Difference in Alarm Events Between Disposable and Reusable Electrocardiography Lead Wires

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Background Disposable electrocardiographic lead wires (ECG-LWs) may not be as durable as reusable ones.

Objective To examine differences in alarm events between disposable and reusable ECG-LWs.

Method Two cardiac telemetry units were randomized to reusable ECG-LWs, and 2 units alternated between disposable and reusable ECG-LWs for 4 months. A remote monitoring team, blinded to ECG-LW type, assessed frequency and type of alarm events by using total counts and rates per 100 patient days. Event rates were compared by using generalized linear mixed-effect models for differences and noninferiority between wire types.

Results In 1611 patients and 9385.5 patient days of ECG monitoring, patient characteristics were similar between groups. Rates of alarms for no telemetry, leads fail, or leads off were lower in disposable ECG-LWs (adjusted relative risk [95% CI], 0.71 [0.53-0.96]; noninferiority \( P < .001 \); superiority \( P = .03 \)) and monitoring (artifact) alarms were significantly noninferior (adjusted relative risk [95% CI]: 0.88 [0.62-1.24], \( P = .02 \); superiority \( P = .44 \)). No between-group differences existed in false or true crisis alarms. Disposable ECG-LWs were noninferior to reusable ECG-LWs for all false-alarm events (N [rate per 100 patient days], disposable 2029 [79.1] vs reusable 6673 [97.9]; adjusted relative risk [95% CI]: 0.81 [0.63-1.06], \( P = .002 \); superiority \( P = .12 \)).

Conclusions Disposable ECG-LWs with patented push-button design had superior performance in reducing alarms created by no telemetry, leads fail, or leads off and significant noninferiority in all false-alarm rates compared with reusable ECG-LWs. Fewer ECG alarms may save nurses time, decrease alarm fatigue, and improve patient safety. (American Journal of Critical Care. 2015; 24:67-74)
Durability of electrocardiographic lead wires (ECG-LWs) may be an important factor in alarm fatigue. Cleaned, reusable ECG-LWs are used in multiple patients and are generally replaced when soiling is excessive, casings are fractured, and wires are exposed, or signals are improper or lead to excessive alarms and interruptions in ECG monitoring. When ECG alarms are identified as false alarms due to excessive signal noise (artifact) or monitoring failures, inappropriate responses of nurses and patients may follow. Nurses may interrupt patient care or other activities to assess the patient’s status, diagnose the problem, and make treatment decisions, all of which may be inappropriate, unimportant, or wasteful in terms of time spent and may increase the cost of health care.

Leads-off alarms could be presumed to be low priority when there may actually be high-priority events in progress. False crisis alarms due to double counting of high-amplitude ECG complexes or failure to count low-amplitude QRS complexes prompt nurses to shift priorities away from the true needs of their patients. Frequent noise associated with ECG alarms may lead to nurse desensitization of alarms, also known as alarm fatigue, that compromises patient safety, especially if alarms are disabled or ignored. Further, alarm noise may surprise patients, leading to anxiety, especially when nurses are delayed in responding or alarms prevent rest and sleep.

The rate of false alarms and lead failures may be excessive in relation to the total number of ECG alarms. In one non–critical care observational study, 9 nurses were observed during routine patient care to identify responses to ECG alarms. After 54 hours of alarm monitoring, 205 alarm events were recorded, and of those, 9 (4.4%) were for artifact and another 27 (13.2%) were for LW failures. In another report involving patients on a telemetry unit, the mean number of alarms per patient during a mean monitoring period of 16.5 hours per patient was 69.7. In 30 patients who had critical alarms adjudicated, the number of false (artifact) alarms exceeded the number of true alarms (209 vs 119), leading to a 34% true alarm rate after accounting for uncertain alarms. In 5 hospitals, when the relevance of alarm monitoring was assessed in adult intensive care units, nearly 24% of alarms were due to staff manipulation and another 17.5% were due to technical issues, leading to a low 58% alarm specificity. Finally, in a study of monitor alarms in a 15-bed medical progressive care unit, a shocking 16,953 alarms involving a mean census of 12 patients monitored per day occurred in an 18-day period. After an intervention was implemented to improve management of alarms, the overall number of alarms decreased; however, the proportion of technical leads-fail alarms increased, serving as a reminder that solving one ECG alarm problem may herald new issues.

