Remote operation for non-fluoroscopic navigation of complex tachycardias

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Abstract

Purpose Remote system operation technology was developed and applied to a non-fluoroscopic navigation system in order to overcome Spanish mobility restrictions caused by Covid-19 pandemic infection and subsequently used routinely.

Methods and results Fifty consecutive complex ablations were performed in different days using this technology. All these procedures were assisted remotely with the only intervention of a field clinical specialist located at his home who took full control of the navigation system (keyboard, mouse, and screen) and had bidirectional real-time audio/video feedback with the operating physician. Once the connection was established, the remote field clinical specialist replicated the Rhythmia screen at the remote location with all its features, and interacted identically with the physician, essentially with no perceptible differences from being physically present. There were neither interruptions nor perceptible delays in the bidirectional communications between the remote field clinical specialist and the operating physician during the procedures. Video signal delay ranged from 265 to 325 ms. All the procedures were uneventful.

Conclusions Remote system operation allowed full teleoperation of a non-fluoroscopic navigation system (keyboard, mouse, and screen) as well as bidirectional real-time audio/video feedback with the operating physician, providing a fully autonomous remote assistance in 50 complex ablation procedures. This technology ensures workflow continuity and optimal workforce flexibility and has relevant and promising implications in the field of training, teaching, and resource optimization that deserves further development.

Keywords Non-fluoroscopic navigation · Remote system operation · Rhythmia · Covid-19 · Telemedicine

1 Introduction

As the complexity of the mapping systems continue to increase, electrophysiological procedures often require additional collaboration of non-medical staff such as field clinical

specialists (FCS) to provide on-site support [1–3]. Remote operation of the navigation system could avoid unnecessary exposure of this staff to a high-risk hospital environment.

Remote system operation (RSO) is a required functionality for some mission-critical scenarios that must be commanded remotely under certain circumstances, like air traffic control, production plants, telecommunication network management or telemedicine [4]. There are different ways to provide RSO capabilities. Some are exclusively based on software, while others, more complex, require dedicated hardware.

This paper describes the design and clinical results of a hardware-based solution that allowed a fully remote control of a cardiac navigation system without modifying any of its components in a series of 50 consecutive patients. The system was originally intended to overcome travel restrictions in Spain during the Covid-19 crisis and subsequently used routinely. To the best of our knowledge, this is the first experience on RSO applied to a non-fluoroscopic navigation system.

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2 Methods

The hardware used for the application was a KVM (keyboard, video, mouse) switch (Raritan Inc., NJ, USA), connected to a Rhythmia mapping system (Boston Scientific, MN, USA) and to a network with Internet access.

This KVM device stands between the local computer (the one to be remotely commanded) and the network. It recreates the screen and replicates the keyboard and mouse interactions performed remotely by the operator into inputs to the local machine in the EP lab. KVM also sends back the screen video signal to the remote operator in order to control and provide real-time remote interaction with the screen.

2.1 Network architecture

The local area network (LAN), namely, the components working within the limits of hospital's network, were the KVM, an IP router, and the Rhythmia navigation system (Fig. 1). The key part of the worldwide area network (WAN), that is to say, the element necessary to allow a remote access to the LAN part in a secure manner, was an IP router. This router granted access to the KVM if the credentials of the remote user were valid. It was also designed to provide a redundant standard 4G mobile communication network (Fig. 1).

2.2 Redundancy

In order to provide an alternative method to keep commanding Rhythmia in case of failure of the hospital's network, a second network not depending on the same physical infrastructure was planned. Thus, a standard 4G Long-Term Evolution (LTE) network (Movistar, Telefonica S.A, Spain) that provided enough bandwidth to allow continuous operation was configured as a backup.

As an additional precautionary measure, and according to the manufacturer's advice, a Boston Scientific FCS was physically present during this first pilot procedures at the hospital in order to check the system and to retake the control of the system if needed. Finally, as a last resort measure, the hospital team had basic operational skills in case of failure.

