INNOVATIVE & EMERGING TECHNIQUES

REMOTE MONITORING

Novel Cardiac Device Management System Using Remote Online and Real-time Interrogation with Guided Reprogramming at the Cardiologist's Office

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ABSTRACT. *The study tests the feasibility, safety and acceptance of a new online interrogation and a real-time remote management system with guided reprogramming of cardiac devices in the cardiologists' office. Usually cardiac implantable electronic device (CIED) evaluation in non-specialists' offices involves company representatives managing the programmer and adding to the report printout a note with personal input. This is a non-company representative-dependent model of "cardiac devices clinics". Patients presenting at the cardiologists' office for routine CIED (Medtronic) check underwent online remote interrogation. In designated patients real-time remote management was additionally used. The CIED data were uploaded to a dedicated server account that was reviewed by the principal investigator (PI) who is an electrophysiologist. The standard device report (PDF file) was then edited, adding pertinent relevant clinical interpretation, the document was sent back to the cardiologist for final review and filing. The real-time remote viewer allows visualization of the programmer screen and pointer manipulation via the Internet. An onsite operator communicating by phone with the PI followed the pointer activating the programmer, reprogramming the device when needed. Remote online interrogation was performed in 100 patients (91 pacers/9 ICD) at four cardiologists' offices; in 30 patients real-time remote management was also used with guided reprogramming in 11 patients (36%). Two patients had incomplete transmissions requesting a standard check, not allowing a transmission reattempt. Online transmission time: 10.6 ± 3.4 min and the total patient room turn around: 17 ± 7 min. Real-time remote view session time: 7 ± 2 min. The vast majority of patients: 93 (93%) were satisfied with the service and if available without schedule restrictions: 77 patients (77%) would use the system; 23 patients (23%) patients were undecided. There were no complications. CIED management at the cardiologists' office using online and real-time remote interrogation with guided reprogramming and added expert clinical report information is feasible, safe and accepted. A new service model may be conceived using this technology with further reach and more effectiveness using less manpower.*

KEYWORDS. *cardiac pacing, implantable defibrillation therapy, remote monitoring.*

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Introduction

Usually cardiac implantable electronic devices (CIED) evaluation in non-specialist offices involves company representatives managing the programmer and adding a note to the report printout with personal input about the findings. This model has evolved in many instances, stretching the boundaries of the role of representatives, when general cardiologists find hard to keep up and stay current with the nuances and technicalities of the ever-evolving field of cardiac devices (**Figure 1**).

We tested the feasibility, safety, and acceptance of a new “non-company representative-dependent” model of the “CIED clinic” in the cardiologist’s office using an online remote and a real-time interrogation and guided reprogramming system by a professional expert along with the generation of a customized report. We present a different service alternative, which can be used at any time during office hours and still allows clinical decision-making by the cardiologist with a remote device check and generation of an interpreted report.

Background

The online cardiac device remote check system in the hospital (CareLink Express™ (CLE), Medtronic, St. Paul, MN) has been established for use predominantly in the emergency room but has also been extended to other hospital general areas of care. This is a proprietary system that allows the remote interrogation of a particular company’s CIED. Once the device is interrogated with a dedicated terminal unit, the uploaded information is

transmitted to a central company server. At this point, there is the option of receiving a plain printout of the device interrogation via fax or PDF format; alternatively, a report with a technician-limited analysis can be received along with the conventional device report.

The technical report highlights and summarizes some of the device interrogation findings but with no commitment to clinical definitions, i.e. an atrial electrogram with high-frequency inscriptions and variable amplitude and cycle length would be called AHR (atrial high rate rhythm) and not atrial fibrillation. Different institutions may adopt one or the other reporting modality according to their individual needs. The turnaround time for this check is about 15 min, with about 5–10 min dedicated to set up and upload time.

A less common alternative for CIED evaluation is the use of a real-time remote system (Remote View™ (RV), Medtronic, St. Paul, MN,) with direct visualization of the patient’s side programmer. This, also a proprietary system, is different from CLE allowing for real-time interrogation of devices via a secure Internet connection. Although this system has not been extensively used, we have successfully designed and clinically tested a non-proprietary version in the emergency room. During this initial experience the devices were interrogated remotely with the assistance of a bedside operator; guided testing and reprogramming was also utilized when deemed necessary.^{1–3}

Implementing the online cardiac devices remote check system (RV) requires downloading special software that is different from the conventional device programmer (Medtronic 2090, Medtronic, St. Paul, MN), which has a connectivity card for Internet access. Once the programmer

CARDIAC DEVICE MANAGEMENT in the CARDIOLOGIST’s OFFICE CONVENTIONAL WORK FLOW

Based on sample of 50 patients of the same study offices.