Signaling durability that affects the service life of ECG-LWs is not well understood. No peer-reviewed publications have included reports about signaling durability in reusable ECG-LWs and how often the wires should be discarded in order to optimize sensitivity and specificity of true alarms and minimize excessive signal noise. Disposable ECG-LWs are single-use, but durability, based on appearance (e.g., width of LW, flexibility without crimping, and ease with which wires are exposed) and connectivity of ECG-LW tips (snaps) to sensing pad electrodes may vary by brand. It is unknown if reusable and disposable ECG-LW systems create the same numbers of false alarms that require nurse action. False-alarm issues can be grouped into the following categories: flat-line

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waveforms that might resemble a true crisis from a cardiac arrest requiring emergent care or may simply be a disconnection of an LW from a sensor (no telemetry, leads fail, or leads off), signaling issues that cause false monitoring or nuisance alarms, for example, excessive signal noise from patient movement interference (artifact) or ECG configurations that lead to double counting or undercounting of QRS waveforms (false crises). Further, it is unknown if true crisis alarms (defined as emergent tachydysrhythmias, bradydysrhythmias, pauses, or flat-line alarm events that are true events) are identified at the same rate in reusable and disposable ECG-LWs. If durability of disposable ECG-LWs is below expectations, the cost to replace them during a patient’s admission may be prohibitive. The purposes of this study were to determine if differences exist in the frequency of false ECG alarm events (no telemetry, leads fail, or leads off; artifact; and false crises) and true crisis events between reusable and disposable ECG-LWs in patients who were capable of free movement and were encouraged to ambulate during the hospital episode of care.

Methods

This cluster randomized (randomization by telemetry units, not patients), controlled, blinded trial was a prospective, comparative effectiveness research project with a crossover design. One brand of reusable ECG cable and LW system (standard care) and the Kendall DL disposable cable and LW system with patented push-button design (intervention care) were used. This study was approved by the hospital’s institutional review board before the start of the study and was carried out following the ethical standards set forth in the Helsinki Declaration of 1975.

Setting and Sample

The study was conducted between September and December 2011 at Cleveland Clinic, a quaternary care medical center in northeastern Ohio that had more than 1200 beds. Four 24-bed postoperative cardiac surgical step-down/telemetry units that accepted cardiac medical overflow were randomly assigned to usual care (2 units) or intervention (2 units) ECG-LW groups. Random assignment was completed by having 2 nurse managers select sealed envelopes with the ECG-LW assignments. Of adult patients treated on each unit, some had multiple telemetry stays during one episode of care, especially if they were transferred to an intensive care unit, and then returned to telemetry care; thus, each admission to a study unit was considered a study case, and data were assessed by patients’ length of stay on the unit. During the 4-month study period, the following schedule was followed: months 1 and 3, both groups received usual-care ECG monitoring; months 2 and 4, groups received reusable or disposable ECG-LWs, depending on assignments (see flow diagram, Figure 1).

Sample size was based on false- or nuisance-alarm sightings and remote monitoring team crisis calls per month at the unit (not patient) level. In 2009, the adult cardiovascular telemetry unit census was approximately 550 patient days per month and the rate of false alarms was between 0.35 and 0.75 alarms per patient day per unit. It was assumed that false-alarm rates would be the same within groups, and that the aim was to show that the false-alarm rate in the disposable ECG-LW group was not higher than the rate in the reusable ECG-LW group. Completing statistical tests of noninferiority of the new product (disposable ECG-LWs) compared with the existing product (reusable ECG-LWs) was important because it would provide evidence of statistical and clinical similarity of disposable ECG-LWs and

![Flow diagram of patient enrollment in study of electrocardiographic lead wires (ECG-LWs)](image-url)

Figure 1 Flow diagram of patient enrollment in study of electrocardiographic lead wires (ECG-LWs).

*a “case” reflects a patient’s admission to 1 of the 4 study units. Some patients were admitted to the same or another unit study unit allocated to the same type of ECG-LW more than 1 time per hospital admission; thus, there were more cases than patients in each study group.

*bSome patients were admitted to both groups during a hospital admission; reflecting an admission, transfer out, and readmission to cardiac surgical step-down/telemetry units allocated to different types of ECG-LWs; thus, such patients were listed as a case in both groups.
reusable ECG-LWs, the standard approved product in use. It was also assumed that the number of days in each group would be similar; knowing that the crossover design led to double the number of cases in the reusable ECG-LW group, compared with the disposable ECG-LW group. Based on a 1-sided noninferiority test and .05 significance level, power calculations were performed by using R software (version 2.8), and the method described by Lui yielded a sample size of 1172 patient days to show noninferiority within a 25% boundary for a false-alarm rate of 0.30 with 80% power.