2.3 Security

Independently of the network used (main network or redundant 4G LTE), several cybersecurity precautionary measures were defined to guarantee that only an authorized user could remotely command Rhythmia. A layered approach to this crucial point was used. The first step consisted in defining a virtual private network (VPN) between the IP router and the remote user. We opted for a hardware base solution that uses AES 256-bit encryption (same standard used for mission critical applications or banking purposes). This VPN allowed an

Fig. 1 Local and wide area network architecture

encrypted communication between the hospital and the remote user. In this case, in order to break it and get into the channel, a huge computational power would have been required, i.e., one supercomputer checking a billion of billions of keys per second—until now non-existent—and would take 3.7×10^{51} years to cover all possible combinations.

There was a second layer that consisted in a credential check at KVM level. This could be defined as a user/password combination that changes over time or a Lightweight Directory Access Protocol (LDAP) server to manage credentials for remote users. There were different additional policies that could be set as IP address whitelisting, remote MAC address filtering, maximum number of attempts setting, etc.

Finally, a human interaction was also needed at the hospital level, where a physician or nurse was required to allow a specific connection with the remote user. A 2-step verification process was followed so the local user could verify the identity of the remote user (after VPN and KVM layers granted the access).

2.4 Privacy

Patient records' privacy was guaranteed as there were no records stored in the Rhythmia system driven by the RSO. All patients' specific data were substituted for anonymized codes. Even if an attacker could remotely access to the system, there would not be any patient specific data, just a set of codes not connected to any patient identification.

2.5 Measurement of the operational delay

In order to quantify the delay between the remote operator and the Rhythmia workstation at the EP lab—that is to say, the

operational delay—the time-lapse interval between T1 (remote operator time) and T2 (visualization of T1 at the remote operator screen) was assessed. Remote operator time reference value (T1) was captured with the digital chronograph of the computer on the remote operator's webcam. This image traveled back and forth through the entire circuit: it reached the Rhythmia workstation, was displayed at the screen, and traveled back to the remote operator screen. Then, T1 and T2 were captured simultaneously with a screenshot. The time lapse between the remote operator and the hospital was then calculated as the result of dividing by two total time differences (T2–T1). Video delay measurements were calculated in five different cases from three different sites (Pamplona, Bilbao, and Tarragona) (Fig. 2).

2.6 Workflow

The remote FCS, located in a different city, logged into the KVM and then, once a member of the lab staff actively granted access on site, commanded Rhythmia according to the physician's needs. The interaction workflow between the physician and the remote FCS was essentially identical compared to the routine procedures.

Patient data was not used, recorded, or disclaimed, verbally or written, during the procedures as an additional measure to protect patient data confidentiality. Audio connection was established through a different channel that allowed multiple invited persons to participate during the call. There was a dedicated backup phone line (Fig. 1). The large display monitor configuration (Artis Zee, Siemens, Germany) of the EP lab, containing the fluoro-image and the EP recorder screen, was also duplicated at the remote site from case 27 onwards. Patient data was also anonymized in this system.

Fig. 2 Representative example of the video latency measurement

3 Results

The RSO was installed on March 15th, 2020, the day before the declaration of State of Alarm by the Spanish Government due to the Covid-19 crisis. Total system set-up took approximately 8 h.

Between March 16th and June 4th, 50 patients underwent ablation guided by remote navigation using Rhythmia and RSO. All the procedures performed during the Covid-19 lockdown were considered urgent or preferent according to the patient's clinical condition. After this period, the system was used routinely for elective cases. All patients were screened for SARS-Cov-2 24 h before the procedure by PCR and chest X-ray or CT scan. Two patients had SARS-Cov-2 while 48 patients were free of the disease. Mapping and ablation were performed by 2 different operating physicians, and technical remote support was executed by 3 different FCS from 3 remote locations. The clinical characteristics of the patients, the different substrates approached, and the ablation procedures are summarized in Table 1.

Once the connection was established, the remote FCS replicated the Rhythmia screen with all its features and interacted normally with the physician, essentially with no differences from being physically present. There were no perceptible delays nor interruptions or loss of connection of the bidirectional real-time video and audio communication between the remote FCS and the operating physician throughout the procedures.

