Clinical Experience with the LifeSite Hemodialysis Access System

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Introduction

• The use of catheters for hemodialysis are often associated with inadequate dialysis, increased risk of infection and poor device survival

• The LifeSite Hemodialysis Access System was designed as a totally subcutaneous alternative to hemodialysis catheters

• Results of studies to date comparing the LifeSite System to catheters have shown that the device is associated a:
  – Decreased rate of infectious complications
  – Reduced need for thrombolytic infusions
  – Improved device longevity

• As is common with new technologies, there is a learning curve associated with the use of this device
Objective of Study

The objective of our study was to:

• Identify complications associated with the clinical use of the LifeSite System in our institution

• Document management approaches utilized to treat these complications
The LifeSite System

- Totally subcutaneous alternative to hemodialysis catheters
- Implanted in upper chest
  - Right, left or bilaterally
- RIJ the preferred vein
- Two valve design allows for blood draw and return and maximum implant flexibility
- Can be used immediately after implantation
The LifeSite System

Valve:
Titanium Housing with Titanium, Stainless Steel and Silicone Internal Parts

Cannula:
Medical Grade Silicone with Barium Sulfate for Radiopacity

Length: 65 cm (cut to correct length during implantation)

Outer diameter: 12 French

Cannula configuration allows insertion with or without side holes
Cannulated with a 14-gauge dialysis needle via “buttonhole” technique

Internal pinch clamp in valve only opens to allow blood flow when 14-gauge needle is inserted

Blood flow stops when 14-gauge needle is removed
Antimicrobial Irrigation

- 70% isopropyl alcohol used to irrigate valve and valve pocket
- 25-gauge needle utilized – does not open internal pinch clamp
- Irrigation is done before and after hemodialysis session
Placement of LifeSite Valve and Cannula

- Cannulas inserted into vein(s)
- Two pockets created
- Cannulas tunneled to pockets
- Cannulas trimmed to length and attached to valves
- Valves sutured into pockets
Correct Placement of Valves

Draw/Arterial (Medial) → Return/Venous (Lateral)
Correct Cannula Tip Placement in Right Atrium
LifeSite patient during hemodialysis
Study Patient Population

- 32 patients implanted with the LifeSite System between December 2000 and September 2001
- 28 of 32 (87.5%) patients still dialyzing via the device
Kt/V comparison

Catheter = Average of monthly Kt/V’s during 6 month period for patients prior implantation of LifeSite

LifeSite = Average of monthly Kt/V’s during 6 month period for patients after implantation of LifeSite

* $p \leq 0.001$
Blood Flow comparison

Catheter = Blood flow measurements during 6 month period prior to implantation of LifeSite
LifeSite = Blood flow measurements during 6 month period after implantation of LifeSite
Occurrence of Complications

- Minor to Severe Complications: 65%
- No Complications: 35%
Complications (in order of frequency)

- Pocket infection
- Pocket hematoma
- SVC syndrome
- Poor flow
- Skin erosion
- Seroma
- Misalignment of buttonhole
- Wound dehiscence
## Valve or Cannula Revision

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th># of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor flow (managed by cannula exchange)</td>
<td>7</td>
</tr>
<tr>
<td>Skin erosion</td>
<td>1</td>
</tr>
<tr>
<td>Pocket infection</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9</strong></td>
</tr>
</tbody>
</table>
## Outcomes in Patients with Infections

<table>
<thead>
<tr>
<th>Management Strategy</th>
<th># of Patients</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-operative (antibiotics and alcohol irrigation)</td>
<td>10</td>
<td>Infection resolved in 7 patients</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Devices removed in 3 patients</td>
</tr>
<tr>
<td>Open drainage of pocket with medical management</td>
<td>1</td>
<td>Infection resolved</td>
</tr>
<tr>
<td>Immediate device removal due to unstable sepsis</td>
<td>1</td>
<td>Devices removed</td>
</tr>
</tbody>
</table>
Infection Management Algorithm

1. Suspected Infection
2. Take blood cultures via LifeSite and from a peripheral site to obtain differential counts.
3. Culture results indicate LifeSite Infection?
   - No: Treat according to clinical situation
   - Yes: Alcohol irrigation of LifeSite pockets daily and intravenous antibiotics for 2 weeks
4. Cultures obtained through LifeSite 1 week after finishing antibiotics are positive?
   - No: Observe Patient
   - Yes: Exchange Cannulas, Continue Alcohol irrigation of LifeSite pockets daily and Intravenous antibiotics for additional 2 weeks
5. Cultures obtained through LifeSite 1 week after finishing 2nd administration of antibiotics are positive?
   - No: Observe Patient
   - Yes: Remove LifeSite
Management of Poor Flow: Nursing Strategies

• Insure correct needles are being utilized
• Insure needles are properly seated in valve
• Adjust pump pressures
• Reverse lines
• Aspirate/flush with saline/aspirate

If the above are unsuccessful towards improving blood flow, nursing staff should contact physician for further orders
Possible Causes of Poor Blood Flow

- Persistent clotting
- Cannula tip malposition
- Kinked cannula
- Fibrin sheath formation
Management of Poor Flow

- **t-PA required for suspected intraluminal clot**

  - Third occurrence? **No** → Proceed with prescribed t-PA protocol

  - Yes → Perform upright, plain chest X-ray

  - Tip position correct? **Yes**
    - Perform dye study to rule out other causes of poor flow (kinks, fibrin sheath)
  
  - **No** → Exchange Cannulas
Pocket Hematomas

- Occurred more frequently during early experience with the device
- May have resulted from:
  - Improper seating of needle in valve
  - Heparin volume or concentration utilized for cannula lock
- Management
  - Irrigation and expression of hematomas via buttonhole tract
- Preventative strategies
  - Nursing education and vigilance
  - Utilization of proper cannulation technique
  - Use of appropriate heparin lock volume based on implanted cannula length
  - Use of heparin 1,000 units/ml for cannula lock
Exposure of Valve via Buttonhole Site

- Observed in two patients
- Developed as a result of misaligned buttonhole
- Establishment of a new buttonhole site is recommended if it is not properly aligned over the center of the valve
- Both cases successfully managed
- Application of triple antibiotic ointment to buttonhole site after dialysis and daily after showering/bathing is recommended
Insertion of Needle Via Misaligned Buttonhole
Insertion of Needle Via Misaligned Buttonhole

- May result in:
  - Enlargement of buttonhole
  - Bleeding
  - Patient discomfort
  - Hematoma formation
  - Possible infection
Exposure of Valve Outside of Buttonhole Site

• Observed in two patients
• Can result from inadequate tissue depth over valve (1 to 1.5 cm recommended)
• One case required device revision
• Sepsis developed in other case requiring device removal
• Application of triple antibiotic ointment after dialysis and daily after showering is recommended in these patients
Superior Venal Caval Syndrome

- Occurred in 4 patients
- Managed non-operatively
- Removal of LifeSite’s was not indicated
Summary

- Complications with the LifeSite System can be reduced or avoided by insuring proper:
  - Cannulation technique
  - Access care
  - Implant technique
    - Valve placement (location and spacing)
    - Tissue depth
    - Cannula tip positioning

- Most complications we experienced did not result in device removal

- The majority of the infections we observed resolved after successful medical management
Conclusions

• The LifeSite System is an effective alternative to hemodialysis catheters

• Understanding the potential complications associated with this device and the management of these complications is essential