Drowning in Data: Workflow Changes Improve the Collection of Clinically Relevant and Actionable Data

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Background

The implantable loop recorder (ILR) is valuable for recording and evaluating clinically relevant arrhythmias. Devices with wireless capabilities are programmed to automatically transmit data to a secure website for retrieval by cardiology staff. However, increased data review time, memory saturation, and overwriting of true arrhythmia episodes can result unless alerts are programmed to appropriately detect meaningful (or actionable) cardiac data. Patients are instructed to manually activate the ILR to initiate simultaneous recording of rhythms as part of routine, scheduled assessments or during symptomatic events. However, patients may feel overwhelmed or intimidated when attempting to generate their own cardiac data because of the large volume of new information and unfamiliar equipment instructions.

Objective

To determine if workflow changes and enhanced patient education improve the collection of more meaningful data from the ILR.

Methods

A retrospective chart review was conducted of rhythm data from patients with implantable Medtronic Reveal Linq cardiac monitors. Cardiac rhythm data were gathered three months before and after workflow changes to compare quality and quantity of remote transmissions.

Results

Significant improvements were noted following workflow changes and enhanced patient education. Scheduled transmissions increased, unscheduled transmissions decreased, and missed transmissions decreased per patient each month.

Conclusion

Workflow changes improved the quality of transmissions and decreased the quantity of transmissions. The capacity to provide high-quality care also improved, as evidenced by the ability to obtain more clinically relevant and actionable data.

Keywords: implantable loop recorder, transmissions, patient education, workflow changes, meaningful cardiac data

Introduction

The implantable loop recorder (ILR) is well-established tool for recording and diagnosing arrhythmias and cardiac rhythm disturbances.[1] The ILR is a slim, self-contained wireless device consisting of electrodes mounted on a recorder that is implanted in the subcutaneous tissue of the chest.[2] The device is programmed to automatically detect and record cardiac rhythm disturbances, such as atrial fibrillation. Patients can also manually activate the ILR to initiate simultaneous recordings of rhythms as part of a routine, scheduled check or during symptomatic events.[3] Common indications for the ILR include unexplained syncope, palpitations, symptomatic cardiac rhythm disturbances, and asymptomatic cardiac rhythm disturbances (such as ventricular tachycardia, atrial fibrillation, and cryptogenic stroke).[4]

Remote monitoring is an effective strategy for managing patients with arrhythmias and can safely reduce the number of visits a patient is required to make to a physician's office.[5] Devices with wireless capabilities are programmed to automatically transmit data to a secure website for retrieval by cardiology staff. Staff are then responsible for monitoring and sharing abnormal findings with the cardiologist so that a plan of action can be developed and communicated to the patient. However, effectively managing the large amounts of data generated by ILRs presents several challenges for staff. First, alerts must be programmed in a manner that appropriately detects meaningful (or actionable) cardiac rhythms.[6] Secondly, some devices may not fully detect certain heart rhythms and may unnecessarily trigger an alert for a pause in normal rhythm. This scenario, called ventricular undersensing, results in erroneous recordings of irrelevant electrocardiograms (ECGs), which fill up counters and decrease the amount of space available to record true pauses in rhythm.[7] A third challenge in ILR data management concerns the amount and quality of transmissions manually generated by patients. Remotely monitored patients are frequently instructed to send routine transmissions of cardiac data on specified days for review and evaluation by cardiology staff. Placing responsibility for data collection on the patient can result in frequent (and often unnecessary) transmissions, or no transmissions at all.[8]

Numerous factors can negatively affect the quality and quantity of cardiac transmissions sent by patients receiving remote monitoring. These factors include lack of understanding regarding how to use the monitor, inability to correctly complete the setup process for home monitoring, and inability to physically come into the office for supportive guidance and assistance.[9] Other barriers that hinder compliance relate to the newness of the procedure, unfamiliar equipment instructions, and large amounts of discharge information.[10] Unlike the hospital setting, patients seen in an ambulatory care setting (such as those receiving an ILR) have limited time to receive and process the large amounts of education and discharge instructions provided to them by the nurse.[11] Typical discharge instructions include care of the surgical site and dressing, postoperative pain management, activity level, and follow-up care.[12] Patients frequently find the amount of discharge instructions to be stressful and overwhelming, which may result in little or no recall of important postoperative information.[13] Additionally, patients may experience an amnesia effect from the anesthetic or narcotic, making it difficult to recall critically important monitoring and transmission instructions after the procedure.[14]

