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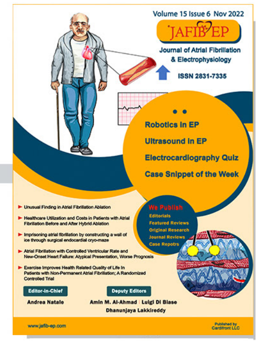

Challenges of the COVID-19 pandemic in healthcare and the use of robotic technology - The Robotic Magnetic Navigation, to manage them in the field of electrophysiology | A single-center experience with case studies

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Abstract

The coronavirus (COVID-19 also known as SARS-CoV-2) with its global pandemic scale has affected, threatened, and changed the healthcare system. Numerous hospital restructurings were needed to provide care for those suffering from COVID-19 and to contain its spread. In many hospitals, COVID-19 wards were established, other wards therefore closed, staff was reallocated, medical services were downsized, and elective procedures were suspended. All of this resulted not only in performance pressures on the medical staff but also in significant patient burden and economic losses for many hospitals. A new way of safely caring for COVID-19 positive or even (presumed) negative patients' needs to be thought through to contain the spread of the virus in the hospital itself, e.g., between patient and medical staff, but also be effective in a time of waiting lists, staff and bed shortages. Respiratory involvement is usually a hallmark of the clinical course of COVID-19 disease, but myocardial involvement and arrhythmic events have also been associated with a non-negligible number of patients which may also need to be treated. The use of robotic technology seems advantageous here to deal with these challenges. This article addresses the challenges of the COVID-19 pandemic in healthcare, especially in the field of electrophysiology (EP) and our experience at St. Elisabeth Hospital Neuwied with the use of robotic technology - the Robotic Magnetic Navigation (RMN) to handle it. In detail, two case studies show how complex procedures can continue to be performed in difficult times of the pandemic.

Introduction

The coronavirus (COVID-19 also known as SARS-CoV-2) with its global pandemic scale has affected, threatened, and changed the world on many levels, especially the healthcare system. Numerous hospital restructurings were needed to provide care for those suffering from COVID-19 and to contain its spread. In many hospitals, COVID-19 wards were established, other wards therefore closed, staff was reallocated, medical services were downsized on a large scale, and elective procedures were suspended. All of this resulted not only in performance pressures on the medical staff but also in significant patient burden and economic losses for many hospitals.[1,2,3,4,5,6,7]

A new way of safely caring for COVID-19 positive or even (presumed) negative patients' needs to be thought through to contain the spread of the virus in the hospital itself, e.g., between patient and medical staff, but also be effective in a time of waiting lists, staff and bed shortages. Respiratory involvement is usually a hallmark of the clinical course of COVID-19 disease, but myocardial involvement and arrhythmic events have also been associated with a non-negligible number of patients[1] which may also need to be treated. The use of robotic technology seems advantageous here to deal with the new challenges.

This article addresses the challenges of the COVID-19 pandemic in healthcare, especially in the field of electrophysiology (EP) and our center experience at St. Elisabeth Hospital Neuwied with the use of robotic technology - the Robotic Magnetic Navigation (RMN) to handle it. In detail, two case studies from our center show how complex procedures can continue to be performed even in difficult times of the pandemic.

Challenges in health care delivery

Attempts to contain the spread of the virus and address the growing demand for care of COVID-19 patients has led to restructuring

Key Words

COVID-19; Electrophysiology; Robotic Magnetic Navigation; RMN; Robotic Technology

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Photo 1 NEUWIED Lab/ Control room

and resource savings by, e.g., suspending non-urgent interventions in all medical departments, including the field of electrophysiology. Such delay of care requires dynamic risk and benefit assessment. The number of patients with deferred care continues to increase despite the recognition that morbidity and mortality are associated with delays in cardiac care. This includes treatments for cardiac arrhythmias such as ablation of severely symptomatic atrial fibrillation or atrial flutter. Increased resources of testing and personal protective equipment make experts argue against for the resumption of elective procedures.[5]

Bed supply

Hospitals face several challenges, including the bed supply in the intensive care unit (ICU). Because hospital beds in the ICU are limited, elective procedures have had to be canceled with the increased patient influx to allow for the reorganization of ICU beds.[2] San Raffaele Hospital, a hospital reorganized as a COVID-19 center, reported a gradual reduction of 71% (35 to 10) of the number of beds in their EP department.[6] At our hospital, we also at times experienced up to a 50 percent reduction in ICU bed capacity for non-COVID-19 patients.

