IV catheter placement remains the most common invasive hospital procedure performed worldwide. More than 300 million peripheral IV catheters are sold each year in the United States alone, and 60% to 90% of hospitalized patients require an IV catheter during their hospital stay, providing direct administration of fluids and medications into the bloodstream. PIV infiltration is the most common form of IV catheter failure, responsible for between 16 and 34 percent of all catheter-related failures [1].

Until now, no product has been available to provide continuous monitoring for early detection of IV infiltration—when a peripheral IV infusion begins to “leak” allowing drugs and fluids intended for intravenous delivery to pool in subcutaneous tissue. The patient harm caused by an IV infiltration can range from pain and redness to tissue and nerve damage to limb amputation. An IV infiltration of simple saline solution can lead to compartment syndrome resulting in nerve, tissue and joint damage. In addition to the possible localized physical damage, every IV infiltration represents a drug delivery error that can impact the effectiveness of treatments for patients requiring time-sensitive and life-saving drugs.

This whitepaper summarizes the clinical research that established the operational capabilities of the ivWatch device, and formed the basis of the data submitted to the FDA in support of the ivWatch 510(k) Premarket Notification. This clinical research was performed as part of the validation of the ivWatch Model 400—the first FDA-cleared device capable of providing continuous monitoring of peripheral IVs in the forearm and back of the hand for the early detection of infiltration and extravasation of optically-clear infusates.

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EARLY STAGE DETECTION OF PERIPHERAL IV INFILTRATIONS
ivWatch® is designed to serve as an aid to the clinician in the early detection of peripheral IV infiltration and extravasation events. The patented technology represents years of research and development in close partnership with leading hospitals and clinicians in the vascular access space.

ivWatch is the first device to provide continuous, cost-effective, noninvasive monitoring and assessment of peripheral IVs to aid clinicians in the early detection of subcutaneous infiltration and extravasation.

ivWatch consists of a patient monitor, an optical sensor cable, and a small disposable receptacle for attaching the sensor to the patient’s skin, near the IV site. A proprietary ivWatch signal-processing algorithm is tuned for maximum detection sensitivity, while minimizing false alarms that can contribute to alarm fatigue.
ivWatch® PATIENT MONITOR

ivWatch provides continuous monitoring of peripheral IVs on the forearm and back of the hand and can aid clinicians in the early detection of infiltration and extravasation of visually clear infusates.

Light from the patient monitor is transmitted to the skin with a reusable fiber optic sensor cable, paired with a single-use ivWatch receptacle.

The patient monitor provides continuous monitoring of the IV site using ivWatch’s proprietary algorithms; audible and visual notifications alert clinicians when the early stages of an infiltration or extravasation have been detected.
Minimizing Alarm Fatigue
/ Associated with Infiltration Detection

BACKGROUND
An IRB-approved clinical study was performed to measure the rate of false notifications issued by ivWatch. Forty healthy adult volunteers were enrolled in a 24 hour study. Each research subject was monitored from a site on either the forearm or the dorsal aspect of the hand.

THE STUDY OBJECTIVES
1. Quantify the rates of red notifications and self-correcting yellow notifications.
2. Identify conditions that may cause a non-infiltration notification by the ivWatch device.
3. Demonstrate insensitivity of the device to interference with other near infrared devices and common hospital activities such as blood pressure measurement.

METHODS

40 PARTICIPANTS + 24 HOUR STUDY
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

SENSOR LOCATION
The ivWatch sensor was randomly placed on either the forearm or dorsal aspect of the hand. A vein viewer was used to place the sensor immediately adjacent to a typical vein. No catheterization was performed, but the site was dressed following standard protocols, with the tubing taped down.

STUDY ENVIRONMENT
The observation area included a hospital bed, television, and video camera. The video camera provided a record of the subject’s motion activities throughout the study.
_SENSOR NOTIFICATION_

The ivWatch monitor issued notifications if signals consistent with an infiltration were detected.

 DEMOGRAPHIC RESULTS

<table>
<thead>
<tr>
<th>GENDER TYPE</th>
<th>SKIN PIGMENTATION</th>
<th>BODY MASS INDEX</th>
<th>AGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 MEN</td>
<td>11 MEDIUM</td>
<td>19 NORMAL</td>
<td>10</td>
</tr>
<tr>
<td>24 WOMEN</td>
<td>19 LIGHT</td>
<td>19 OBSESE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 DARK</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FALSE NOTIFICATIONS

A false red notification was issued at a rate of 0.255 notifications per day, or less than 1 notification every 4 days.