Figure 1: Usually cardiac implantable electronic device (CIED) evaluation in non-specialist offices involves a company representatives managing the programmer and adding a note to the report with personal input, to be reviewed and signed off by the office physician.

is online, the software allows it to become visible for remote connectivity via a secure Internet server system (Bomgar). A random “key” number generated by the programmer is assigned to each connection. The remote computer operator using the “key” number connects to the programmer. The computer then displays a mirror image of the programmer screen. The position of the programmer pointer can be controlled remotely with the computer mouse but not its functionality. In order to activate the pointer function, the patient’s side operator has to “tap” the screen at its position, which is visualized by the remote operator for supervision and approval.

The practical operation of this system requires telephone communication between the remote and patient’s side operators for effective use. Of note, the bedside operator has a basic instruction in the programmer function only to allow its use with remote guidance but never independently. The bedside operator is in essence a mechanical extension of the remote operator (Figure 2).

Methods

This was a non-blinded, non-randomized study carried out in four independent cardiologist offices that had been selected for participation. The principal investigator (PI), who is an electrophysiologist, worked from a remote management office site. It was predetermined to enroll 100 patients, to perform 100 CIED interrogations via the online remote check system (CLE), 30 of which would additionally have a real-time cardiac device remote check (RV).

The inclusion criterion was all patients with Medtronic devices presenting for a check who were willing to participate. The exclusion criterion was patients with no Medtronic devices.

The study was approved by the Western Institutional Review Board and performed under guidelines for human subjects. As part of their practice, these offices have a regular scheduled dedicated “device clinic” day for different companies. The standard operation is for a group of patients having a particular company device to be checked by that company’s representative. Once the representative has checked the device a report is submitted to the cardiologist for review and approval. A baseline timing measurement of this model was obtained from 50 consecutive patients for reference purposes, and not for direct comparison of the systems (Figure 1).

The patients presenting at the cardiologist’s office for a routine Medtronic CIED check were offered the alternative of participating in the study in a consecutive unselected fashion. After written informed consent was obtained, all patients underwent an online cardiac device remote check (CLE). A nurse and a cardiovascular technician independent of the cardiology office were used as dedicated personnel for the study, to assist the patients in obtaining consent and help perform CIED testing. The patients were encouraged to apply the wand and press the CLE monitor button themselves.

In 30 patients, at the discretion of the PI, real-time cardiac device remote view interrogation and guided reprogramming (RV) was additionally used.

Figure 2: The real-time remote viewer system allows visualization of the programmer screen (on a laptop, right), with control of the screen pointer movement (without its functionality). The wireless set-up has an office programmer (left) connected to a modem that communicates via Bluetooth and a cellular “HOT spot” to the Internet. The programmer screen can then be accessed remotely by using a dedicated secure service Internet connection carrier. The onsite and remote operators communicate over the phone to coordinate the operation.

Hardware, software, connectivity, and work flow

The office hardware consisted of a dedicated Medtronic programmer 2090 with Remote View™ software and data card. Additionally, a wireless programmer set-up was established by connecting the data card to a modem that was programmed to connect with a specific cellular hotspot device (**Figure 2**). In a few situations where the cellular signal was suboptimal, the programmer was directly connected to the office data line.

The PI in the remote location had a computer with a connectivity software program that allowed access to the programmer via a secure Internet service (Bomgar).

The CLE monitor was connected to a dedicated cellular modem (WireX). The CLE monitor transmitted information that was collected on a CLE network company server, and upon completion of the transmission an automatic notice was generated and emailed to the PI's study account. Once the notice was received the PI opened the report, and, after review, a summary of the findings with relevant clinical interpretation was added to the original report. The edited (PDF) document was emailed back to the office nurse and printed for final review and filing by the cardiologist. The onsite operators were provided with a cellular tablet (Microsoft Surface Pro) and a wireless printer to perform this task (**Figures 3–5**).

The real-time remote interrogation (RV) was decided by the PI on the basis of the reports' findings and observing an adequate sample distribution along the study. As detailed above, RV software allows visualization of the programmer screen and pointer manipulation using a computer from a remote location via the Internet.