**Intervention Implementation**

Units allocated to the intervention group received a supply of disposable ECG cables and LWs with 6 leads for use during the crossover months. Nursing staff were oriented to disposable ECG-LW cable-to-monitor connection, patient connection, and supply storage sites. When patients assigned to the intervention group were discharged from units, their disposable ECG-LWs were discarded. On the intervention units, during the disposable ECG-LW monitoring months, reusable ECG cables and LW were removed from the units. One research nurse and 1 research coordinator made daily rounds to each intervention group unit to assess application of disposable ECG-LWs and ensure an adequate supply. For the 2 units that crossed over between reusable and disposable ECG-LWs, on the first day of each month, all patients in the unit had their ECG-LW switched at 7 AM, during a 30-minute period. An alarm-silencing feature of the monitoring system prevented an alarm signal during the disconnection and reconnection procedure.

**Outcomes and Data Collection**

Data on alarms associated with true and false crisis ECG events per unit, per month were collected by personnel completing usual job responsibilities on a remote monitoring team. The remote monitoring facility is located off campus and personnel were blinded to ECG-LW group assignment. Remote monitoring team personnel routinely report the 5 following categories of alarms: (1) no telemetry, leads fail, or leads off; (2) monitoring alarms (artifact), (3) false crisis alarms (apparent crisis that was not a crisis when the patient was assessed), (4) all false alarms (no telemetry, leads fail, or leads off + monitoring alarms + false crisis), and (5) true crisis alarms. Members of the remote monitoring team communicate with nursing staff while or after an alarm sounds to ensure that they are recording the event correctly. The remote monitoring team calls nursing personnel for all perceived or actual crisis alarms even if the alarm shuts off automatically. For noncrisis alarms, remote monitoring team members use clinical judgment to determine if self-terminating alarms warrant communication with the nursing team and are included as reportable alarms. The ECG electrode sensors used in this study were the usual care product in place at the time of study enrollment and did not vary between groups. In both groups, nurses and other members of the health care team completed usual-care procedures to prepare individual patients’ skin for ECG monitoring. Patients’ characteristics were provided from an administrative billing database.

**Statistical Analysis Methods**

Categorical factors were described by using frequencies and percentages; continuous measures were shown as mean (SD). Characteristics of patients in different cohorts were compared by using mixed models for continuous measures and logistic regression with generalized estimating equations for binary measures. Generalized linear mixed models were used to test for differences in superiority and noninferiority between disposable and reusable ECG-LWs. Noninferiority of the disposable LWs compared with reusable LWs used a 1-sided test and a noninferiority region of 25%. Superiority of the disposable ECG-LW compared with reusable ECG-LW used a 2-sided test. All models were weighted by the patient’s length of stay in the unit; alarm rates were described by using total counts and rate per 100 patient days. In analyses, no adjustment for multiple comparisons was performed. Models were fit by using the GLIMMIX procedure within SAS software (version 9.2). A P value less than .05 was considered statistically significant for most comparisons, and a 1-sided significance level of .025 was used for noninferiority testing.

**Results**

A total of 1611 unique patients had 2330 admissions (each of which counted as 1 case) to the 4 study units. By type of admission, 534 patients had 596 medical admissions and 1175 patients had 1734 surgical admissions. In total, 9385.5 days of ECG monitoring occurred, with 2566 days of disposable ECG-LW monitoring and 6819.5 days of reusable ECG-LW monitoring. Patients’ characteristics did not differ between ECG-LW monitoring groups. Mean (95% CI) age of patients allocated to reusable ECG-LWs was 65.03 (64.4–65.6) years and in those
Table 2

<table>
<thead>
<tr>
<th>Alarm type</th>
<th>No. (rate per 100 patient days)</th>
<th>Adjusted relative risk (95% CI)</th>
<th>( p^{\alpha} )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No telemetry, leads fail, leads off</td>
<td>764 (29.8)</td>
<td>654 (29.1)</td>
<td>.31</td>
</tr>
<tr>
<td>Monitoring( ^{\beta} )</td>
<td>751 (29.3)</td>
<td>702 (29.2)</td>
<td>.31</td>
</tr>
<tr>
<td>False crisis</td>
<td>514 (20.0)</td>
<td>767 (29.1)</td>
<td>.31</td>
</tr>
<tr>
<td>All false( ^{\gamma} )</td>
<td>2029 (79.1)</td>
<td>6673 (79.1)</td>
<td>.31</td>
</tr>
<tr>
<td>True crisis</td>
<td>501 (19.5)</td>
<td>1334 (19.6)</td>
<td>.31</td>
</tr>
</tbody>
</table>

\( ^{\alpha} \) Includes 112 patients who were counted as cases in both groups.

