Ethanol Lock Efficacy and Associated Complications in Children With Intestinal Failure

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The authors report

NO RELEVANT FINANCIAL RELATIONSHIPS
Intestinal Failure

• No single accepted definition

• A failure of the intestine to support the nutritional and hydration needs of the body

• Central access required for $\geq 30$ days to support fluid, electrolyte, and/or nutritional needs
Central Line-Associated Blood Stream Infection (CLABSI)

• Primary bloodstream infection in a patient who has a central line

• No other identified source with identical organism

• Measured in: Events per 1,000 catheter days
CLABSIs

• CLABSI rates for inpatient pediatric units
  – 0.5-1.9 per 1,000 catheter days

• CLABSI rates among pediatric IF
  – 8.0-10.2 per 1,000 catheter days
  – Proposed reasons
    • Relative immune-deficient state
    • Poor intestinal motility
    • Reduced barrier function
    • Frequency of line access/Line colonization

Locking Solutions

- **Antimicrobial locking solutions**
  - Expensive
  - Encourage resistant organisms

- **Ethanol**
  - Cheap
  - Antimicrobial
    - Kills bacteria, fungi, and viruses
  - Penetrates biofilms
Ethanol Lock Therapy

- ELT in pediatric IF
  - Effective?
    - Several studies examined small groups using ELT
      - up to 23 patients per study
    - Meta-analysis: CLABSI *reduction* of 7.7 per 1,000 catheter days
    - Problems: low number of patients, diverse practices with ELT
  - Safe?
    - *No* studies, only anecdotes of *occlusion* and *breakage*

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>SE</th>
<th>Weight</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
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<tbody>
<tr>
<td>Cober 2010</td>
<td>6.7</td>
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<td>44.3%</td>
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<tr>
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<td>9.30 [5.63, 12.97]</td>
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<tr>
<td>Total (95% CI)</td>
<td>100.0%</td>
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<td>7.67 [5.87, 9.47]</td>
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Heterogeneity: \( \chi^2 = 1.26, \text{df} = 3 \) (\( P = .74 \)); \( I^2 = 0\% \)
Test for overall effect: \( Z = 8.36 \) (\( P < .00001 \))

Dannenberg *Clin Infect Dis* 2011; Opilla *JPEN* 2007; Oliveira *Pediatrics* 2012
AIM of our study

• ELT in pediatric IF
  – Effective?
    • Several studies examined small groups using ELT
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Heterogeneity: $\chi^2 = 1.26$, df = 3 ($P = .74$); $I^2 = 0$

Test for overall effect: $Z = 8.36$ ($P < .00001$)

**AIM:** Describe **SAFETY** and **EFFECTIVENESS** of ELT in our population

Dannenberg *Clin Infect Dis* 2011; Opilla *J PEN* 2007; Oliveira *Pediatrics* 2012
Intestinal Rehabilitation Registry

- >200 registered patients
- >6 years of data
  - Demographics
  - Lab values
  - CLABSI events
  - Admissions
- Maintained by database specialist

Purpose:
- Retrospective clinical studies (Data collected prospectively)
- Quality improvement
  - 4 current projects

Current Outcomes
- CLABSI rate: 1.3 per 1,000 catheter days
- % of population with total bilirubin level <0.2: 100%
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<th>Inclusion Criteria</th>
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<tr>
<td>Greater than two line infections in a one year period with gram negative enteric organisms</td>
<td>Allergy to ethanol</td>
</tr>
<tr>
<td>One previous instance of a fungal positive blood culture from a central line</td>
<td>Hypercoagulable state</td>
</tr>
<tr>
<td>Continuation of home or outside hospital-initiated therapy</td>
<td>Loss of two or more catheters to occlusion</td>
</tr>
<tr>
<td>More than three line infections with any organism in a one year period</td>
<td>A psychosocial situation that prevents the use of ethanol</td>
</tr>
<tr>
<td>Removal of a second vascular catheter due to infection</td>
<td>Parent(s) or guardian(s) objecting to the use of ethanol</td>
</tr>
<tr>
<td></td>
<td>Lines not known to be compatible with ethanol locks</td>
</tr>
</tbody>
</table>
CCHMC ELT Method

- Determine ELT priming volume
- Educate caregiver
- Schedule dwell time
  - >2hrs up to length of window (12hrs)

1. Flush w/ NS
2. Instill priming volume of **70% Ethanol**
3. Dwell (no access to CVC)
4. Withdrawal with small flash of blood
5. Flush line with >5 mL NS
6. Resume use

<table>
<thead>
<tr>
<th>Tunneled Catheter</th>
<th>Priming Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard</td>
<td></td>
</tr>
<tr>
<td>2.7 Fr</td>
<td>0.15 mL</td>
</tr>
<tr>
<td>4.2 Fr</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>6.6 Fr</td>
<td>0.7 mL</td>
</tr>
<tr>
<td>7.0 Fr DL Red</td>
<td>0.8 mL</td>
</tr>
<tr>
<td>7.0 Fr DL White</td>
<td>0.6 mL</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Cook</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Fr</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>5 Fr</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>4 Fr DL White</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>4 Fr DL Blue</td>
<td>0.1 mL</td>
</tr>
<tr>
<td>5 Fr DL White</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>5 Fr DL Blue</td>
<td>0.2 mL</td>
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## Demographics of Study Participants