Once a suitable subject was found, the PI called the onsite operator to activate the real-time remote operation. A security code was generated by the programmer, and once the PI matched the code through his secured Internet connection, access was granted. The onsite operator maintained communication by phone with the PI for the duration of the session, and followed the pointer position (governed by the PI) activating the functionality of the programmer and eventual reprogramming as directed. This was all carried out under direct PI real-time visualization of the pointer tracking and the programmer screen. (**Figure 2**).

Results

A total of four independent cardiologists' offices (with a combined 13 cardiologists) were used to achieve a target of 100 (91 pacers/9 ICD) consecutive online (CLE) cardiac device remote checks. In 30 of those patients, real-time remote interrogation (RV) was also performed. The device check systematically evaluated underlying rhythm, thresholds when necessary, and events data.

Permanent guided reprogramming was performed in 11 patients (36%), including pacing modes, adjustments of AV delays and outputs, and changes in VT monitor zone. The average online remote (CareLink Express™) transmission time was 10.6 ± 3.4 min and the total patient room turnaround was 17 ± 7 min. The average real-time remote session (Remote View™) time was 7 ± 2 min (**Figure 6**).

There were no complications during the study. No transmission issues were experienced with the real-time remote interrogation (RV) sessions. Two patients failed to complete the baseline online remote device check (CLE)

Figure 3: Cardiologist office set-up and hardware involved in the online device interrogation. The device data is downloaded to the Device check Unit (CLE), which then transmits it via a cellular modem to a company server. Once analyzed and informed by the PI, the final report with comments was emailed back to the cardiologists' office, to be printed, reviewed and filed.

Figure 4: Example of initial pacemaker interrogation obtained using online remote interrogation (CLE). This was a “normal” device for standard parameters (green). However, there are areas, clearly depicted in red, that would benefit from optimization for which a real-time remote session was performed.

transmission, requesting to proceed with a regular check, by not allowing a download reattempt.

As a point of reference, a regular device check taken by a company representative in a sample of 50 patients at the same study offices was obtained. The interrogation and report generation time was 5 ± 2 min, and the total in-room time was 12 ± 3 min.

Patients were asked to complete a survey questionnaire once the check was completed. Physicians completed a survey when the study terminated.

Overall 93 (93%) patients were satisfied, 7 (7%) neutral, 0 not satisfied. If available on any office day, with no schedule restrictions, 77 patients (77%) would adopt the system and 23 patients (23%) were non-committal. Their main reservation was the limited human interaction with this model.

Of note, only nine patients (9%) used home remote follow-up services for their device (CareLink® Network). The cardiologist post-study satisfaction survey (12/13 responders) showed that 10 (93%) were Overall Satisfied, 2 (7%) Neutral, and 0 not satisfied. In answer to the question “If available any day would you adopt the

system?”, 12 (100%) replied Yes. The main reservation of three cardiologists was the limited human interaction, but they would still adopt the system (Figure 8).

Discussion

Although opinions may differ regarding the role of a company’s representative with different levels of expertise “checking” devices in the offices of cardiologists (and other points of care, i.e. primary care physicians’ offices), this frequent occurrence cannot be disputed.

As stated above, in our experience a regular device check (including interrogation and report generation with additional input) by a company representative takes on average 5 min, with the patient’s average total room time ~12 min. The standard model is based on servicing sequential patients, one after the other, “in serial” operation. It is significantly demanding on specialized onsite manpower and dependent on the availability at the point of care of a company’s representative, which needs to be scheduled ahead of time. The presented novel system, although somewhat slower (~10 min more) for a single check or “in serial” operation,

Initial Interrogation Report

Pacemaker Model: Medtronic: Adapta L AODRL1 Serial Number: MW225547 Date of Interrogation: 5/22/14 1:44 PM

Selectable Diagnostics	
Chronic Lead Trend	On
High Rate Detail	
Include Refractory Senses?	Include
High Rate Type	AVR and VHR
ECM Type	ASCM
ECM Allocation	8 for 2/2 sec
ECM Timeout	24 weeks

CARELINK EXPRESS STUDY
 Battery: OK DDD 60-130
 Estimated longevity: 5.5 years
 Presenting rhythm: AP/VP: ~99.30%
 Lead status OK: adequate impedance, sensing and pacing.
 Device with adequate function under programmed parameters.
 Heart rate histogram shows a flat heart rate, may benefit for rate response
 Events of Note: Isolated limited NSVT, lat episode 7/6/14.

