Clinical Pearls – Sharing Experience-Based Central Venous Catheter Management Strategies in Home Infusion

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Disclosures

The speakers declare no conflicts of interest or financial interest in any service or product mentioned in this program.

Clinical trials and off-label/investigational uses will not be discussed during this presentation.
Clinical Pearls
Sharing Experience-Based Central Venous Catheter Management Strategies in Home Infusion

Melissa Leone, RN, BSN
Manager, Nursing Operations
Coram CVS/specialty infusion services
Research Importance

• Evidence-based practice
  – Standards of care and development of guidelines
• Error prevention
  – Learning from others
• Improved outcomes
• Qualitative vs. quantitative
  – Specific to site of care
Hierarchy of Evidence

- Sys Reviews-Metanalysis
- RCT's
- Cohort studies
- Case-Control
- Cross-sectional studies
- Case series, Case reports
- Ideas, opinions, editorials, anecdotal
Pay for Performance

• Informally applied in home infusion today
• Formally applied by Medicare in other settings
  – October 1, 2008 CMS changes
  – Third-party reporting
    • Example: Press Ganey patient satisfaction
• The Medicare Home Infusion Site of Care Act
  – Reintroduced in 2015
Data Collection

- Company-specific research to develop policies
- Internal data to select products and develop bundles of care
- Trends in patient outcomes to modify policy or product selection and generate improvement in patient outcomes
- Aggregation or repetition of other provider information to generate standards of care in the industry
Applicability of Findings and Tools

• Importance of consistent definitions
• Retrospective vs. prospective
• Third-party validation
• Agency for Healthcare Research and Quality (AHRQ) Initiative
  – Engage: How will this make the world a better place?
  – Educate: How will we accomplish this?
  – Execute: What do I need to do?
  – Evaluate: How will we know we made a difference?
Clinical Pearls
Research Challenges and Limitations in Home Infusion / Antibiotic Locks

Caryn Dellamorte Bing, RPh, MS, FASHP
CB Healthcare Consulting
Las Vegas, NV
Background: Antibiotic Lock (ABL) Research and Guidelines

Rationale for Research Project in ABL
What is Antibiotic Lock (ABL)?

• Antimicrobial solutions placed in a central venous catheter (CVC) to prevent recurrence of and/or treat catheter-related bloodstream infections (CRBSIs)
• Concentration of antimicrobial typically < as dispensed for systemic administration
• ABL instilled for specified dwell times
• ABL aspirated or flushed based on order
Guidelines related to ABL

• Initial uses of ABL preceded evidence based guidelines
• 2009 IDSA guidelines provided some support for ABL in catheter salvage, recommended maximum dwell times, use with and without systemic therapy, and specifics on vancomycin ABL concentration (exceed MIC by 1000-fold)
“Use prophylactic antimicrobial lock solution in patients with long term catheters who have a history of multiple CRBSI despite optimal maximal adherence to aseptic technique.” (Category II)
2011 CDC Guidelines / ABL

• Summarize and cite studies using a variety of antimicrobial lock solutions with and without heparin, primarily in the hemodialysis population and pediatric oncology patients

• Do NOT provide dosage, dwell time, or other specifics on ABL use

Presenter’s opinion: these still leave a lot for the clinician to figure out.
Selection Considerations in ABL

• No FDA approved indications for antimicrobials used as ABL agents (reimbursement challenges)
• Catheter material compatibility is generally not an issue with ABL (will discuss later with ethanol lock therapy [ELT])
• No ‘standardized’ solutions of ABL (although some pediatric oncology and hemodialysis program may have standardized order sets)
• As with all anti-infective therapies, obtain the microorganism culture, sensitivity and Minimum Inhibitory Concentration (MIC)
Dispensing Considerations in ABL²

- Dilute the antimicrobial agent to a concentration appropriate for the MIC—this WILL vary
- Stability data may be unavailable in the concentrations and/or syringes/containers required for treatment
- As with many antimicrobials, heparin compatibility (known or unknown) may require a compatible solution flush before/after dwell times
- Ideally, each flush/lock solution should be dispensed ready to administer (e.g. unit of use syringe appropriate for the type of CVC, not just the volume of ABL dosage unit)
Example of a Retrospective ABL Study\textsuperscript{5}
Objective of study

• “..to evaluate the outcomes of ABL in preventing central-line associated bloodstream infection (CLABSI) for patients receiving home infusion therapy”