0.255 - 95% Confidence Interval: 0.104 to 0.622

A false yellow notification was issued at a rate of 0.526 notifications per day, or about 1 notification every 2 days.

0.526 - 95% Confidence Interval: 0.193 to 1.435.

NON-INFILTRATION NOTIFICATION CONDITIONS

In an analysis of the surveillance footage, many of the red and yellow notifications were associated with motions of the research subject that either applied pressure to the site or applied force to the sensor cable/receptacle assembly. Most notifications were associated with sites on the hand. Device interference did not cause any false red or yellow notifications.
STUDY CONCLUSIONS

1. The red and yellow non-infiltration notification rates of 0.255 and 0.526/day, respectively, are sufficiently small suggesting a minimal impact on clinical alarm fatigue.
2. Many of the non-infiltration notifications in this study were associated with patient activities that applied a force to the site.
3. No red or yellow notifications were generated by the interference of common near-infrared devices.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 40 sites of the study.

REFERENCES


DATE OF STUDY

January 2014

INTERNAL PROTOCOL ID

IVW400CS-05

CHESAPEAKE IRB

Pro00009175

SPONSOR

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Effect Of Infiltration Rate
/ On Infiltration Detection

BACKGROUND
An IRB-approved clinical study was performed to assess the effect of infiltration rate on the detection of early stage infiltrations. Twenty-four healthy adult volunteers received two subcutaneous infusions of isotonic saline solution in either the forearms or the dorsal aspect of the hands. The catheter was placed immediately adjacent to a vein using ultrasound guidance. The rate of each infiltration was randomly selected between 5 and 150mL/hr. ivWatch monitored each site and issued notifications if an infiltration was detected.

THE STUDY OBJECTIVES
1. Determine how the infiltration rate affects the sensitivity of the ivWatch device.
2. Determine how the infiltration rate affects the detection volume for the notifications of the ivWatch device.
3. Examine which patient attributes (skin tone, pigmentation) and infiltration characteristics (infiltration rate, IV site) affect the detected volume.

METHODS

24 PARTICIPANTS + 48 INFILTRATED IV SITES
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

- Weight
- Height
- Blood Pressure
- Forearm Circumference
- Skin Pigmentation

SENSOR LOCATION
Each subject received two IVs randomly placed on either the forearm or dorsal aspect of the hand.

PLACEMENT SEQUENCE
Nurses performed the IV procedure. The IV catheter was placed immediately adjacent to the vein using ultrasound guidance.
**ISOTONIC SALINE SOLUTION**
All subjects were infused with 10mL of isotonic saline solution.
The infiltration was started after 5 minutes of monitoring by the ivWatch monitor.

The infiltration rate for each IV site was randomly selected from one of four infiltration rates: 5mL/hr, 50mL/hr, 100mL/hr, 150mL/hr

**SENSOR NOTIFICATION**
The ivWatch monitor issued notifications if signals consistent with an infiltration were detected.

**DEMOGRAPHIC RESULTS**

<table>
<thead>
<tr>
<th>GENDER TYPE</th>
<th>SKIN PIGMENTATION</th>
<th>AGE</th>
<th>BODY MASS INDEX</th>
</tr>
</thead>
<tbody>
<tr>
<td>11 WOMEN</td>
<td>LIGHT</td>
<td>75-80</td>
<td>OBESE (&gt;30)</td>
</tr>
<tr>
<td>15 MEN</td>
<td>MEDIUM</td>
<td>70-75</td>
<td>OVERWEIGHT 25-29.99</td>
</tr>
<tr>
<td></td>
<td>DARK</td>
<td>65-70</td>
<td>NORMAL 18.5-24.99</td>
</tr>
</tbody>
</table>

**EFFECT OF INFILTRATION RATE**

- 75-80
- 70-75
- 65-70
- 60-65
- 55-60
- 50-55
- 45-50
- 40-45
- 35-40
- 30-35
- 25-30
- 20-25
- 15-20

- OBESE (>30)
- OVERWEIGHT 25-29.99
- NORMAL 18.5-24.99
- UNDERWEIGHT (<18.5)
Effect Of Infiltration Rate

/ On Infiltration Detection - CONCLUSION

STUDY CONCLUSIONS

1. The red and yellow notifications were issued by ivWatch for all 48 infiltrations in this study prior to 10mL infiltrated volume.
2. The average volume at the red notification was 1.7mL, 3.0 mL, 3.7mL, and 5.6mL for 5, 50, 100, and 150mL/hr.
3. The ivWatch device has a 2 minute response time which results in larger detection volumes for faster infiltration rates.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 48 sites of the study.
5. The measured patient attributes of gender, skin pigmentation, age, and body mass index did not have statistically significant impacts on the sensitivity or detection volume measured in the study.

