tr>
<tr>
<td>Machine Malfunction</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Other (SAE)</td>
<td></td>
<td></td>
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<tr>
<td>FNHTR</td>
<td>7</td>
<td>0.137</td>
</tr>
<tr>
<td>Allergic</td>
<td>18</td>
<td>0.351</td>
</tr>
<tr>
<td>DHTR</td>
<td>1</td>
<td>0.019</td>
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<tr>
<td>GI</td>
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</tr>
<tr>
<td>Citrate</td>
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</tr>
<tr>
<td>Machine Malfunction</td>
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</tr>
<tr>
<td>Other (SAE)</td>
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<td>0</td>
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<tr>
<td>Any AE</td>
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<td>0.780</td>
</tr>
<tr>
<td>Any AE (citrate &amp; malfunction excluded)</td>
<td>40</td>
<td>0.780</td>
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## Results - Transfusion Adverse Events

<table>
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<tr>
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<th>Simple 5125 U</th>
<th>aRBX 8462 U</th>
<th>Odds of AE with Simple Compared to aRBX</th>
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<tr>
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<tr>
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<td>40</td>
<td>0.780</td>
<td>32</td>
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</tbody>
</table>
Summary

• Despite an increase in unit exposure with aRBX, there was no significant difference in transfusion adverse events with the exception of lower alloimmunization with aRBX
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Summary

• Despite an increase in unit exposure with aRBX, there was no significant difference in transfusion adverse events with the exception of lower alloimmunization with aRBX

• There were significantly increased odds of iron overload with simple compared to aRBX

• Future Directions: compare clinical outcomes between simple and aRBX
  – New/progression cerebral infarcts or cerebral vascular disease
  – Transcranial doppler
    – Normalization or development of abnormal TCD
  – Pre-transfusion HbS, reticulocyte count
  – Hospitalizations (any, vaso-occclusive pain episode, acute chest syndrome)
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  – Keith Quirolo, MD
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  – Lynne Neumayr, MD
  – Anne Marsh, MD

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  – Shanda Robertson
  – Deanna Fink