Testing the Effectiveness of a New Device to Prevent Medical Line Entanglement in Pediatric Patients

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By the end of this presentation, the learner will be able to:

1. Describe the safety and effectiveness of the Medical Line (ML) Wrap in the prevention of medical line entanglement among pediatric patients.

2. Discuss the importance of implementing the ML Wrap into clinical practice to help protect children from medical line entanglement adverse events during hospitalization.
The Problem Posed by Patient’s Medical Lines

- Hospitalized children are at risk for **unintentional injuries** from their medical lines

- At least two documented **deaths** of infants due to asphyxiation from IV lines wrapped around their necks (Institute for Safe Medication Practices, 2005)
The Problem Posed by Patient’s Medical Lines

- Children receive many treatments while hospitalized:
  - IV therapy, oxygen therapy, tube feedings, pulse oximetry, cardiac monitoring, apnea monitoring, etc.
The Problem Posed by Patient’s Medical Lines

- Lines can be tangled with other lines, get pulled out, wrap around a body part or worse, wrap around a patient’s neck
Review of the Literature

Injury
- Accidents leading cause of death in children
- Children greater risk for accidental strangulation

Patients
- Have had “near misses”, injuries, or been strangulated by medical lines (Evans et al., 2007; Garros et al., 2003; Günther et al., 2009; Lunetta & Laari, 2005)

Solutions
- Other devices found such as IVY Device™, Beata Clasp™ (2012), or Koala Klip™ do not prevent strangulation
Medical Line Entanglement

- Among 486 pediatric patients, 28% (n=136) had problems with medical line entanglement

- 31 patients had lines wrapped around a body part and 2 toddlers were observed with lines around their necks (Janiszewski Goodin, Ryan-Wenger & Mullet, 2012)
Medical Line Safety Model

Pediatric Patient Human Factors
- Age
- Illness Acuity
- Length of stay
- Activity level
- Position

Caregiver Human Factors
- Presence
- Knowledge
- Assumptions
- Fatigue
- Distractions
- Problem Solving

Medical Line Safety

Patient Outcome
- Positive: No injury or adverse events
- Negative: Delayed therapy, Increased LOS, Injury, Medication Error, Asphyxia

System Factors
- Physical environment
- Safety Culture
- Workload
- Patient Monitoring
- Education

Level of Harm
- No harm
- Potential Harm
- Real Harm
The Medical Line (ML) Wrap

- Flexible with rigid sections
- Easy to apply/remove
- Easy to access lines and ports
- Easy to see lines
- Latex free
- No sharp edges or small parts
- Light weight - ~38 gm
- Can hold many lines
Randomized, Control Testing of the ML Wrap
Research Objective/Hypothesis

Evaluate the safety and effectiveness of the ML Wrap to prevent medical line entanglements and related preventable adverse effects.

H₁: Children in the ML Wrap group will experience fewer medical line entanglements and preventable adverse events compared to children in the Control group, as measured by the Medical Line Entanglement Severity Scale.

H₀: There will no differences in ML Entanglement Severity Scale scores between the Control and ML Wrap group.
Instruments

- Digital Observation Form
- Medical Line Entanglement Severity Scale
- Demographic Data
<table>
<thead>
<tr>
<th>Digital Observation Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Date/Time/ID #</td>
</tr>
<tr>
<td>- Level of Activity</td>
</tr>
<tr>
<td>- Presence of Caregiver</td>
</tr>
<tr>
<td>- Total # of Medical Lines</td>
</tr>
<tr>
<td>- Details regarding each medical line (type, location, level of entanglement, severity score, notes)</td>
</tr>
<tr>
<td>- If Phase 2, then:</td>
</tr>
<tr>
<td>- was Medical Line (ML) Wrap on line(s), how many wraps used, how many lines per wrap, were wraps labeled, were wraps closed and not altered?</td>
</tr>
</tbody>
</table>
Medical Line Entanglement Severity Scale

Each medical line is ranked on a scale from 0 to 10:

0 = No Harm (no medical lines attached to body, one saline locked IV or no entanglements)

1 = Potential Harm (Level 1) (lines are tangled with each other; patient is actively moving)

2 = Potential Harm (Level 2) (Patient lying on 1 or more medical lines)
Medical Line Entanglement Severity Scale

3 = Potential Harm (Level 3) (Patient has both tangled lines and is lying on medical line(s))
4 = Potential Harm (Level 4) (Medical line loosely wrapped around a patient’s body part)
5 = Potential Harm (Level 5) (Medical line loosely wrapped around a patient’s neck)
6 = Real Harm (Level 1) (Medical line is compressing skin around body part - no discoloration)
Medical Line Entanglement
Severity Scale

7 = Real Harm (Level 2) (Medical line is compressing skin around neck - no discoloration)

8 = Real Harm (Level 3) (Patient’s IV line or feeding tube was dislodged or disconnected)

9 = Real Harm (Level 4) (Medical line constricting blood flow (with discoloration) around body part)

10 = Real harm (Level 5) - medical line constricting blood flow (with discoloration) around a patient’s neck
Demographic Data

- Age (in months)
- Sex
- Length of Stay
- Ethnicity and Race
- Unit and Type of Bed
- Primary and Secondary Diagnosis
Participants

Inclusion Criteria:

