PIV Failure—Why a New Standard of Care is Needed

Russ Nassof, JD
RiskNomics, LLC
Russ Nassof is a member of the speaker's bureau/KOL for the following organizations:

- Becton Dickinson (Bard)
- Ethicon
- Cepheid
- Accelerate Diagnostics
- Adhezion
- Eloquest Healthcare
- Synexis
- Aerobiotix
- Prior affiliations with BBraun and Teleflex
Objectives

- Review the underrecognized and underappreciated risks surrounding PIV catheters and why enhanced stability and securement are critical to prevent PIV complications and meet the standard of care
- Identify the elements necessary to meet the evidence-based standard of care and the necessity to incorporate current best evidence along with new technology
- Describe what the evidence-based studies have shown with respect to the use of tissue adhesives and PIV failure
- Analyze why the failure to incorporate new products/technology which have been proven to prevent adverse events in PIVs resulting from stabilization/securement issues may be a breach of the standard of care and result in poor patient outcomes and increased costs as well as potential liability
The Issues with PIVs

- The Neglected Catheter
  - Everyone gets one... so how important can they be
  - “It’s only a” peripheral
  - Product name implies lack of importance
  - No clearly defined intervention bundle
  - Not officially tied to reimbursements
  - Lack of consensus on standards
  - Minimal training on insertion/maintenance
  - Not even recognized as infection source if CVAD is also present
  - Maximum sterile precautions upon insertion?
The Issues with PIVs

- Our PIVs are Failing
  - >300 million PIVs/year (175 million placed) in the USA and nearly 2 billion worldwide
  - Up to 90% of patients receive a PIV during hospital stays
  - Up to 69% or more fail due to dislodgement, phlebitis, occlusion, infiltration, or infection before therapy is completed
  - PIV median infection rate is .2% but this may amount to >500,000 infections based upon device sales*
  - PIV infiltration/extravasation median rates 22.2% or >35,000,000 infiltrations/extravasations*
  - PIV Catheter dislodgment median rates of 7% or >12,000,000 dislodgments*
  - Studies have shown that PIVs are the most commonly dislodged catheter

The Issues with PIVs

- Nearly everyone in a hospital gets a PIV
  - Why is no one looking at PIVs?
  - Why are so many PIVs failing?
    - If > 50% of PICCs or CVADs were failing everyone would be paying attention
  - Why is PIV data documentation so poor?
  - Why are infection rates only stubbornly decreasing?
  - Are we overlooking our biggest issue?
  - How do we make changes and improve PIV practice?
  - Do we need a new Standard of Care for PIVs?
VAD Stabilization/Securement

Where Do We Look for Answers?
VAD Stabilization/Securement

For a catheter to perform successfully over the intended duration:

- Made of biocompatible materials
- Inserted steriley
- Maintained pristinely
- Removed when no longer needed
- Accessed aseptically
- Placed in the right location
- Inserted deep enough in the vein
- **Secured optimally**

What’s in your bundle?

- Importance of even the smallest intervention !!!
Stabilization/Securement

- Catheter Securement- “means to anchor” catheter to skin
- Catheter Stabilization- “minimize catheter movement”
- WHY?
  - Movement of catheters is problematic-domino effect of negative outcomes
  - Vessel (endothelium) injury and pain → phlebitis
  - Fibrin/platelet deposition → catheter tip thrombosis
  - Vessel perforation → extravasation/infiltration
  - Catheter migration → catheter dislodgement
- Applicable to all catheters (but we will focus on PIVs)
Stabilization/Securement

- Adverse Events - Emmy Gunther
Catheter Placement - Why are we always putting these things where they don’t belong and then wondering why they move around and don’t last?

- INS - Use the site most likely to last the full duration of therapy
- INS - Use the forearm to increase dwell time and prevent accidental removal and occlusions
- INS - Use veins in the upper extremities and not the lower unless you have no option
- INS - Avoid the wrist, areas of flexion and areas of pain on palpation

Vein Purchase

- Migration of PIVs out of the vein will impact access even though it appears to be a viable insertion
Stabilization/Securement

- **Negative Outcomes**
  - Catheter restart (therapy still needed)
  - Additional pain/anxiety for patient
  - Increased cost of care
  - Potential reduction in acceptable access sites
  - Delay in therapy
  - Infection risk
  - Need for sedation/anesthetic for reinsertion

- **LIABILITY**

*Photos courtesy of Kathy Kokotis*
Experts frequently have different opinions as to what constitutes the standard of care (SOC)

Nursing has always been based on some form of evidence
  - You are allowed to be wrong
  - You are allowed to make mistakes
  - You are NOT ALLOWED to be NEGLIGENT !!

