

LifeSync[®] Wireless ECG System with LeadWear[®] Disposable Cable Replacement System Reduces Artifact and Increases ECG Alarm Accuracy

Background

The need to improve alarm accuracy and enhance the ability of healthcare professionals to properly assess and interpret alarm systems is not new. Desensitization to clinical alarms and the possibility of true patient events not alarming are indisputable challenges in today's patient monitoring environment. The acuity level of hospitalized patients has increased over the past several years as has the burden placed on the healthcare professionals charged with caring for these patients. It is increasingly critical given this new environment that current alarm systems be enhanced wherever possible to provide more reliable information, thus leading to more responsible patient monitoring. This problem has not gone unnoticed: as part of their ongoing initiatives to continuously improve the safety and quality of patient care, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has established a series of National Patient Safety Goals. The requirement of Goal 6, first established for 2003 and reinstated through 2006, is to "Improve the effectiveness of clinical alarm systems".¹

Cardiac monitor algorithms are typically set for high sensitivity at the expense of specificity. As a result, numerous false alarms occur that must be evaluated to minimize the likelihood of over-treatment of patients.²

Currently, manufacturers of patient monitors have attempted to alleviate the problem of inaccurate or "nuisance" alarms by incorporating various algorithms and filters into their products. However, the situation remains today that a clinician may ignore an alarm due to a (mis)perception that it does not indicate a true medical emergency. Or, a more serious cardiac event such as a lethal arrhythmia may not trigger an alarm because some other problem with the monitoring equipment has occurred. "Problems such as a lead not directly adhering to the body or a dead battery usually are lower-grade alarms that do not transmit a continuous audible or visual alarm. If these conditions are not corrected promptly, however, then a patient could experience a serious arrhythmia or ischemic event that would go undetected."³

It is clear that other approaches are needed to increase the likelihood that (a) an alarm is accurate, i.e., it indicates a true patient event, and (b) serious events do not go undetected because they are masked by lower-level alarms or other equipment problems.

Clinical Study

Methods

A study of 47 patients was conducted at five different hospitals located in California, Florida, New York, and Massachusetts to assess the performance of the LifeSync[®] Wireless ECG System incorporating the LeadWear[®] Disposable Cable Replacement System (GMP Wireless Medicine, Inc., Fort Lauderdale, FL). Patients at all study sites were monitored using Philips patient monitors (Philips Medical Systems, Andover, MA).

ECG electrodes were connected to the LifeSync[®] System LeadWear[®], a single-patient-use disposable lead set composed of printed flexible circuits. ECG and respiration data was acquired using LeadWear[®] and transmitted to existing ECG monitors. Transmission was performed either wirelessly via patient and monitor transceivers (radios) utilizing Bluetooth[®] transmission technology or through standard cables.

Patients participating in the study were located in an ICU department or a telemetry unit. Each patient was first monitored up to 24 hours using traditional ECG monitoring and leadwire systems, then subsequently monitored up to 24 hours using the LifeSync[®] System.

Resulting trend data was analyzed for the occurrence of arrhythmia alarms.

Results

When monitored using traditional leadwire methods, alarm accuracy was found to be 46%:

- Of the total 1712 alarm events which occurred while study subjects were monitored using traditional leadwires, only 781 were attributable to true patient alarm conditions, while the remaining 931 were due to motion artifact or other causes of artifact such as poor skin preparation, poor connections, degradation of leadwires or other causes of electrical noise.

With the use of the LifeSync® System, alarm accuracy increased to 92%:

- Of the total 1300 alarm events that occurred during the total time the study subjects were connected using LeadWear®, 1194 were attributable to true alarms, while only 106 were due to motion artifact or other factors as described above.

Figure 1. Alarm Accuracy

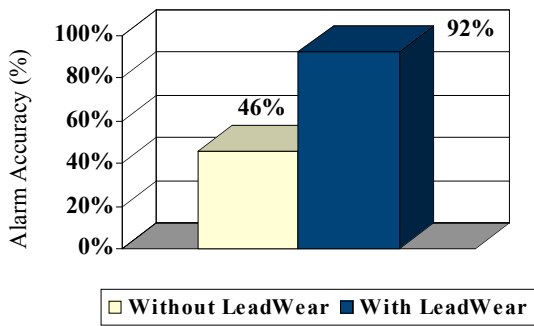
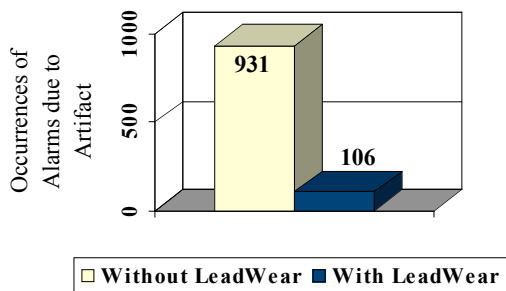


Figure 2. Artifact



Discussion

The results revealed a marked improvement in the percentage of accurate alarms and a significant decrease in the incidence of false alarms resulting from motion artifact or other causes of artifact such as poor skin preparation prior to electrode placement, poor connection between leadwires and electrodes, poor connection between leadwires and the monitor, degradation of leadwires due to normal usage, or other causes of electrical noise or interference.