Nevertheless, for the relative calmer times of the pandemic, it is necessary to design a new organizational model for patient admission. The shortest possible length of stay in the sense of a day-clinic or a one-night admission for elective procedures seems to be a suitable strategy to minimize the risk of infection and to make optimal use of resources.[7]

Surgical freeze

The Heart Rhythm Society advised postponing ablation of clinically stable patients.[5] Patients with life-threatening cardiac arrhythmias such as urgent non-posttraumatic EP procedures or patients with an indication of symptomatic drug-refractory VT recurrence should remain treated.[6,7]

Medical staff

Healthcare workers are at higher risk of contracting COVID-19 than the general population. Reports showed that as of July 2020, more than 1.800 identified healthcare workers from 64 countries died from the disease, and with data from late August 2020, there have already been 1.079 fatal cases in the United States alone.[2]

Robotics in the catheter lab - EP

In general, there is a trend that robotics, through increasingly advanced systems and more familiar handling, improves the effectiveness of procedures, shortens operating time and hospital stay/recovery, can help reduce costs, and improves clinical outcomes. However, a key consideration is user acceptance and seamless integration into routine clinical practice. In addition, effective collaboration between the clinical team, the medical technologist, and the manufacturer is important, for example, to ensure ease of use.[2]

We have succeeded in this integration of the Niobe® robotic magnetic navigation system (RMN) (Stereotaxis Inc., St. Louis, MO, USA) and the collaboration of the various interfaces at our hospital. We have been performing procedures using robotics daily since 2008 (Photo 1). The system is based on robotic control of two permanent magnets, each positioned on the side of the patient, which generate a magnetic field that is used to navigate the ablation catheter remotely from the protected control room via a computer mouse.

This robotic asset is valued for its reliable precision and stability in navigating an atraumatic and flexible ablation catheter.[8] In addition, RMN presents clinically as a safe method compared to manual intervention with a greatly reduced complication rate as well as low fluoroscopy time for patients and physicians.[9,10] The clinical success is comparable or in some cases better than with manual intervention (e.g., the acute success rate in VTs).[9,10] Furthermore, software features provide additional functionalities such as the e-Contact™ indicator of tip-to-tissue contact.[11]

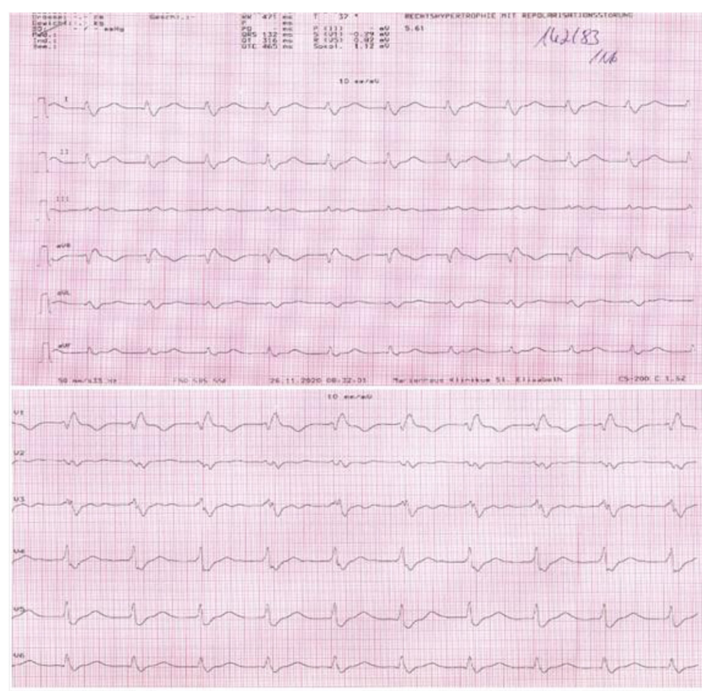

Figure 1 ECG before ablation

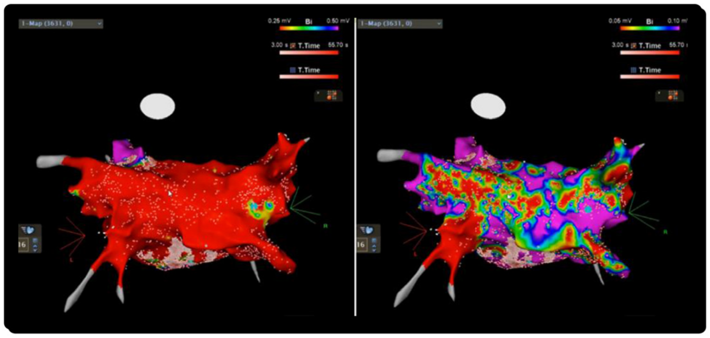

Figure 2 CARTO high-density Voltage MAP with normal (left) and extra sensitive setting (right)