To fully gain the benefits of remote monitoring, organizational processes must be in place to proactively address situations that could negatively affect the quality and effectiveness of remote monitoring.[15] Devices should be programmed in a variety of ways to reduce the amount of memory required to record a set number of episodes. Timely reporting of issues with the device can be facilitated by conducting nightly wireless sweeps of the device to monitor for data that fall outside predetermined parameters. Programmed alerts for technical issues with the device can also reduce the delay to diagnosis.[16] This type of troubleshooting promotes the remote detection of issues that can be addressed without requiring a

scheduled office visit. Additionally, troubleshooting is effective as a quality control measure because it can result in early identification of clinical problems before the patient becomes symptomatic.[17]

A successful cardiac monitoring program needs competently trained staff capable of monitoring and filtering alerts for accurate reporting to the physician.[18] Staff must be technologically competent to understand and interpret the data and must possess the requisite clinical knowledge to accurately identify and assess health issues associated with any cardiac arrhythmias. Staff also need to have the time necessary to manage, and be responsive to, the large amounts of data generated by remote transmissions. Data that are found to be clinically significant require staff to contact patients to explain the monitoring results, any new orders received from the physician as a result of the data, and any changes in the treatment plan for ongoing monitoring.

Purpose of Study

Implantable loop recorders are known to be a valuable tool for evaluating clinically relevant arrhythmias. However numerous inappropriate detections can lead to increased data review time, memory saturation, and overwriting of true arrhythmia episodes. Additionally, the volume of new patient information and unfamiliar equipment instructions can overwhelm and intimidate patients who suddenly find themselves responsible for routine data generation. However, a comprehensive review of the literature showed a lack of empirical research describing the effects of patient education on the quality of cardiac transmissions. The purpose of this study was to determine whether patient education and workflow changes resulted in the collection of more meaningful data from the ILR.

Methods

Setting and Sample

This study was completed by a group of nurse researchers acting independently and in the absence of any sponsor or funding. Researchers applied for and received approval to conduct the study from the hospital's Institutional Review Board (IRB). A retrospective chart review was conducted using archived Paceart Optima (Medtronic) data and stored records within Epic Systems software from April 1, 2016, through November 30, 2016. Data were abstracted from the records of all eligible patients over 18 years of age with Medtronic Reveal Linq recorders implanted before April 1, 2016 ($n = 140$). Patients who discontinued monitoring for any reason (e.g., a move or transfer of care) during the study period or who later required a defibrillator or pacemaker were excluded from data collection procedures.

Generation of Data

The CareLink Network (Medtronic), a secure system capable of generating large amounts of data, was used to generate three types of reports: event, summary, and full reports. The event report provided a daily wireless audit, which was generated (1) when programmed data fell outside of the parameters programmed for the patient or (2) when a patient experienced symptoms and initiated an event report. A summary report was automatically generated to provide a snapshot view of all cardiac rhythm disturbances over a designated time period. Unlike the event and summary reports, the full reports required a manual download to view multiple episodes stored in the device. The number of transmissions per month, number of scheduled and unscheduled transmissions, missed transmissions, and actionable versus nonactionable transmissions were retrieved as reports from CareLink Network. The data from these reports were anonymously transcribed to an Excel spreadsheet.

Actionable transmissions were defined as those that resulted in an office visit, phone call, or medication change. Data collected from Medtronic Reveal Linq recorders were analyzed to measure the quantity and quality of transmissions during the three months before the implementation of the new workflow process through three months after implementation of the new workflow process.

Workflow Changes

Workflow changes were designed to improve the quality and quantity of ILR data in several ways. First, implant-specific clinics were created with targeted alerts on the website. This process involved programming the devices in a manner more specific to the patient's indication for the implant in order to decrease the occurrence of nonactionable alerts. Sub-clinics were also created on the CareLink site to assist with the generation of actionable alerts using specific parameters defined by the physician.

Another change in workflow processes involved automated scheduling of summary reports, which minimized the reliance on patient-generated manual transmissions. These reports were linked with ECG data and scheduled to occur automatically every 30 days. The data provided a consistent tool for measuring the number of episodes detected in a 30-day period and proved particularly beneficial for comparison of the atrial fibrillation burden over a consistent interval to assess for trends.