Are we meeting the SOC when it comes to PIV practice?
Standard of Care (SOC)

Meeting the Standard of Care (SOC)-avoiding negligence

- SOC is rarely 100% evidence-based but just like in court, the stronger the evidence the stronger the standard

- Where do we look?
  - Standards (Clinical Practice Guidelines-CPGs)
  - Evidence (Evidence-based Medicine-EBM)
Standard of Care (SOC)-PIVs

- SOC for PIVs
  - Skin antisepsis (i.e. clean the site prior to insertion)
  - Puncture the skin and vessel wall with the device (creating a SURGICAL WOUND which will ooze blood as a result)
  - Protect puncture site wound from skin organisms (should be closed as a wound)
  - Reduce VAD movement (pistoning) and dislodgment (securement/stabilization)
  - Cover insertion site with dressing
  - Reduce unplanned dressing changes (contamination/cost)
  - Protect the integrity of the skin!
  - Reduce adverse events including infections!
Standard of Care (SOC)

- Potential Indications of a Failure to Meet the SOC
  - Infection - systemic and local
  - Vessel Trauma - thrombosis
  - Skin damage
  - Catheter failure requiring early replacement or loss of access
Standard of Care (SOC)

Or more simply the Standard of Care for PIVs requires... DEVICES MUST BE SECURED and... DRESSINGS FOR THOSE DEVICES MUST BE KEPT CLEAN, DRY, AND INTACT !!!

But... 21-71% of PIVC dressings are soiled, moist, loose, or inadequately secured at any time point and our PIVs are failing*

Critical for Vascular clinicians to look for new technology to meet the standard of care

Where Do We Look for Answers - The Standards - CPGs

INS-1/2016

Consider using engineered stabilization devices (ESDs) as inadequate stabilization/securement can cause dislodgment and complications requiring premature VAD removal

Avoid use of tape/sutures/rolled bandages

Do not rely on dressings for VAD stabilization

Be aware of medical adhesive-related skin injury (MARSI) associated with adhesive-based ESDs
CPGs

- Problems

  - Existing CPGs **may limit innovation** at least until new CPGs gain adherents and form a new (revised) standard of care

  - CPGs **may not necessarily be current** *

  - Defendants have been found liable for medical malpractice for **failure to adopt new technologies/procedures even when near universal custom did NOT involve using them** **

  - **Malpractice standards of care include a DUTY TO STAY ABREAST** ***

  - **If guidelines are outdated, compliance will NOT excuse poor practice!**

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Where Do We Look for Answers - The Evidence - EBM

Levels of Evidence

- Level I: Evidence from one or more RCTs
- Level II-1: Evidence from controlled trials without randomization
- Level II-2: Evidence from cohort or case-control analytic studies
- Level II-3: Evidence from multiple time series (observational studies)
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees (ideally using formal consensus methods)
- Level IV: "Evidence" based on personal anecdote ("In my experience...")

Randomized Controlled Trials (RCTs) “the gold standard”
Evidence-based Medicine (EBM)

Evidence-based Medicine (EBM)

- Don’t keep doing what you’re doing if it’s not working just because everyone else is doing it !!!!
- Risk, Liability (Negligence ??), Poor Outcomes
Evidence-based Medicine (EBM)

- Defendants have been found liable for medical malpractice for failure to adopt new technologies/procedures even when near universal custom did not involve using them*
- If guidelines are outdated, compliance will not excuse poor practice
- EBM instructs clinicians to rely on current scientific evidence even before that evidence is regarded as prevailing custom**
- Malpractice standards of care include a DUTY TO STAY ABREAST.**
  - Validates the importance of small evidence-based studies if RCTs unavailable

EBM and Off-Label Usage

- Duty to Stay Abreast and Off-Label Usage
  - Off-label Usage
    - May become the standard of care
    - FDA does not want to stifle “the duty to stay abreast” and does not want to regulate the practice of medicine- Rationale for Learned Intermediary Doctrine
    - Off-label use is allowed and necessary in some cases (orphan disease, pediatrics, oncology, psychiatry, etc.)
    - Does not require informed consent but should be obtained if possible
  - Criteria to consider
    - Used in the best interest of the patient without fraudulent intent
    - Urgency
    - Benefit outweighs risk
    - Used successfully by other practitioners in the field (i.e. validation of small-evidence based studies again)
EBM and New Technology

- Technology Implementation
  - Readily available
  - Reasonably reliable
  - Competent to use
  - Will not harm the patient but could provide real benefit
  - Then it MUST be used!