Opportunities for robotics in medicine - general and EP

Exposure reduction

The opportunities for robotics in medicine in general, as well as in EP are numerous, such as the aspect of reduced exposure to x-ray. Performing interventions outside the operating room via completely contactless robot-assisted interventions are to be favored in the current situation. It has also been reported in other fields that modern robotic systems generally require less staff in the operating room than, for instance, in conventional open surgeries. Staff are exposed to fewer infectious aerosols, body fluids, smoke, and gases, and the direct risk of contamination can be further minimized.[2,3,4,12] Therefore, limiting the number of medical staff in the operating room and maintaining spacing represents the ultimate scenario for reducing pathogen spread.[2] In the field of interventional cardiology, robotic PCI with the surgeon 2 m away from the patient is already recognized as having the potential to reduce the risk of infection transmission.[13] A technology that advances further toward this goal, with the surgeon outside the catheter lab, is the RMN previously described, which was originally intended to reduce radiation exposure to medical staff.[2] The Luigi Sacco Hospital (Milan, Italy) has reported using the Niobe® RMN system to minimize unnecessary exposure to EP staff and any COVID-19 positive patients.[1]

TeleRobotic Procedures

Remote surgery, as it is known, is another important advantage of robotics. It potentially allows patients to access specialists remotely. Costly patient transport or the need for travel can be reduced and interventions can be monitored remotely by specialists or controlled via virtual interfaces.[2] This could also be thought of more widely as a tool for difficult circumstances such as infectious diseases, natural disasters, and medical care in war zones and remote areas.[14,2] Ethical and legal concerns must be addressed to integrate such novel technologies in the highly sensitive area of health care.[2] The applicability of telerobotic systems such as tele-echography for patients with COVID-19 pneumonia or robot-assisted percutaneous coronary interventions in non-critically ill patients has already been reported. These and similar technologies could reduce the likelihood of infection in medical personnel and serve as an additional layer of protection.[14,13,4]

Through the Niobe® system, we also have the ability for telerobotic application. Currently, it is used to receive assistance from the telerobotic support center during the procedure. For instance, specialists can be requested by the clinic at the touch of a button and dial into the robotics system online. This also includes remotely identifying and resolving technical issues or providing real-time assistance with clinical and software issues, thus ensuring an efficient and safe procedure. A stable Internet VPN is sufficient for this. Furthermore, compliance with the General Data Protection Regulation (GDPR) guidelines is guaranteed by the supplier.

Moreover, it can be used to collaborate with other colleagues, as seen live in 2020 during a telerobotics symposium. Jointly assisting each other in navigating through two procedures were Prof. Adragao at Hospital Da Luz (Lisbon, Portugal) and Prof. Pappone at Policlinico San Donato Research Hospital (Milan, Italy).[15]

Complication reduction & efficient resource utilization

Furthermore, benefits in robotic adoption have already been reported across several fields concerning low complication rates, better clinical outcomes, and earlier patient mobilization. Along with this, increased implementation can result in improved resource utilization, such as shorter hospital stays and more efficient bed occupancy. In turn, it is possible to reduce the likelihood of COVID-19 spreading to inpatient units or additional health system consultations and emergency department visits.[3,4] Our center was able to use robotics support to provide a combination of a strong hygiene concept, efficient use of resources as well as personnel, and reduce risk of complications to continue treating patients rhythmologically.

Efficient staffing

Due to many COVID-19 infected individuals, there is a shortage of skilled staff in the healthcare system. In this case, the use of robotics can help to allocate staff efficiently, and also helps to shorten the time patients/staff are exposed to the virus.[16] With fewer staff needed, we were able to transfer staff to normal and intensive care units but continue to offer EP treatments.