The final change involved extensive revisions to patient education materials to promote better understanding of the ILR and the importance of routine follow-up. An in-service training was provided to all staff involved with device follow-up. Revised patient education materials with more detailed information about remote monitoring were discussed and distributed. The in-service training included case study reviews of current patients to analyze causes of frequent transmissions. Examples of ECG data and the programming solutions that could be initiated to decrease false positives were provided. All information provided during the in-service training was reiterated in an email that summarized the new process and provided the new patient education materials as attachments.

The revised workflow for normal transmissions included a printed report for review by the physician. If the normal transmission was unnecessary, education was provided to the patient, along with a summary report to the physician. Abnormal transmissions that were not clinically significant (and fewer than three per month) were reported to the physician. Patients with three or more monthly transmissions that were not clinically significant were also reviewed with the physician and a new plan of care was developed. An in-office evaluation was arranged for these patients to facilitate possible device reprogramming and reinforcement of device-related education. All clinically significant transmissions were reviewed with the physician and the patient contacted regarding the new plan of care.

Patient Education

Patient education was completed during in-office evaluations, as well as telephonically, to reinforce information about the device and how to use home monitoring. Patient education was revised, and a written form was developed that fully explained the ILR and the monitoring processes used by the staff. In-office education included education regarding the purpose of the ILR, proper incision care, appropriate use of the symptom activator, and how and when to send a transmission. Educational materials reinforcing the instruction and listing contact phone numbers were also provided. Telephonic education was conducted on an as-needed basis for patients with any identified issues with transmissions. The education included reminders of how to appropriately use the symptom activator, how and when to send transmissions, and the overall purpose of the ILR.

Results

Implantable loop recorder data were analyzed to determine the impact of workflow changes on the remote transmissions for an average of 140 patients. The numbers of transmissions, scheduled transmissions, missed transmissions, and actionable versus nonactionable transmissions were compared before and after workflow changes to improve quality and quantity of cardiac rhythm data (Table 1).

Related-samples *t*-testing was conducted to compare mean differences for each type of transmission before and after the enhanced patient education and workflow changes (see Table 1). The mean difference was calculated between the pre- and post-intervention scores for each variable. *P*-values less than 0.05 were considered statistically significant. Statistical analysis showed that the average number of transmissions per month decreased, but this finding did not represent a significant change. Statistically significant improvement was noted in the average number of monthly scheduled transmissions increased 0.2), unscheduled transmissions (decreased 0.6), and missed transmissions (decreased 0.2) per patient. Both actionable and nonactionable transmissions decreased, but not significantly (Table 2).

Discussion

Missed transmissions significantly decreased and scheduled transmissions significantly increased after the study interventions were implemented. These findings suggest that a more rapid time to diagnosis and treatment was achieved, which offers the potential for improved survival. While not statistically significant, the decrease in the overall number of transmissions was considered another benefit associated with improved workflow. The reduction in the transmission rate was accomplished by (1) limiting patient alerts to only those rhythm disturbances that pertained to the reason for the implant, (2) bringing patients into the office for reprogramming of the device when false positives were noted, (3) improving education during the one-week incision check by giving written information about the ILR, and (4) re-educating patients on the reason for monitoring and the proper use of equipment when a significant number of transmissions were being sent. The impact of fewer unscheduled transmissions along with improvement in the number of scheduled transmissions positively affected the workflow of this clinic by facilitating better time management for staff. The ready availability of scheduled transmission data improved the efficiency of the workflow for staff, who also spent less time following up with patients who had not sent transmissions as scheduled.

Limitations

Data analysis was limited to only those patients who had a device implanted on or before April 1, 2016, and who were followed by our institution. The small sample size was not sufficient to analyze the impact of workflow by demographic data (age, gender, socioeconomic status). Finally, this study was limited to patients who were cared for at one site, making it difficult to generalize to other centers or populations.

Implications for Future Research

Further research is recommended to examine the impact of workflow changes with other patient populations and demographics. Future research should also include an examination of the influence of efficient workflows and improved collection of actionable data on morbidity and mortality rates among patients receiving remote cardiac monitoring.