- Malpractice standards change because of changes in technology NOT changes in law.
EBM and New Technology

- When Should New Technology NOT beImplemented?
  - Involves new clinical risks to patients or a particular patient
  - Changes the underlying process of care and compliance is questionable
  - FDA classification failure/clinical trial results questionable
  - Special training/expertise/competency needed that is not available
  - Informed consent?
  - Requires maintenance which cannot be provided/unavailable
  - Cost outweighs benefit
EBM and Tissue Adhesive

What’s All This Talk About Glue (Tissue Adhesive)?
- Cyanoacrylate - liquid monomer that binds to other molecules to form polymers
- Used for wound closure in orthopedic, facial, cranial, spinal surgeries
- Product recently approved for vascular access
- Bactericidal - barrier to microbial ingress
- Protects skin integrity
- Reduces VAD movement/dislodgement
- Reduces unplanned dressing changes
- Nominal cost
- Easy to use and remove
EBM and Tissue Adhesive

► What Do The Guidelines Tell Us?

► INS- Cyanoacrylate tissue adhesives for securement plus standard transparent dressings have shown a slight trend toward reduction in catheter failure - **But Larger Trials are Needed**
Evidence-based Medicine (EBM)

What Does the Evidence Tell Us? (Pilot RCT)*

<table>
<thead>
<tr>
<th></th>
<th>Standard polyurethane (SPU) control group</th>
<th>Bordered polyurethane</th>
<th>Sutureless securement (SSD) + SPU</th>
<th>TA + SPU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>21</td>
<td>20</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td># failed</td>
<td>8</td>
<td>5</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Failure rate</td>
<td>6.92</td>
<td>3.82</td>
<td>3.14</td>
<td>2.40</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
</tbody>
</table>

Results suggest lower PIV failure rates associated with the use of tissue adhesives (TAs)
>63% lower than standard polyurethane (SPU) dressing
>46% lower than bordered polyurethane (BPU) dressing
>36% lower than sutureless securement device (SSD)

Evidence-based Medicine-(EBM)

What Does the Evidence Tell Us? (Small RCT)

<table>
<thead>
<tr>
<th></th>
<th>BPU + tape</th>
<th>TA + BPU + tape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>190</td>
<td>179</td>
</tr>
<tr>
<td>Failure No (%)</td>
<td>52 (27%)</td>
<td>31 (17%)</td>
</tr>
<tr>
<td>Dislodgement</td>
<td>26 (14%)</td>
<td>13 (7%)</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>9 (5%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Occlusion</td>
<td>20 (11%)</td>
<td>15 (8%)</td>
</tr>
</tbody>
</table>

Results demonstrating 37% overall reduction in PIV failure and 50% reduction in PIV dislodgment with the use of TA for securement with application of 1 drop at insertion site, 1 drop under catheter hub and a 30 second dry time.

Evidence-based Medicine (EBM)

- Securing All Intravenous Devices Effectively (SAVE) RCT/Australia
- Lancet/July 2018
- Large RCT >1800 patients
  - Comparison of dressings/securement methods for PIVs
    - Low-cost polyurethane (SPU)
    - Bordered polyurethane (BP)
    - Securement devices with polyurethane (SPU+SSD)
    - Tissue adhesive (glue-cyanoacrylate) with polyurethane (TA+SPU)
  - GOAL- Identify an **OPTIMUM** dressing/securement method for PIVs
  - Optimum- “**most conducive to a favorable outcome**”
## Evidence-based Medicine (EBM)

<table>
<thead>
<tr>
<th></th>
<th>Standard polyurethane (SPU) - control</th>
<th>Bordered polyurethane</th>
<th>Sutureless securement (SSD) + SPU</th>
<th>TA + SPU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>454</td>
<td>454</td>
<td>453</td>
<td>446</td>
</tr>
<tr>
<td><strong>% Failure: Total Failure</strong></td>
<td>43%</td>
<td>40%</td>
<td>41%</td>
<td>38%</td>
</tr>
<tr>
<td><strong>% Failure: Pre-Protocol Analysis</strong></td>
<td>34%</td>
<td>35%</td>
<td>34%</td>
<td>26%</td>
</tr>
<tr>
<td><strong>Failure rate/100 PIV days</strong></td>
<td>18.3</td>
<td>19.6</td>
<td>15.9</td>
<td>12.7</td>
</tr>
<tr>
<td><strong>% due to Occlusion</strong></td>
<td>22%</td>
<td>19%</td>
<td>23%</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Dislodgement/100 PIV days</strong></td>
<td>3.5</td>
<td>3.5</td>
<td>3.0</td>
<td>2.5</td>
</tr>
</tbody>
</table>
What do these numbers really mean for PIV Adverse Events

- Catheter Failure
  - TA+SPU was approximately 8% less than SPU and SPU+SSD
  - TA+SPU was approximately 9% less than BP

- Is 8 or 9% really significant?