In a typical EP lab, one physician guides the catheters in the procedure room and another manages the systems from the control room. One or two nurses are also present. With the help of robotics,

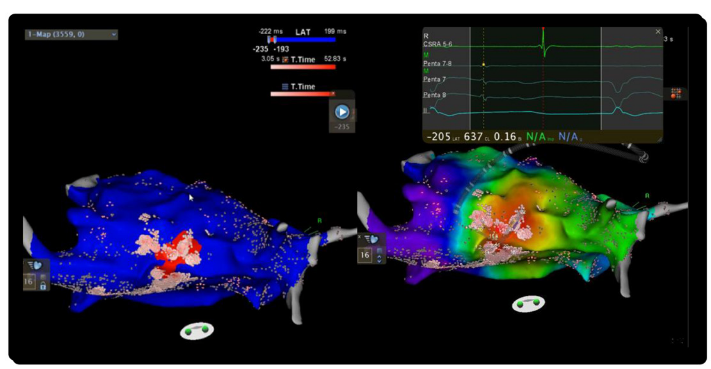

Figure 3 CARTO activation MAP (left) and LAT pre-timing MAP (right)

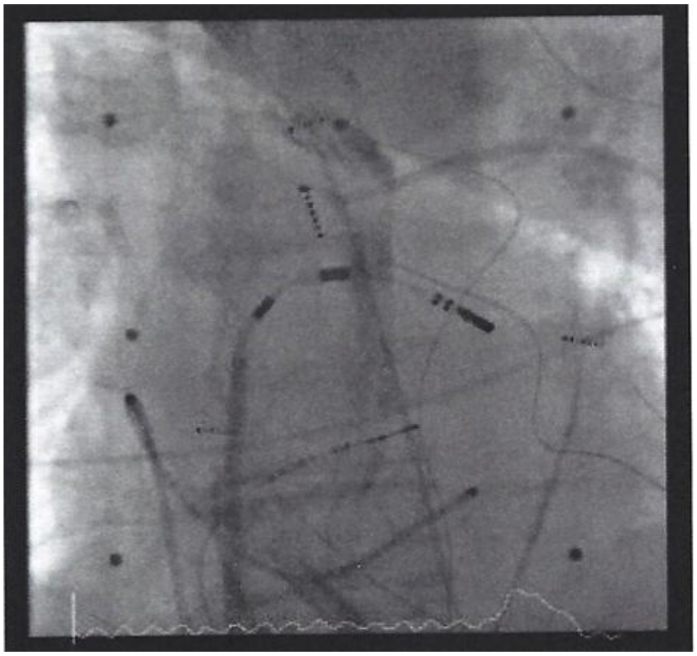

Figure 4 X-ray thorax: RMT ablation catheter in the LA

we have established a highly efficient department where a single physician and a single nurse suffice since after the introduction of catheters the procedure is managed entirely from the control room.

Case studies

Procedures considered important during the COVID-19 pandemic but classified as elective can still be performed safely and efficiently with robotic assistance. This is demonstrated by the following complex procedures from our center.

The procedures were performed by one physician and one nurse. Our standard approach is without the use general of anesthesia. Propofol is used and managed by the operating physician and a special trained nurse. The nurse uses monitoring systems allowing to maintain distance to the patient.

In technical emergency cases tele-support from the industry-partners is possible but in this cases not necessary.

Case 1 - Focal left atrial tachycardia

A 76 year-old male patient, presented with heart failure and a new symptomatic arrhythmia - left atrial tachycardia (Figure 1). A recurrent refractory persistent atrial fibrillation (PVI 2016 & 02/2020), from which the patient has suffered for more than 15 years, and a left atrial focal tachycardia (540ms) (07/2020) were previously ablated Figure 1.

Under propofol the placement of a multipolar catheter in CS, RA, and another multipolar catheter at the His position was performed. This was followed by a transseptal puncture with the placement of an SL1 sheath into the LA. Using a Pentaray catheter (Biosense Webster, USA) and the 3D mapping system CARTO (Biosense Webster, USA), an atrial tachycardia (CL 540ms) was mapped with origin at the roof of the LA. A switch to the cooled RMT ablation catheter NAVISTAR Thermocool (Biosense Webster, USA) was made (Figure 2, 3 and 4). With the help of the RMN system, the procedure was continued from the control room outside the lab. During ablation in the identified roof region, the tachycardia terminated and could not be thereafter induced. By using the robot, the time in the immediate proximity of the patient could be reduced. Of the total procedure time of approximately 1.5-2 hours the following times were spent directly next to the patient: Catheter placement and transseptal puncture - approximately 10 minutes, mapping time - approximately 9-12 minutes, removal of catheters and care of the puncture site - approximately 10 minutes, therefore approximately 29-32 minutes in total. The remaining time was spent in the control room. In general, mapping with the RMN catheter is also possible and can further reduce the time spent directly close to the patient. It can be assumed that without the use of an RMN system the total procedure time of approximately 1.5-2 hours would have been spent directly next to the patient vs. with the use of a RMN system only approximately 29-32 minutes (Figure 5).

