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CLINICAL EVALUATION OF THE VIOS MONITORING SYSTEM - INITIAL REPORT OF A PILOT STUDY

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INTRODUCTION: Continuous vital sign (VS) monitoring with stand alone bedside monitors is standard practice in ICUs and operating rooms; however, these systems are expensive and constrained to certain environments. The Vios System (VMS, Vios Medical, Inc. St. Paul, MN, USA) is the first FDA-cleared platform to utilize commercially available hardware for wireless patient monitoring in low, mid, or high acuity settings. The VMS system allows for flexible and low-cost monitoring through a wireless (Bluetooth) sensor placed on a patient's chest. VMS has capability for real-time analysis and display on a bedside or central station monitor, and synchronized for remote viewing from any global location. In this pilot study we evaluated the accuracy of VMS as compared to gold-standard bedside monitoring systems.

METHODS: After IRB approval and informed consent 1 physician and 8 nurses were trained on the VITALS1 protocol. 55 adult patients indicated for monitoring within the cardiac step-down unit following cardiac catheterization were enrolled into the study.

VS data was acquired simultaneously by the VMS (figure 1) and the existing bedside monitor. Specifically, ECG (lead I and II morphology/artifacting), HR, RR, SPO2, pulse rate, axillary temperature, and posture were captured by each system.

Each patient was monitored for a minimum of 10 minutes, during which 5 comparative data points were captured for each VS. For patient posture, the nurse recorded a visual assessment of the patient. The nurses and patients each completed a questionnaire about the VMS system after use. The data was analyzed using regression analysis and Bland-Altman plots with $p < 0.05$ considered significant

RESULTS: The patients had a mean age of 55 years (range 19-82), mean weight 65kg (range 48-90), and mean BMI 26.2 kg/m2 (range 20-67). None were unstable. The comparative data was highly correlated for ECG, HR, RR, pulse rate and SPO_2 with significant agreement between the traditional and VMS (Table). Patient posture was accurately reflected 100% of the time. The nurses and patients were favorably impressed and preferred the VMS to the existing system.

DISCUSSION & CONCLUSIONS: This pilot study confirmed the successful transmission, analysis, and accuracy of the VMS that was well-received. Several studies are being planned to evaluate its acceptance into standard clinical practice and its capability to extend vigilance into environments beyond the hospital allowing remote patient management services. Monitoring patient orientation and activity are additional value points of the VMS system. Benefits of this new clinical metric are: 1) ability to monitor neurological status, 2) potential to decrease pressure ulcers and DVT, and 3) be used as a readiness for discharge tool.

Table: Correlation and Bland-Altman plot results

Parameter	*Heart Rate	*Respiratory Rate	SPO₂ (%)	*Pulse Rate	Posture	ECG morphology & artifacting
†Relationship between the two systems (95% confidence)	$r^2 = 0.99$	$r^2 = 0.81$	$r^2 = 0.71$	$r^2 = 0.98$	100%	Equivalent (qualitative analysis)
†Bland-Altman agreement (95% confidence)	±1.1%	±4.2%	±2.8%	±1.4%	N/A	N/A

*beats or breaths per minute; † $p < 0.00$ for heart rate, respiratory rate, pulse oximetry and pulse rate (for pulse rate n=17)

Figure . The Vios Monitoring System

Vios Chest Sensor & Nonin Pulse Oximeter

Chest Sensor
• 2 lead ECG (I & II)
• Heart rate
• Respiratory rate
• Axillary temperature
• Accelerometer
• Patient distress

Nonin Pulse Oximeter
• Oxygen Saturation
• Pulse Rate

Bluetooth

Vios Bedside Monitor
• Portable, lightweight Bedside Monitor
• Displays real-time vital signs data acquired from sensors
• Adjustable alarm parameters including threshold limits if vital signs fall outside of high/low values
• Alarms for non-lethal arrhythmias