This improvement in performance is largely attributed to several factors, including the composition of the materials used in the LeadWear® disposable leadwires vs. traditional multistranded leadwires as well as the inherent stability of LeadWear®. First, the strands of copper in traditional leadwires which rub against one another when the leadwire is flexed or in motion produces triboelectric noise. This noise can manifest itself as artifact. Conversely, printed flexible circuits used in LeadWear® transmit data through silver epoxy ink tracings that provide excellent conductivity and minimal artifact.

Secondly, since patients are not tethered to bedside monitors when the LifeSync® System is utilized wirelessly, there is not the usual pulling and tugging of cables that is common with traditional leadwires, thus removing another likely cause of artifact.

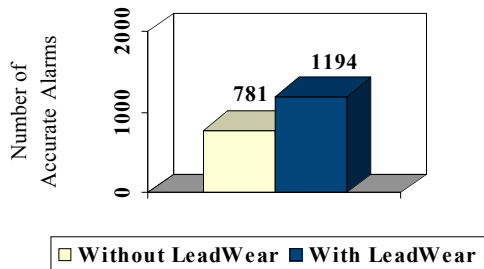
Additionally, the nature of reusable vs. disposable cables may also be a contributing factor to the improvement in alarm accuracy and the reduction in artifact. Typically, manufacturers provide only a 90-day warranty on their traditional reusable leadwires. In practice, they are often reused up to six months or more. During this use period, there is a slow but predictable performance degradation due to normal wear-and-tear and caustic cleaning agents. Because this reduction in transmission quality is gradual over time, clinicians may not notice the degradation and will continue to use the leadwires past their effective useful life. In contrast, with LeadWear® disposable leadwires, a new set of leadwires is used with each patient application, ensuring optimal cardiac monitoring every time.

Lastly, a closer examination of the study results exposes another critical difference between monitoring with traditional leadwires vs. monitoring with the LifeSync® System. The LifeSync® System provided a two-fold improvement in alarm accuracy. However, the high incidence of nuisance alarms that occur in traditional monitoring practices may be

obscuring true alarm conditions. These true alarms are then able to surface with the use of the LeadWear[®] system. In other words, once false alarms are minimized, the incidence of true alarms may increase.

Therefore, it is important to note that the *number* of accurate alarms seen in the study increased from 781 to 1194. This is an equally significant finding.

Figure 3. Number of Accurate Alarms



Conclusions

The findings from this study are noteworthy and have important implications for the improvement of alarm accuracy. However, additional studies with larger patient populations and a wider variety of patient monitoring equipment are needed.

Further studies notwithstanding, the potential for improvements in patient monitoring with the use of the LifeSync[®] System incorporating the LeadWear[®] Disposable Cable Replacement System is promising. Given the current environment of high staff turnover and high patient-to-nurse ratios, any such improvements can be expected to result in improved patient care and improved efficiencies within the hospital setting. Without the distraction of constantly turning off false alarms and, perhaps more importantly, with the added assurance that true patient alarm conditions will result in audible and visible alarms that are properly addressed, the prospects for improved patient safety and better utilization of scarce nursing resources are compelling.

Addendum

An additional investigation was conducted at one of the participating study sites which revealed that the stability of the LifeSync[®] System and especially the disposable LeadWear[®] portion of the system may have additional benefits beyond improved alarm accuracy. During a 24 hour period, data was collected from patients monitored in a traditional fashion where lead-off conditions were commonplace. A patient had either one lead off or two leads off over 60% of the time (15 hours) when tethered to bedside monitors using traditional leadwires. When the LifeSync[®] System LeadWear[®] was applied in place of leadwires for a subsequent 24 hour period, the patient had either one lead off or two leads off less than 1% of the time (9 minutes).

Figure 4. "Lead-Off" Time Without LeadWear

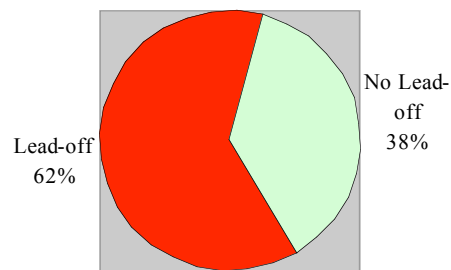
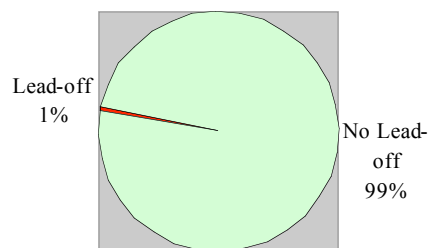


Figure 5. "Lead-Off" Time With LeadWear



More work will be done to collect data around this issue in light of the potential serious clinical implications associated with lead-off situations.

¹ Joint Commission on Accreditation of Healthcare Organizations, retrieved from www.jcaho.org.

² Drew BJ, Califf RM, Funk M, Kaufman MW, Laks MM, Macfarlane PW, Sommargren C, Swiryn S, Van Hare GF. Practice standards for electrocardiographic monitoring in hospital settings. *Circulation* 2004;110(17): 2721-46.

³ Ibid.