\( ^{\beta} \) Monitoring alarms, caused by artifact.

\( ^{\gamma} \) All false alarms include no telemetry, leads fail, leads off, monitoring (artifact), and false crisis alarms.
types were in use), there were no differences between disposable and reusable ECG-LW groups.

**Discussion**

In this study of patients treated on cardiovascular step-down/telemetry units, less than 20% of all alarms were due to true crises, reflecting a high rate of false alarms. When considering the totality of false alarms encountered during the study, concerns about alarm fatigue seem very plausible. Our results were similar to results of Gross et al, who also reported that false alarms outnumbered true alarms; however, the ratio of true to false alarms was much higher in our study, compared with other reports. In other reports, the patients had medical-surgical conditions, but not necessarily cardiac histories and acute cardiac conditions. Patients receiving telemetry on cardiac medical-surgical telemetry units may be more likely to have wide, bizarre QRS complexes, low-amplitude QRS complexes, or abnormally high-amplitude non-QRS complexes and waveforms that lead to false crisis alarms. Regardless of the cause of the false alarms, the high frequency of false alarms raises concerns related to interruptions of nurses who are providing patient care and cost of care related to nursing time. Further, remote monitoring team personnel must respond to each alarm. In responding, excess noise is created from ringing phones and patient care is further interrupted so that the nurse can communicate with remote monitoring personnel. Finally, fewer false alarms could be important in terms of patient satisfaction and patient stress.

Disposable ECG-LWs were statistically and clinically noninferior to reusable ECG-LWs for all false alarms and monitoring alarms and were superior to reusable ECG-LWs for no-telemetry, leads-off, or leads-fail alarms. Further, the groups did not differ in sightings of true crisis alarms. In this study, the adjusted relative risk reduction in all false alarms in the disposable ECG-LW group compared with the reusable ECG-LW group reflected nearly 1 fewer false alarm per 5 alarms encountered. The noninferiority statistical analysis and use of confidence intervals show the relative risk levels for which the disposable ECG-LWs could be considered noninferior to the reusable ECG-LWs. Disposable ECG-LWs were noninferior, so clinicians should have confidence that they would not be exposed to excess false alarms, above and beyond the noninferiority bound stated. Further, the disposable ECG-LW superiority in no-telemetry, leads-off, or leads-fail alarms may reflect direct cost savings related to ECG paper use, as well as the benefits described earlier.

Although it was not the purpose of this study to evaluate alarm fatigue or cost of nursing care related to false alarms, in one report, nurses were the responders to 46.8% of all ECG alarms. Further, when an alarm sounded, it took between 3 and 5 minutes to communicate telemetry alarm events to caregivers. Nursing time is expensive, and fewer false alarms could decrease costs of nursing care. When nonnursing staff (eg, remote monitoring personnel) are first responders, 2 people are automatically involved in alarm adjudication, increasing time and costs. Further research is needed to determine if more costly, disposable ECG-LWs are cost neutral or save costs compared with reusable ECG-LWs when indirect expenses associated with ECG monitoring are considered.

Loss of ECG signal due to no telemetry, leads off, or lead failures was improved with disposable ECG-LWs. False asystole crises may be due to many issues that involve patient and ECG monitoring systems. For one company’s monitoring system, electromagnetic interference was the culprit in a false asystole alarm. Other patient issues could be agitation, pulling of ECG-LWs against the electrode with activity, and sweaty or hairy skin that decreases