DATE OF STUDY
October-November 2013

INTERNAL PROTOCOL ID
IVW400CS-03

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Early Stage Detection
/ Of Peripheral IV Infiltrations

BACKGROUND
An IRB-approved clinical study was performed to measure the sensitivity of the ivWatch device for detecting early stage infiltrations. Healthy adult volunteers received two peripheral IVs in either the dorsal aspect of the hand or the forearm. Enrollment criteria for a range of skin pigmentations and body types ensured a representative sample of the intended population of the device.

THE STUDY OBJECTIVES
1. Determine sensitivity of the ivWatch device for detecting early stage infiltrations (<10mL of isotonic saline solution).
2. Demonstrate performance for different skin pigmentations, body types, infiltration rates, and common PIV locations.
3. Demonstrate statistically significant improvement for detecting early stage infiltrations in comparison to hourly observations by a perfect clinician.

METHODS

70
PARTICIPANTS

+ 140
INFILTRATED IV SITES
FIVE ATTRIBUTES WERE MEASURED FROM EACH RESEARCH SUBJECT

- WEIGHT
- HEIGHT
- BLOOD PRESSURE
- FOREARM CIRCUMFERENCE
- SKIN PIGMENTATION

SENSOR LOCATION

Each subject received two IVs randomly placed on either the forearm or dorsal aspect of the hand.

IV PLACEMENT METHOD

The IV catheter was placed immediately adjacent to a typical vein using ultrasound guidance. One of seven nurses performed the IV procedure. All subjects were infused with isotonic saline solution.

PLACEMENT SEQUENCE

Nurses performed the IV procedure. The IV catheter was placed immediately adjacent to the vein using ultrasound guidance.
**ISOTONIC SALINE SOLUTION**

All subjects were infused with 10mL of isotonic saline solution. Infiltration rates were randomly selected between 5mL/hr (KVO) and 150mL/hr.

**INfiltrATION TIMING**

The infiltration was started randomly between 5 and 30 minutes after starting monitoring by the ivWatch monitor.

**SENSOR NOTIFICATION**

The ivWatch monitor issued notifications if conditions consistent with an infiltration were detected. The infiltrated volume was recorded when the yellow and red notifications were issued.

**DEMOGRAPHIC RESULTS**

The infographic shows the distribution of gender, skin pigmentation, and body mass index among the participants.

- **Gender Type**
  - 42 Men
  - 28 Women

- **Skin Pigmentation**
  - 20 Dark
  - 10 Medium
  - 40 Light

- **Body Mass Index**
  - 23 Normal
  - 23 Overweight
  - 1 Underweight

The ivWatch monitor issued notifications if conditions consistent with an infiltration were detected. The infiltrated volume was recorded when the yellow and red notifications were issued.
**EFFECT OF INFILTRATION RATE**

Red notifications were issued prior to 10mL for all infiltration rates. The detected volume is slightly larger (~5mL) for faster rates compared to slower rates (1-2mL).

**NOTIFICATIONS ISSUED**

A red notification was issued for 96.4% of the infiltrations, corresponding to 135 of 140 infiltrations.

96.4% | 95% Confidence Interval: 91.4 to 98.7%

A yellow notification was issued for 99.3% of the infiltrations, corresponding to 139 of 140 infiltrations.

99.3% | 95% Confidence Interval: 95.5 to 99.96%
Early Stage Detection
/ Of Peripheral IV Infiltrations - CONCLUSION

STUDY CONCLUSIONS

1. The red and yellow notifications issued by the ivWatch device were highly sensitive to PIV infiltrations and would alert clinicians to the early stages of an infiltrated PIV site.
2. The yellow and red notifications can often detect infiltrations faster than a perfect clinician assessing the site hourly (p-value less than 0.05 for rates ≥ 25mL/hr).
3. The device worked well for a range of common infiltration rates, skin pigmentation, body types (as measured by the body mass index), and ages.
4. No adverse events were recorded. No skin irritation or disruption to skin integrity was observed from the 140 sites of the study.

REFERENCES


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