5
Retrospective Review: Population

**Exclusion:**
- ABL before July 2009
- ABL after Sept 2010

**Exclusion:**
- Incomplete catheter information

**ABL population**
- n = 24

**Survey:**
National home infusion provider
- n = 26

3/12/2015 NHIA 2015 Annual Conference & Exposition
Results: Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>15 (63%)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (37%)</td>
</tr>
<tr>
<td>Adults (19 - 65 years)</td>
<td>16 (67%)</td>
</tr>
<tr>
<td>Pediatric (&lt; 19 years)</td>
<td>7 (29%)</td>
</tr>
<tr>
<td>Senior (&gt;65 years)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Parenteral nutrition (PN)</td>
<td>12 (50%)</td>
</tr>
<tr>
<td>Anti-infective</td>
<td>7 (29%)</td>
</tr>
<tr>
<td>Oncology</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>Other therapies</td>
<td>2 (8%)</td>
</tr>
</tbody>
</table>
Results: Average Catheter Days per ABL$^5$

<table>
<thead>
<tr>
<th>Medication</th>
<th>n</th>
<th>Average Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin</td>
<td>3</td>
<td>182</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>4</td>
<td>134</td>
</tr>
<tr>
<td>Linezolid</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>16</td>
<td>190</td>
</tr>
</tbody>
</table>
Results/Conclusions

- Primary objective:
  - 2 CLABSI on ABL during defined time frame
  - 0.5 CLABSI on ABL per 1000 catheter days
- Secondary objective:
  - Hospitalization could not be directly correlated with ABL therapy
- Clearly underpowered study, no statistical validity
- Primary researcher focused on two cases to evaluate clinical implications, if any, of CLABSI related to ABL
Study challenges and limitations

• Small sample size (unexpected)
• Documentation differences (in house and outside nursing, non-standard tools at the time)
• ABL formulas varied greatly
• Compliance validation/correlation to findings
• Limitations of retrospective design/review
The bottom line

• Home infusion practitioners must rely on limited data studies, often conducted in different settings, populations, and types of CVCs, to determine if orders for ABL are appropriate.

• Dispensing limitations can be partially overcome with standardization and some stability studies.
  – Organizations should publish/share this data for the benefit of all patient care.

• Well-designed prospective studies in home infusion are still needed.
Selected references/ABL


Clinical Pearls
A Randomized Controlled Comparison of Flushing Protocols in Home Infusion Patients with Peripherally Inserted Central Catheters

Martha Michael, BSN RN CRNI
Study Description

• Randomized, controlled, prospective, single blind study
• Exclusions: pregnancy, cancer
• Compared 3 flushing protocols for PICCs:
  1. Saline 10 mL SAS (saline, administration of drug, saline)
  2. Heparin 100 unit/mL, 3 mL SASH high (saline, administration of drug, saline, heparin 100 u/mL)
  3. Heparin 10 unit/mL, 5 mL SASH low (saline, administration of drug, saline, heparin 10 u/mL)
Impetus for Conducting Research

• Absence of consensus on optimal flushing solution

• Line occlusions on saline-only flush protocol—17.69% of patients with a central line were dispensed alteplase (Cathflo Activase®) over 28 months

• Desire to base practice decisions on empirical evidence
Findings

• No one flushing protocol was more effective than the other

• The Heparin Low Group (10 units per mL) had the lowest incidence of occlusions, additional RN visits, and missed medication doses
### Results

<table>
<thead>
<tr>
<th>Occurrences of PICC Sluggishness / Occlusion</th>
<th>SAS (1) (% within group)</th>
<th>SASH High (2) (% within group)</th>
<th>SASH Low (3) (% within group)</th>
<th>Overall incidence (%)</th>
<th>Pearson Chi-Square p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occurrences of additional RN visits to assess PICC Sluggishness / Occlusion</td>
<td>9 32.1%</td>
<td>9 32.2%</td>
<td>8 26.7%</td>
<td>26 28.9%</td>
<td>.893</td>
</tr>
<tr>
<td>Number of PICC occlusions requiring alteplase (Cathflo Activase®) administration</td>
<td>7 25.0%</td>
<td>3 9.4%</td>
<td>3 10.0%</td>
<td>13 14/4%</td>
<td>.160</td>
</tr>
<tr>
<td>Number of subject missed or delayed medication doses related to PICC occlusion</td>
<td>4 14.3%</td>
<td>2 6.2%</td>
<td>1 3.3%</td>
<td>7 7.8%</td>
<td>.275</td>
</tr>
<tr>
<td>Number of Catheter Replacements or Exchange over Guidewire</td>
<td>1 3.6%</td>
<td>1 3.1%</td>
<td>1 3.3%</td>
<td>3 3.3%</td>
<td>.995</td>
</tr>
</tbody>
</table>
Operational Applications

• Findings reviewed by Agency Clinical Standards Committee
• Identified baseline occlusion rate
• Adopted 10 unit/mL heparin, 5 mL as flush for PICCs for a trial period
• Concentration and volume recommended by the Infusion Nurses Society
Operational Applications