<table>
<thead>
<tr>
<th>Demographic Category</th>
<th>Number</th>
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<tr>
<td><strong>Number of Patients</strong></td>
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<td><strong>Median Patient Age (Range)</strong></td>
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<td><strong>Sex</strong></td>
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<td>6</td>
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<td>Congenital Enteropathy</td>
<td>1</td>
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<tr>
<td>Metabolic</td>
<td>3</td>
</tr>
<tr>
<td>Post-multivisceral transplant</td>
<td>9</td>
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Primary Diagnosis

- Multivisceral transplant support: 28%
- Pseudoobstruction: 21%
- Metabolic/Mitochondrial myopathy: 10%
- Necrotizing enterocolitis: 7%
- Gastrochisis: 7%
- Jejunal atresia: 7%
- Ileal atresia: 10%
- Primary enteropathy: 10%
- Resection following severe abdominal trauma: 4%

Other diagnoses include:
- Gastroschisis
- Jejunal atresia
- Ileal atresia
- Primary enteropathy
- Resection following severe abdominal trauma
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<td>Total Line Days</td>
<td>23,202</td>
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</table>

- **Off ELT**: 8,865 days (median 210)
- **On ELT**: 14,337 days (median 296)

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<th>Line Type</th>
<th>Total Line Days</th>
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<tbody>
<tr>
<td>Tunneled Central Venous Catheter</td>
<td>87</td>
</tr>
<tr>
<td>Peripherally Inserted Central Catheter</td>
<td>61</td>
</tr>
<tr>
<td>Port</td>
<td>8</td>
</tr>
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</table>
Blood Stream Infections

Events per 1,000 line days

Off ELT: 5.53
On ELT: 3.14

*Difference significant (p<0.013) by Poisson regression modelling
Infecting Organisms Recovered by Blood Culture

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<th>Conditions</th>
<th>Events per 1,000 line days</th>
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<td>Gram Positive Off ELT</td>
<td>2.48</td>
</tr>
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<td>Gram Positive On ELT</td>
<td>1.39</td>
</tr>
<tr>
<td>Gram Negative Off ELT</td>
<td>1.35</td>
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<tr>
<td>Gram Negative On ELT</td>
<td>0.84</td>
</tr>
<tr>
<td>Fungal Off ELT</td>
<td>0.07</td>
</tr>
<tr>
<td>Fungal On ELT</td>
<td>1.13</td>
</tr>
<tr>
<td>Polymicrobial Off ELT</td>
<td>0.84</td>
</tr>
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Central Line Complications

*Difference significant (p<0.006) by zero-inflated Poisson regression modelling
Conclusions

ELT is a SAFE and EFFECTIVE method for reducing CLABSIs in the pediatric IF population.

- CLABSI rates are reduced with ELT (p<0.013)
- Central line perforations or breaks are reduced with ELT (p=0.006)
- Central line occlusion rates trended downward with ELT (p=0.056)
- Low rates are possible with fastidious line care

Future Directions:
- Be able to distinguish translocation from line infections
- Determine how antibiotic exposure changes the ability to grow
- Create a collaborative improvement network
Conclusions

ELT is a **SAFE** and **EFFECTIVE** method for reducing CLABSIs in the pediatric IF population.

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Thank you for your support!!!

This work was supported in part by:
NIH grant P30 DK078392 of the Digestive Disease Research Core Center in Cincinnati
NIH grant T32 DK007727 (EAM)
NIH grant R21 DK88027 (CRC)

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ELT Administration Workflow

Ethanol Lock Administration

1. Gather all equipment. Perform HAND HYGIENE
2. Place equipment on clean surface.
3. Place barrier under catheter hub.
4. Apply non-sterile gloves.
5. Remove passive disinfection device. (if passive disinfection device not in place or compromised, scrub the needleless connector using alcohol prep pad for 30 seconds. Allow to dry for 15 seconds.)
5a. No
6. Access cap with normal saline syringe.
7. Pull back on plunger until blood flash back visualized.
7a. 1) Reposition patient, 2) Have patient take deep breath, and 3) Access cap with empty 1 or 3 ml sterile syringe, reattempt to aspirate blood.
7b. Flash back obtained
7c. Set up for hub entry.
7d. Complete cap change and heparinize line per policy
7e. Notify MD and consider Alteplase
8. Flash back obtained
8. Flush with normal saline as ordered
9. Instill ordered Ethanol volume
10. Cover cap with sticker “ETHANOL LOCK”
ELT Withdraw Workflow

1. Gather all equipment. Perform HAND HYGIENE
2. Place equipment on clean surface.
3. Place barrier under catheter hub.
4. Apply non-sterile gloves.
5. Passive disinfection device in place &/or uncompromised
   - yes
   - Remove passive disinfection device.
   - no
     - 5a If passive disinfection device not in place or compromised, scrub the needleless connector using alcohol prep pad for 30 seconds. Allow to dry for 15 seconds.
6. Access cap with empty 1 or 3 ml sterile syringe and withdraw instilled amount of Ethanol + 0.1 ml
   - yes
   - 6a
     - 1) Reposition patient,
     - 2) Have patient take a deep breath, and
     - 3) attempt to aspirate slowly
   - no
     - 6b Flush line with normal saline as ordered
    - yes
      - Line able to Flush
      - yes
        - Blood return
        - no
          - 6d Apply sterile cap
          - 6e Notify MD and consider Alteplase
          - yes
            - 6c Perform hub entry and attempt to aspirate.
3. Ethanol Lock Withdraw
   - yes
   - Ethanol and Blood Withdrawn
     - yes
       - 6c Attempt to draw blood back.
     - no
       - 6b Flush line with normal saline as ordered
  - no
    - 7 Flush with normal saline as ordered using push-pause or vigorous flush