- Typical hospital PIV insertions = 100,000/year or 8-9000 additional catheters each year NOT FAILING

- Total PIVs sold worldwide = 2 Billion/year with 1 Billion insertions or 80-90 million additional catheters each year NOT FAILING
What do these numbers really mean for PIV Adverse Events?

- Occlusion
  - TA+SPU was approximately 6% less than SPU
  - TA+SPU was approximately 7% less than SPU+SSD
  - TA+SPU was approximately 3% less than BP

- Is 3% or 6-7% really significant?

Typical hospital PIV insertions - 100,000/year or **3-7000 catheters each year not having occlusion**

Total PIVs sold/year = 2 billion with 1 billion insertions or **30-70 million catheters/year not having occlusion**
Evidence-based Medicine

- What do these numbers really mean for PIV Adverse Events?
  - Dislodgement
    - TA+SPU was approximately 1% less than SPU and BP
    - TA+SPU was approximately .5% less than SPU+SSD
  - Is there any significance in such small %?
- Based upon 100,000 PIVs inserted per year per hospital even 1% = 1000 fewer dislodgements along with potentially 1000 fewer infiltrations, extravasations, occlusion, and/or loss of access OR from worldwide perspective of 1 billion PIV insertions this still translates into 10,000,000 fewer dislodgements!
Evidence-based Medicine

- Cost/Benefit Analysis of Tissue Adhesive
- What are the extra costs of adding tissue adhesive to your PIV bundle?
Evidence-based Medicine

What are the Risks/Costs of NOT ADDING tissue adhesive to your PIV bundle?

- Up to 9000 additional PIV failures/year (SAVE)
- Up to 7000 additional PIV occlusions/year (SAVE)
- Up to 1000 additional PIV dislodgements/year (SAVE)
- Catheter failure rate per 100 catheter days using TA was 20-35% LOWER than with any other dressing/securement evaluated (SAVE)
- Increased risk of infection and catheter failure complications
- Average Cost of CRBSI = $56,000 plus 7-10 day LOS*
- Penalties/incentives under the Deficit Reduction Act and Affordable Care Act (HAC scores, Value Based Purchasing, Inpatient Quality Reporting)

Evidence-based Medicine (EBM)

- The SAVE RCT Conclusions
  - None of the interventions “significantly reduced” PIV failure-
    - BUT- EVEN IF % ARE SMALL- THE NUMBERS WHEN IT COMES TO PIVs ARE
  - Occlusion rate “significantly lower” with TA+SPU
  - TA+SPU group had no infections- supports infection prevention benefits associated with TA+SPU antimicrobial properties and micromotion reduction
  - Cost per patient using SPU alone was “significantly” less than the other three
  - Securement bundles (i.e. multiproduct combinations of securement/dressings) might be most effective reducing PIV failure
  - Improved dressings and securement is needed to prevent many PIV complications but the “optimal” method remains elusive
Evidence-based Medicine

SAVE RCT- Other Conclusions

While a solution to prevent 100% of PIV catheter failures remains elusive based upon the statistics, the SAVE study did indicate a clear TREND that of the 4 dressing/securement options evaluated TAP was superior in prevention of occlusions, dislodgement and catheter failure.

When we look at 2 billion catheters sold and up to 69% failing these numbers are HUGE !!!

Costs- When primary BSIs were factored in- the TA+SPU dressing was only .55 AUD more than P per patient.

More data soon to be published- Cochrane
Evidence-based Medicine (EBM)

The Price of Prevention?
Evidence-based Medicine (EBM)

Remember:

- EBM instructs clinicians to rely on current scientific evidence even BEFORE that evidence is regarded as prevailing custom.

- Tissue adhesive used in small amounts has been successfully applied to prevent failure for PIVs, peripheral arterial catheters, and non-tunneled CVADs. Tissue adhesive also has hemostatic properties that reduce post-insertion bleeding and hematomas. Tissue adhesive’s bactericidal properties also inhibit all Gram-positive organisms including Staphylococcus aureus (predominant cause of VAD-associated infections).

- “One to two drops of medical grade superglue (cyanoacrylate) applied directly to the wound and under the hub on insertion are an effective way to reduce micro-movement, achieve hemostasis in oozy patients and provide infection prevention”

Why Cyanoacrylate Tissue Adhesive?