• Occlusion rate for 3 months prior to trial:
  5.9%, 7%, 2.8%

• Occlusion rate for 1st 4 months of trial:
  0.9%, 0.6%, 0.8%, 0.6%

• Low dose heparin (10 unit/mL) 5 mL adopted as standard
Lessons learned

• Collect data: you never know when you’ll wish you had it!
• What doesn’t kill you makes you stronger: the IRB
• Don’t be afraid of empiricism: remember Galileo
References


Clinical Pearls
Comparison of Retrospective Findings in Relation to Manufacturer Recommendations for Saline-Only Flush

Maria Engen RN, BSN
Nurse, Primary Case Manager
Coram CVS/specialty infusion services
Background

- Increased referrals for saline-only flushing
- Staff perceived increased catheter occlusions
- Patient experiences included:
  - Interruption in therapy
  - Catheter infections
Objective of Review

• Determine if occlusions occurred more frequently in catheters flushed with saline alone, as compared to catheters flushed using SASH technique
  — SASH = Saline, Administration of drug, Saline, Heparin
Retrospective Review

• Included more than 600 central venous catheters
• Spanned a period of one year, covering various types of infusion therapies
• 269 catheters – 10 mL 0.9% normal saline only
• 359 catheters – SASH method
Results

SASH Occlusion Rate:
0.61/1,000 catheter days
Total: 31,196 catheter days

Saline-Only Occlusion Rate:
3.76/1,000 catheter days
Total: 12,489 catheter days

Total Catheter Occlusions: 66
Manufacturer Recommendations

• Valved catheter manufacturers promoting saline-only flushing: Groshong®, Vaxcel PASV®, PowerPICC Solo*

• Typical recommendation is to flush with 0.9% normal saline 10 mL every 12 hours or after each use

• Some now support locking each lumen with 1 mL heparinized saline as optional or according to MD orders
<table>
<thead>
<tr>
<th>Procedure</th>
<th>PowerPICC Solo*</th>
<th>PowerPICC</th>
<th>Power Groshong®</th>
<th>Groshong®</th>
<th>Vaxcel PASV®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saline flush/saline lock</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Heparinized saline flush/saline lock</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Flush every 12 hours or after each use</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Flush every 7 days or after each use</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
INS Recommendations (Standard #45)

- **Practice Criterion O**: Due to the risk and costs associated with CVAD insertion, heparin lock solution of 10 units/mL is the preferred lock solution after each intermittent use (INS, 2011)

- Consider individual patient needs and orders for heparin use
References


Incorporating Ethanol Lock Therapy to Reduce Catheter Related Bloodstream Infections

Kevin L. Ross, RN, BSN
V.P. of Nursing, Soleo Health
Background

• Central Venous Catheters (CVC) provide necessary venous access but pose risks, including catheter related blood stream infections (CRBSI)

• Ethanol lock therapy (ELT) has been shown to decrease CRBSI and catheter changes

• Increased use of ELT in home infusion shows positive patient outcomes related to CRBSI, hospitalizations, and catheter changes
Objectives

• Identify potential benefits of ELT
• Evaluate the outcomes of ELT including hospitalization rates, infection rates and salvaging CVC associated with CRBSI in patients receiving ELT
Indications for ELT

• Reduction and management of CRBSI
• Prevention of recurrent CRBSI
• Reduction of catheter removal/replacement related to CRBSI
• Reduction of hospitalizations related to CRBSI
Retrospective Review

• Time span of 15 months representing 20,475 catheter dwell days
• Included 79 patients receiving ELT
• Various types of infusion therapy
  – TPN
  – Anti-infective
  – Hydration
  – Catheter care/maintenance
  – Other
Results

• Rate for CRBSI catheters removed or replaced per 1000 catheter dwell days
  – On ELT
    • Rate - 0.41/1000 catheter dwell days
  – Off ELT
    • Rate – 2.46/1000 catheter dwell days
Results

• Rate for CRBSI-related hospitalizations per 1000 catheter dwell days
  – On ELT
    • Rate 1.29/1000 catheter dwell days
  – Off ELT
    • Rate 1.93/1000 catheter dwell days
Results

<table>
<thead>
<tr>
<th></th>
<th>On ELT</th>
<th>Off ELT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVC Pulled/Replaced Rate per 1000 Dwell Days</td>
<td>2.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Hospitalization Rate per 1000 Dwell Days</td>
<td>2.0</td>
<td>1.5</td>
</tr>
</tbody>
</table>
Conclusions

• Rates for CRBSI catheter removal and/or replacement were lower on ELT than off ELT
• Rates for catheter related hospitalizations were lower on ELT than off ELT
• Demonstrated efficacy of ELT for home infusion patients at risk for CRBSI
Considerations and Precautions

• Literature shows ELT has been successfully used in prophylaxis and treatment of CRBSI

• Consider catheter material composition
  – ELT may damage some polyurethane catheters
  – Check with catheter manufacturer

• Ethanol is not compatible with heparin
  – Flush with saline (even if ethanol is withdrawn) prior to instilling heparin
References


Questions?