Remote View
 Underlying rhythm complete AVB.
 Rate response was turned ON.
 AV delays adjusted to physiologic parameters 350ms--180-170.
 Recommended F/U 2-3 months to evaluate NSVT burden.
 Clinical correlation required regarding EF condition and risk of SCD.

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Figure 5: Study clinical report example (red square). After performing an initial pacemaker interrogation by *online* remote interrogation (Figure 4), although it was a “normal” device check for standard parameters a real-time remote session (RV) was performed with guided reprogramming, as described in the provided edited device report.

has significant efficiencies when considering the operation “in parallel” (more than one patient at a time). The system can absorb almost simultaneous information from many patients from different points of care, or within a single locale using multiple CLE monitors. In addition, the check can be done at any given time during office

hours, independently of the availability of a company representative.

Thus, given that the study model of online remote device interrogation and real-time remote device checking (CLE/RV) is to be operated with a different service approach, the patients can be distributed during the week at their convenience and add-ons could be handled at a moment’s notice (Figure 7).

The study was not meant to be a head-to-head comparison of the performance of the new service model with the standard one. A true comparison would require consideration of the time of performing an individual device check, and all-around analysis including scheduling limitations, serial checks versus parallel ones, not only including a particular point of care (one particular office) but across the continuum of CEIDs in office clinical management (any office wanting to have a device check at any given time).

The real-time remote device check system (RV) adds a new layer to remote device testing particularly as in the case of this study when the remote operator is an expert on the field, resulting in a more comprehensive testing with device function optimization performed when needed. This was an advantage not only for the patients but also the onsite cardiologists.

The added clinical input and perspective in device evaluation by “a clinical expert” (PI or electrophysiologist) was welcomed by the cardiologists, adding value to the reports. The fact that the reports were generated by an appropriate qualified reader not only made it more complete but actually took the stress out of the system, which often finds company representatives expected to perform tasks or form opinions beyond the scope of their practice.

REMOTE CARDIAC DEVICE MANAGEMENT STUDY WORK FLOW

Figure 6: Depicts the study work flow and time intervals in its two modalities. Remote *online* interrogation (CareLink Express™, CLE) and *real-time* remote interrogation and assisted reprogramming (Remote View™, RV).

Figure 7: Diagram of a typical example situation at the cardiologist's office. Scheduling under the conventional system for 15 consecutive patients (every 2 weeks) versus the option of the study model where the 15 patients are seen distributed over the 2-week period with room for other patients to be checked as needed without delay.

PATIENT POST VISIT QUESTIONNAIRE

Do you have "CareLink" at home? ☐ Yes: 9 ☐ No: 91

Are you satisfied in how the device check was performed?

☐ 80: Very satisfied

☐ 13: Somewhat satisfied

☐ 7: Neutral

☐ 0: Dissatisfied

Comments i.e. "Is incredible that someone can check my device from space..."; "I miss human interaction..."

If this system were to be available any day of the week with flexible hours, would you prefer it to the usual way?

☐ 77: Yes

☐ 23: Don't mind one way or the other

☐ 0: No

Comments: i.e. "Definitely an advantage..."; "I do like to see my doctor..."

Figure 8

In the future, complete real-time remote control may become available but will require a more effective service model. Of note is that the wireless connectivity piece of the programmer to the Internet, using a modem and cellular technology, worked remarkably well, avoiding the need of a land-line connection to the Internet. This was conceived and designed by the PI and exclusively used in this study. Although most cardiologists had the home remote service available in their office (CareLink), only 9% of the patients in the study were actually enrolled in the home remote system, showing that the system is clearly underutilized. This finding is due to multiple factors and with different opportunities for improvement. The costs and reimbursement aspects of the proposed new service model although important exceed the scope

of the study. Given the many unappraised variables to be considered, a separate specific analysis is required.

Conclusion

The management of CIEDs at the cardiologist's office using remote online interrogation and a real-time evaluation and management system with assisted reprogramming is feasible, safe, and well accepted by patients and cardiologists. The extra clinical information added to the report was welcomed by cardiologists, expanding their understanding and scope of the device check. A new service model may be conceived using these tools and principles in order to facilitate cardiac devices checks in any point of care at any given time without the need of

an onsite company representative. This service model provides further reach, more flexibility, and effectiveness using less manpower.

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