In two occasions, the hospital network failed causing momentarily an internet connection interruption of 2 and 3 min duration. In both occasions, the 4G router monitor automatically switched to the 4G network. After this period, when the hospital network was restored, the system automatically switched back to its original configuration. These two events were barely noticeable from the operator's perspective and did not interrupt the procedures. Measurements of the video delay ranged from 265 to 325 ms (Table 2).

All 50 procedures were completed with no remarkable incidents and the backup on-site FCS did not have to come into play before, during, or after the procedures, as shown in the animation (Online Resource 1). After the first successful 40 cases, the medical staff decided dispense with the presence of the backup onsite FCS. At certain times, up to 6 allied professionals connected simultaneously with the EP lab for different purposes (i.e., teaching or training). Total connection and procedural times were 143 ± 63 min and 216 ± 77 min, respectively.

4 Discussion

As the complexity of the mapping systems continue to increase with advances in interventional electrophysiology, the role of allied professionals such as EP/lab technicians,

Table 1 Types of substrate approached and ablation procedures

Age (year)	69 ± 7
Underlying heart disease (<i>n</i>)	
Ischemic cardiomyopathy	15
Non-ischemic cardiomyopathy	8
Lone atrial fibrillation/none	25
Arrhythmogenic right ventricular cardiomyopathy	2
Underlying clinical arrhythmia (<i>n</i>)	
Atypical flutter	18
Atrial fibrillation	24
Atrial tachycardia	2
Ventricular tachycardia/electrical storm	14/1
Ventricular premature contractions	8
Ventricular fibrillation	2
Mapping procedures (<i>n</i>)	
LA substrate map	18
LA activation map	18
LV activation map	11
LV substrate endocardial map	23
LV substrate epicardial map	4
RV substrate map	1
RV activation map	3
RA activation map	4
Validation maps	19
Ablation procedures (<i>n</i>)	
Left ventricle	
Endocardial substrate modification	21
Epicardial substrate modification	2
Focal ablation on tachycardia/PVC	3/9
Alcohol ablation	1
Left atrium	
Pulmonary vein isolation	28
LA anterior line	8
Atypical LA line	4
Mitral isthmus line	1
Roof line	3
Focal LA ablation	2
Right atrium	
Cavotricuspid isthmus line	7

LA, left atrium; LV, left ventricle; RV, right ventricle; RA, right atrium; PVC, premature ventricular complex

technologists, field service engineers, and clinical specialists has become of increasing importance in the progress of the procedures.

Table 2 Latency measurements

Hospital location	Pamplona	Pamplona	Pamplona
Remote operator location	Bilbao	Madrid	Tarragona
T ₁ (s/ms)	58 s 120 ms	28 s 340 ms	33 s 380 ms
T ₂ (s/ms)	58 s 680 ms	28 s 960 ms	33 s 940 ms
T ₂ –T ₁ (ms)	560 ± 32	620 ± 33	560 ± 30
Latency = (T ₂ –T ₁)/2 (ms)	280 ± 15	310 ± 15	280 ± 10

The key role of the FCS in the EP lab varies among different teams, but essentially provides support to utilize the information gathered by the mapping system and to enhance understanding of the mapping system and the arrhythmia [2]. Among the tasks the clinical specialist could provide guidance are the hardware and software setup, the effective use of beat metrics and triggers to maximize the map efficiency and consistency, the creation of quality maps with complete electrogram coverage relevant to the tachycardia, the map refinement and interpretation with EGM review, and the collaboration with the physician in defining the ablation strategy to treat the arrhythmia safely. Nowadays, EP physicians, physiologists, nurses, and FCS conform a tight-knit team for the care of complex EP procedures.

In this paper, we describe how RSO, a well-known and affordable technology used in critical industry systems for decades, such as air traffic control, production plants, or telecommunication network management, proved to be a robust method to provide real-time fully remote technical assistance with the Rhythmia mapping system.

