PROSPECTIVE STUDY OF THE ACCUCATH® INTRAVASCULAR CATHETER SYSTEM WITH NITINOL GUIDEWIRE COMPARED TO PUBLISHED LITERATURE FOR CONVENTIONAL IV CATHETERS

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BACKGROUND

Patient satisfaction continues to be an important driver in today’s ever changing health care environment. The ability to influence patient satisfaction through improving infusion delivery makes it an important responsibility in the field of intravenous therapy. Currently, peripheral intravenous (PIV) outcomes are multi-challenged:

• Patient satisfaction averages 42% overall.4,5
• First attempt success averages only 40% in adults.1,7
• Complications occur 47% of the time.5,7
• Average PIV dwell time is 44 hours.2,3,7
• 50% of PIV lines require replacement before completion of therapy.1,5,7
• Unsuccessful PIV access may be escalated to midline or central line therapy, potentially increasing complication risk.8
• This sub-optimal care results in poor clinician satisfaction, inefficiencies, and unnecessary costs.7

PURPOSE

• A novel peripheral IV catheter technology that uses a proprietary coiled tip guidewire design is now available.
• This prospective study was to collect catheter performance data with a Vascular Access Team to validate improvement opportunities offered with guidewire technology compared to published literature for conventional catheter outcomes.
• Outcomes evaluated included: first attempt success, complication rates, dwell times, completion of therapy, patient satisfaction, and overall costs of therapy.
• The long range goal being to validate a technology that can significantly improve patient satisfaction.

ACCUCATH® INTRAVASCULAR CATHETER

With INS (Infusion Nursing Society) standards now stating IVs can dwell until complication, there is significant opportunity to improve patient outcomes with technology that offers greater first attempt success, longer dwell time and improved patient satisfaction as seen with the study IV.6

PATIENT SATISFACTION RESULTS

Patient satisfaction using a 5 point Likert Scale (Score 3-5 defined satisfaction):

<table>
<thead>
<tr>
<th>Overall Patient Satisfaction</th>
<th>N</th>
<th>Number Satisfied</th>
<th>Percent</th>
<th>95% Confidence Interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Insertion</td>
<td>95</td>
<td>95</td>
<td>100%</td>
<td>96.2% - 100%</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>At Discharge</td>
<td>95</td>
<td>93</td>
<td>97.9%</td>
<td>92.6% - 99.7%</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

*Compared to 42% average satisfaction rate in published literature for conventional catheters4,5

Indication for Use: The AccuCath® BC Intravascular Catheter System is inserted into a patient’s vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath® BC is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.
**CLINICAL RESULTS**

<table>
<thead>
<tr>
<th>First Attempt Success</th>
<th>N</th>
<th>First Attempt Success</th>
<th>Percent</th>
<th>95% Confidence Interval</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95</td>
<td>81</td>
<td>85.3%</td>
<td>76.5% - 91.7%</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

1.2 catheters were required per IV start compared to 2.18 for conventional catheters.\(^7,9\)
*Compared to 40% average first attempt success in published literature for conventional catheters.\(^1,7\)

<table>
<thead>
<tr>
<th>Complications</th>
<th>N</th>
<th>Complications</th>
<th>Percent</th>
<th>95% Confidence Interval</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95</td>
<td>17</td>
<td>17.9%</td>
<td>10.8% - 27.1%</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

* Compared to 47% average complications in published literature for conventional catheters.\(^3,7\)

<table>
<thead>
<tr>
<th>Completion of Therapy</th>
<th>N</th>
<th>Completion of Therapy</th>
<th>Percent</th>
<th>95% Confidence Interval</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95</td>
<td>82</td>
<td>86.3%</td>
<td>77.7% - 92.5%</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

*Compared to 47% average completion of therapy in published literature for conventional catheters. Defined as original IV in place as long as needed.\(^1,5,7\)

<table>
<thead>
<tr>
<th>Dwell Time</th>
<th>N</th>
<th>Av. Dwell Time Hrs.**</th>
<th>95% Confidence Interval</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>95</td>
<td>58</td>
<td>49.1</td>
<td>66.8</td>
</tr>
</tbody>
</table>

* Compared to 44 hrs. average dwell in published literature for conventional catheters.\(^2,3,7\)
**Hospital av. LOS was 2.98 days during study.

**CONCLUSIONS**

• This novel, proprietary guidewire technology offers a potential opportunity for improvement in patient satisfaction and clinical outcomes by increasing first attempt success, lowering complications, improving dwell time and completion of therapy when compared to conventional catheter published outcomes.

• Change can be accomplished by nursing action to impact review and adoption of innovative technologies, especially those that are evidenced based.

**ACKNOWLEDGEMENTS AND DISCLAIMERS**

ACKNOWLEDGEMENTS:
• AccuCath® Catheter Inventor, Dr. Amir Belson
• Sponsor Vascular Pathways, Inc., now C.R. Bard, Inc.
• Evangelical IV Team Nurses, Nursing Management, ICU/SDU and Medical Surgical Nursing Departments

DISCLAIMERS:
1. Please consult labels and inserts for any indications, contraindications, hazards, warnings, cautions and directions for use.
2. Data on file. Single center, one-arm cohort, post market study. Results may not be predictive of all users. Individual results may vary depending on a variety of attributes.
3. The presenter has been compensated by Bard Access Systems for the time and effort in preparing this study for Bard’s further use and distribution.
STUDY BIBLIOGRAPHY


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