Conclusion

Changes made to the workflow for the management of data from ILRs improved patient care, as evidenced by the ability to obtain more clinically relevant and actionable data. Initially, these changes required a large investment of staff time to categorize patients into specific sub-clinics on the website, educate staff and patients, reprogram devices for implant indications and nonactionable data, and revise educational materials. However, time management improved because overall transmissions, unscheduled transmissions, and missed transmissions all decreased.

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Figure 1

Illustration of Revised Workflow Process Once Remote Transmission Has Been Received

| NORMAL TRANSMISSION | ABNORMAL TRANSMISSION: NOT CLINICALLY SIGNIFICANT | ABNORMAL TRANSMISSION: CLINICALLY SIGNIFICANT |

Normal:
*Routine Report Goes to MD

Normal but Unnecessary:
*Patient Education

<3 Per Month:
*Summary Report Goes to MD

> 3 Per Month:
*Review with MD
*Patient Education
*Possible Office Evaluation
*Possible Device Re-programming

*Report goes to MD

*Review with MD
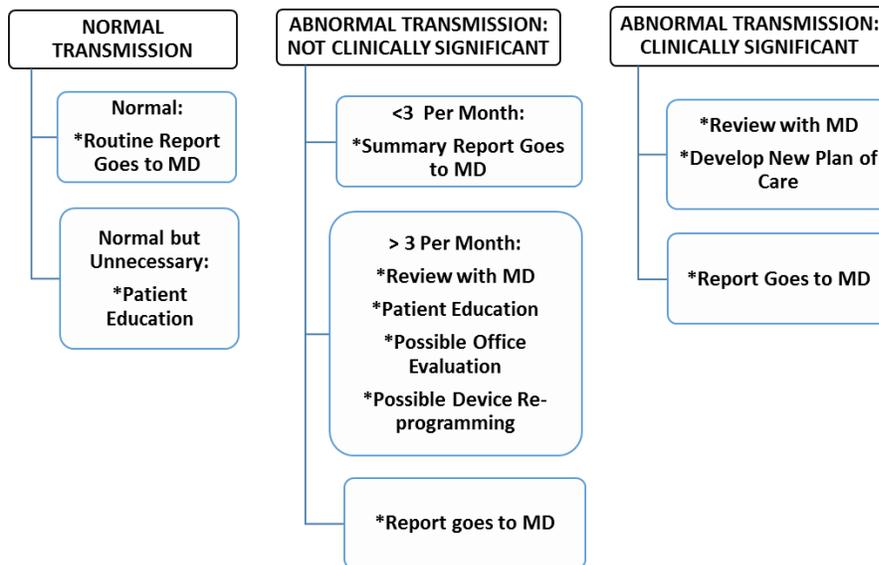*Develop New Plan of Care

*Report Goes to MD

Table 1

Transmissions Before and After Intervention

Average Number of Transmissions per Patient per Month		N	Mean	Std. Deviation	Std. Error Mean
Transmissions	Before	141	1.9	2.59	0.22
	After	141	1.4	1.59	0.13
Scheduled transmissions	Before	141	0.6	0.42	0.04
	After	141	0.8	0.35	0.03
Unscheduled transmissions	Before	140	1.3	2.40	0.20
	After	140	0.7	1.50	0.13
Missed transmissions	Before	140	0.4	0.42	0.04
	After	140	0.2	0.36	0.03
Actionable transmissions	Before	138	0.13	0.37	0.03
	After	138	0.07	0.21	0.02
Nonactionable transmissions	Before	141	1.7	2.40	0.20
	After	141	1.4	1.53	0.13

Table 2

Transmission Type

Average Number of Transmissions Per Patient Per Month	Conclusion	Significance
Transmissions	Number of overall transmissions decreased 0.4	Not statistically significant ($p = .077$)
Scheduled transmissions	Scheduled transmissions increased 0.2	**Statistically significant** ($p < .001$)
Unscheduled transmissions	Unscheduled transmissions decreased 0.6	**Statistically significant** ($p < .01$)
Missed transmissions	Missed transmissions decreased 0.2	**Statistically significant** ($p < .001$)
Actionable transmissions	Actionable transmissions decreased 0.1	Not statistically significant ($p = .081$)
Nonactionable transmissions	Nonactionable transmissions decreased 0.4	Not statistically significant ($p = .114$)