To the best of our knowledge, this is the first worldwide experience of a non-fluoroscopic navigation system entirely handled remotely, and although this paper describes a preliminary experience which should be further assessed, it seems a reliable way to provide remote technical assistance as well as to share technical and clinical decisions or advices.

In this series of 50 complex ablations, RSO of the Rhythmia system provided a smooth, local-like experience, with not a single intervention of the local backup FCS, who was present during the first 40 cases. KVM remote control software to drive the navigation system with all its technical capabilities and fully controlled by the remote FCS, combined with bidirectional audio and video communication, was as helpful for the physician as if the support staff were actually at the EP lab.

Virtual network computing technology can carry some downsides, particularly speed performance. The system performance can become a problem depending on Internet speeds. RSO software is only as fast as the slowest available Internet connection. If you are encountering a slow connection, running programs remotely will likewise prove slow, which is deemed to be unacceptable and unsafe in an electrophysiology procedure. In our system, the small video lag was less than half a second, and was considered imperceptible both for the physician and for the remote FCS. In our study, only video latency was measured and no audio measurements were performed because audio was prioritized by the system and travels faster than the video signal. In that sense, expected sound latency would be expected to be inferior than the measured video latencies.

In addition to speed, security risks can be a concern. The transmission between server and client can potentially be intercepted and give access to malicious users. Most RSO software carries strong encryption protocols, but whenever you

remotely access a computer outside of a network, it creates security risks.

In our system, we designed a multilayered approach similar to those used in different fields of telemedicine and industrial applications, with a software- and hardware-based architecture based on user account access controls, cryptography, and firewalls that provided a high-level protection for system files, data protection, and tampering. All these measures together provided an adequate level of security, privacy protection, and redundancy. However, despite the privacy measures already described, the information provided during the study could be maliciously disclosed to the company. The information acquired during the study should be tightly regulated to ensure that they belong to the patient, the physician, and the hospital. Therefore, the use of these capabilities should be very closely supervised and regulated prior to allow its clinical use.

Besides avoiding unnecessary exposure to the staff to high-risk hospital environments in the course of pandemic scenarios, implementation of RSO technology could offer many advantages and opens up new possibilities. For example, it enables the most experienced technicians/field clinical specialists to connect and drive the navigation system to any EP lab throughout the world, therefore providing the most skillful technical assistance in less experienced centers at the beginning of their learning curve with any new navigation system. Also, it could facilitate the training and increase the skills of not only new FCS trainees but also EP fellow physicians, therefore optimizing industry and health system resources.

Besides having less exposition to any kind of biological threats during pandemic scenarios, the main expected benefits for the electrophysiologist are as follows: [1] the possibility to reach flexible technical support even in non-scheduled, urgent or unexpected cases; [2] the possibility to quickly get the top-quality level of technical support (or even peer's advices) for specific complex procedures or for applying new technical tools of the navigation system; 3) the chance to share and discuss the technical aspects of the procedures with your peers; and [4] for teaching, training, and proctoring purposes. We also think that the abovementioned benefits for the electrophysiologist result eventually in benefits for the own patient.

Finally, considering that this solution could open up the possibility to share also different EP lab screens—not only the navigation system but also the fluoro-image and/or the EP recording system—it would allow physicians and healthcare providers to share knowledge for new techniques and complex cases, and to support and proctor new operators (physicians and FCS's) all around the world.

5 Conclusions

In this series, RSO allowed full teleoperation of a Rhythmia navigation system (keyboard, mouse, and screen) as well as

bidirectional real-time audio/video feedback with the operating physician, providing a fully autonomous remote assistance in 50 complex ablation procedures. Workflow was identical to on-site assistance both for the physician and for the FCS. Video signal delay ranged from 265 to 325 ms. This technology ensures workflow continuity and optimal workforce flexibility and has relevant and promising implications in the field of training, teaching, and resource optimization that deserves to be further developed. The use of this capabilities should be very closely supervised and regulated prior to allow its clinical use.

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Compliance with ethical standards

Conflict of interest IGB has received speaker/proctorship fees from Boston Scientific. DM, RM, AE, and JI are Boston Scientific employees.

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