- Children ages 2 months to 6 yrs of age
- Admitted as in-patients to a large, 354 bed freestanding children’s hospital
- Need to have at least 1 medical line attached to child’s body on first observation
- Parent/Legal Guardian consent for patients in phase 2
Procedure

- Study approval by hospital institutional review board
- Staff in-services were held on each the in-patient units where the data collection was to take place
- ML Wrap Demonstration video and Powerpoint® Presentation uploaded to hospital intranet
- Resource sheet available
Procedure

- Patients were randomly selected from 2 in-patient units (a respiratory unit or an infectious disease unit)

- Phase 1 Observation of Usual Care (Control Group) was done first

- Phase 2 ML Wrap (Intervention Group)
Results From ML Wrap Testing

- Logged 2444 observations:
  - Phase 1 = 1500 total observations
  - Phase 2 = 944 total observations
- Frequency of observations ranged from 1 to 32 observations per participant

Control Group $M = 12.09$ number of observations
ML Wrap Group $M = 7.61$ number of observations
3427 categories of variables to analyze
Results: Description of Sample

Control Group (n = 124)

- $M = 23.61 \text{ mos}$
- Median = 18
- Mode = 2 mos
- S.D. = 20.038

ML Wrap Group (n = 124)

- $M = 31.67 \text{ mos}$
- Median = 25.5
- Mode = 3 mos
- S.D. = 24.401
Number of Participants in Each Age Category

<table>
<thead>
<tr>
<th>Number of Participants</th>
<th>Infants</th>
<th>Toddlers</th>
<th>Preschoolers</th>
<th>School-age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>42</td>
<td>56</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>ML Wrap</td>
<td>35</td>
<td>36</td>
<td>28</td>
<td>25</td>
</tr>
</tbody>
</table>
## Demographic Results

<table>
<thead>
<tr>
<th>Control</th>
<th>Male (n=71)</th>
<th>Female (n=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg LOS</td>
<td>14.18 days</td>
<td></td>
</tr>
<tr>
<td>Ethnicity:</td>
<td>Hispanic (n=10)</td>
<td>Not Hispanic (n=114)</td>
</tr>
<tr>
<td>Race:</td>
<td>Caucasian (n=78), Black/AA (n=21), 2/more races (n=9), other (n=16)</td>
<td></td>
</tr>
<tr>
<td>Primary Diagnosis:</td>
<td>Pulmonary (n=90)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ML Wrap</th>
<th>Male (n=72)</th>
<th>Female (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg LOS</td>
<td>7.12</td>
<td></td>
</tr>
<tr>
<td>Ethnicity:</td>
<td>Hispanic (n=5)</td>
<td>Not Hispanic (n=119)</td>
</tr>
<tr>
<td>Race:</td>
<td>Caucasian (n=79), Black/AA (n=26), 2/more races (n=11), other (n=8)</td>
<td></td>
</tr>
<tr>
<td>Primary Diagnosis:</td>
<td>Pulmonary (n=88)</td>
<td></td>
</tr>
</tbody>
</table>
Incidence of Medical Lines

Number of Medical Lines

- ML Wrap
- Control

Number of Patients

0 10 20 30 40 50

1 2 3 4 5 6 7

ML Wrap
Control
Variety of Medical Lines

- Intravenous Lines (Peripheral & Central)
- Oxygen Tubing (Nasal Cannula, Trach, Mask)
- Feeding Tube (Nasogastric, Gastrostomy +/- Jejunostomy)
- Monitor lines (Cardiac, Pulse oximeter, Apnea)
- Other lines/tubes (Ballard device, straight drain catheters, etc)
Intravenous Lines

Percentage of Entanglements

Series of Observations

Control
ML Wrap
Pulse Oximeter

Percentage of Entanglements

Series of Observations

Control
ML Wrap
Feeding Tube

Percentage of Entanglements

- Control
- ML Wrap

Series of Observations
Other Medical Lines

Number of observations too small to calculate for either group:

Incidence of having a cardiac monitor:
Control - 4.8% (n = 6)  ML Wrap - 5.6% (n = 7)

Incidence of having an apnea monitor:
Control - 4.0% (n = 5)  ML Wrap - 4.0% (n = 5)

Incidence of other lines/tubes (Ballard suctioning device or G-tube to straight drain most common):
Control - 25.8% (n = 32)  ML Wrap - 11.3% (n = 14)
Evaluation of ML Wrap Usage

- Most common lines ML Wrap applied:
  - IV lines, monitor oxygen
  - 1 wrap most common while 34 patients had 2 wraps and 4 patients had 3 wraps (for at least 1 observation)
Discussion

- Significant reduction of medical line entanglements among patients who had ML Wrap(s) on their medical lines (15.1%) versus the total patient observations in the control group (39.9%)

- Patients in the ML Wrap group did not have wraps on their medical lines 100% of the time - but still found significant differences in entanglements
Discussion

- No harmful adverse events were observed for this study (Real Harm)

- Majority patients observed as either No Harm (Level 0) or Potential Harm (Level 1, 2, 3, 4, or 5)

- Medical lines looped around a body part or neck reported infrequently
Medical Line Safety: Future Developments

- Publish results from randomized control study regarding the ML Wrap
- Have ML Wrap used in clinical practice
- Implement a Medical Line Entanglement Risk Checklist on electronic chart
- Pursue Medical Line Safety as a Priority in National Patient Safety Goals
Conclusion

Let’s make Medical Line Safety a priority in our practice!

Any questions?