- Vascular Product Selection-Factors to Consider
- Supported by the Guidelines
  - INS: “Larger trials are needed to confirm reduction in catheter failure associated with cyanoacrylate securement adhesive with standard transparent dressing”
- Supported by clinical evidence (Level I,II,III)?
  - Several RCTs and 15 or more peer-reviewed published studies demonstrating clinical benefit
- FDA Approval?
  - Approved for vascular access securement
- Product Delivery/Composition?
  - 2-octyl/blends cyanoacrylate effective against Gram +/Gram -/Fungi/Yeast
Why Cyanoacrylate Tissue Adhesive?

- Vascular Product Selection - Factors to Consider
- Device Issues/Stability, Securement?
  - Vessel trauma prevention - reduces VAD movement/malpositioning/dislodgement
- Infection Prevention Capability?
  - Immobilizes and kills bacteria (2 octyl-cyanoacrylate effective against bacteria, yeast, and fungi)
  - Minimizes oozing at insertion site (reduces infection risk)
  - Reduces unplanned dressing changes
  - Protects the integrity of the skin
- Product Duration/Durability?
  - Adhesive dissolves easily upon exposure to adhesive remover or will naturally slough off after 4-7 days reducing risk of MARSI
- Cost Benefit?
The Legal Issues:

Was the healthcare-associated clinical adverse event PREVENTABLE?
Is there available technology/product/practice that could have prevented the adverse event with minimal risk, liability, cost, and training?
Can you legally justify permitting PIV failure and infections when products are available to reduce these adverse events? How much PIV failure or infection difference do you need to have to inaugurate change??? What if you were the one with the infection that could have been prevented?
Is a cost difference of .55 AUD/patient justifiable in light of the data?
Standard of Care (SOC)

The Questions to Ask?

Can PIV failure and/or other adverse events attributed to NOT using the optimal securement/stabilization intervention as demonstrated by RCTs (utilizing EBM) constitute a breach of the standard of care?

Is PIV failure which can be attributed to securement/stabilization issues considered negligence when there are available evidence-based products which could have minimized the opportunity for catheter movement?

**Remember: Malpractice standards change not because of changes in the law, BUT rather because of changes in technology (products).**
Standard of Care (SOC)

- Why Is No One At My Hospital Asking Those Questions?
  - PIV- the neglected catheter
  - We are not looking at PIV failures
  - We are not looking at PIVs as the source of infections
  - We are not penalized or incentivized for PIV issues/solutions
  - Patients rarely understand the cascading set of adverse events that catheter movement can precipitate
  - Very little litigation even though the evidence is all too apparent BUT this may be changing
And It’s Not Only for PIVs...

- Evidence Mounting with respect to other catheters as well...
  - Peripheral arterial catheters
  - Central venous catheters
  - Epidural catheters
  - Peripherally inserted central catheters (PICCs)

- And It Comes off Easily
  - Drop of glue leaves small footprint
  - Cyanoacrylate will usually slough off on its own after several days and/or removes easily with commercially available adhesive removers
How Much Evidence Do You Need?

- 15 peer-reviewed published studies demonstrating clinical benefit of TAP
  - Complies with the standards
  - Meets the evidence-based criteria
  - FDA approved
  - Proven to reduce catheter failure
  - Reduces infection risk
  - Provides cost benefit
  - Should improve patient outcomes and reduce costs while meeting the SOC
How Much Evidence Do You Need?

- Do you think you could ever successfully defend these PIV cases resulting from catheter movement?
Final Thoughts

- **Tissue Adhesive Benefits**
  - Enhanced catheter securement
  - Seals around puncture site
    - Decreased contamination of site
    - Reduces oozing/leaking from puncture site
  - Early studies demonstrate feasibility of the concept and suggests reduction of complications
  - Large studies in progress
  - Promoting skin integrity and reducing VAD complications meets the evidence-based standard of care
Summary

- Inadequate stabilization and/or securement of PIVs is a contributing factor to the high incidence of catheter failure.
- PIV catheter failure may be an indication of a failure to meet the evidence-based standard of care.
- To meet the evidence-based standard of care criteria it is paramount to incorporate current scientific evidence and technology looking at both randomized control trials as well as small-evidence-based studies for guidance.
- Both RCTs as well as other studies have shown tissue adhesive to be an effective method of insertion wound closure resulting in reduced infection, occlusion and dislodgement as well as increased catheter dwell time.
- The failure to utilize products that have been shown effective in the prevention of PIV failure and/or infection may be negligent particularly when they can be used with minimal risk, cost, and training.
Questions