**Table 3**

<table>
<thead>
<tr>
<th>Alarm type</th>
<th>No. (rate per 100 patient days)</th>
<th>Adjusted relative risk (95% CI)</th>
<th>pb</th>
<th>Noninferior</th>
<th>Superiority</th>
</tr>
</thead>
<tbody>
<tr>
<td>No telemetry, leads fail, leads off</td>
<td>764 (29.8) 1018 (42.6)</td>
<td>0.70 (0.49-0.99)</td>
<td>0.004</td>
<td>0.04</td>
<td></td>
</tr>
<tr>
<td>Monitoring*</td>
<td>751 (29.3) 792 (33.1)</td>
<td>0.88 (0.58-1.34)</td>
<td>0.04</td>
<td>0.47</td>
<td></td>
</tr>
<tr>
<td>False crisis</td>
<td>514 (20.0) 500 (20.9)</td>
<td>0.96 (0.40-2.28)</td>
<td>0.24</td>
<td></td>
<td>0.91</td>
</tr>
<tr>
<td>All falsed</td>
<td>2029 (79.1) 2310 (96.6)</td>
<td>0.82 (0.60-1.10)</td>
<td>0.008</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>True crisis</td>
<td>501 (19.5) 519 (21.7)</td>
<td>0.90 (0.47-1.74)</td>
<td>0.13</td>
<td></td>
<td>0.71</td>
</tr>
</tbody>
</table>

* Includes 112 patients who were counted as cases in both groups.
* Generalized linear mixed-effects models.
* Monitoring alarms, alarms caused by artifact.
* All false alarms include no telemetry, leads fail, leads off, monitoring (artifact), and false crisis alarms.
the sensor’s contact with the skin. In this study, the disposable ECG-LW selected had a push-button design that could have led to the superior performance in no telemetry, leads off, or lead failures over the reusable ECG-LW system. When company researchers compared 3 brands of disposable LW connectors to determine the mechanical coupling retention force measured in pounds, the disposable ECG-LW used in the trial had significantly greater retention forces than did disposable products from 2 other companies, reflecting a decrease in the likelihood that ECG-LWs would be disengaged from ECG electrodes. Thus, not all disposable ECG-LW systems are the same, and differences in the electrode connector, housing connections, or the wires themselves could lead to different results with respect to false-alarm events. Further research is needed to compare the durability of different disposable ECG-LW systems in a busy hospital cardiac step-down and telemetry unit.

Limitations
This study was conducted at a single center and involved adult patients with cardiovascular surgical and medical diagnoses who required telemetry monitoring. Results may not be generalizable to other hospitals if patients’ characteristics differ from those of patients in this study or in nursing units with predominantly noncardiac patient populations. Alarm level data were not analyzed at the patient level. Although it is known that some patients create more alarms than others, we were unable to determine the mean rate of alarms per patient. Data were obtained by remote monitoring personnel who recorded alarm event occurrence and type of events. Errors of omission (alarm not recorded) or errors in documentation (inaccurate event recording) could have occurred; however, personnel were experienced in their jobs.

It is unknown if all disposable ECG-LWs have the same performance with respect to the frequency of alarm events. In this trial, only 1 brand of disposable ECG-LW was used. Systems used to attach ECG-LWs to electrode sensors vary. In this study, the ECG-LW tips had a patented push-button design that may have been a factor in the superior effectiveness found in no-telemetry, leads-fail, and leads-off alarms for disposable ECG-LWs compared with reusable ECG-LWs. Results are not generalizable to all disposable ECG-LWs.

Conclusion
Disposable ECG cables and LWs with a patented push-button design had superior effectiveness, leading to fewer no-telemetry, leads-fail, and leads-off alarms compared with reusable ECG-LWs. Disposable LWs were significantly noninferior in ECG alarm percentages for all false alarms (no-telemetry, leads-fail, and leads-off alarms, monitoring alarms, and false crisis alarms) and were similar to reusable ECG-LWs for identifying true crisis alarms. Disposable ECG-LWs that decrease false alarms could decrease nurse interruptions and limit unnecessary clinical assessment and decision making, thereby reducing nurse fatigue associated with alarm events. A reduction in alarm events reduces alarm fatigue and increases awareness of important alarms that require nurse action.

Research is needed to learn if a reduction in ECG-LW assessments and adjustments significantly reduces nursing and adjunct personnel costs related to unnecessary paper recordings. Less ECG-LW artifact/noise and other unnecessary alarms may improve the patients’ experience by decreasing noxious noise and stress associated with perceived ECG abnormalities. Research is needed to learn if patients’ anxiety is reduced when ECG-related alarms are reduced.

FINANCIAL DISCLOSURES
Covidien LP provided disposable electrocardiographic lead wires used by the intervention groups and funded data collection and study analysis. Other research processes were internally funded.

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