The early treatment of AF is critical, ablation is therefore an important treatment option. Recently, a multicenter randomized trial compared early rhythm control with usual care for patients with early AF and cardiovascular disease. Results showed that early rhythm control reduced death rates and complications from cardiovascular causes [17], which makes the term 'elective' debatable when applied to these patients. This was reflected in 2020 guidelines. They upgraded ablation as a treatment recommendation from Class II a to Class I in case of AF after failed medication therapy and as a first-line therapy in AF patients for recovery of LV function when tachycardia-related cardiomyopathy is likely and regardless of the patient's symptom status. [18]

Case 2 – "Concealed" WPW with left lateral accessory pathway

That even young patients have an urgent need for treatment during the pandemic is shown by following the case of a 19-year-old female patient with frequent AV reentry tachycardias, after already unsuccessfully ablated left atrial exclusively retrograde conducting accessory pathway (2019, CL 330ms). The severely symptomatic tachycardias required emergency hospitalization every 1-2 weeks.

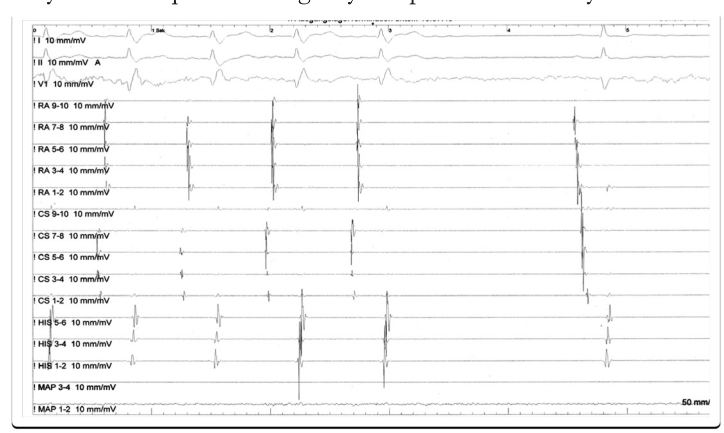

Figure 5 ECG: termination of tachycardia during ablation

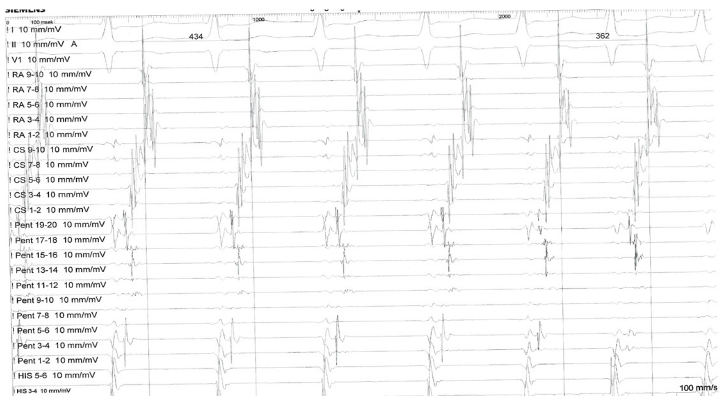

Figure 6 ECG: Tachycardia

Early treatment of tachycardias with CL of more than 200ms is crucial to prevent escalation into atrial fibrillation and sudden cardiac death.

Sudden cardiac death is the most feared manifestation of WPW syndrome, typically because of pre-excited atrial fibrillation that conducts through the accessory pathway to the ventricle and provokes ventricular fibrillation. [19]

The patient was therefore admitted as an inpatient for electro physiological examination, and recurrent left atrial exclusively retrograde conduction accessory pathway was confirmed. In addition, a nonpermanent retrograde block in the CS- sequence was suggested. On the same day, it was decided to perform a robot-assisted ablation.

After placing a catheter in CS and RA as well as a catheter at the His position and one in the RV, transseptal puncture followed, and an activation map of the easily triggered tachycardia (CL 362ms) (Figure 6) was performed using the Pentaray catheter and the CARTO 3D Mapping System (Figure 7). Thereafter, a switch to the cooled RMT catheter was made. The area of the left lateral to the mitral valve annulus was robotically ablated with visible potential on the catheter (Figure 8, Figure 9). Termination of the tachycardia occurred during ablation (Figure 10). Even after a waiting period of 60 minutes, no further tachycardia could be induced. The CS sequence during retrograde stimulation of RV came only via the AV node. In this case, the RMN system also reduced the time spent in the proximity of the patient. Of the total procedure time of approximately 1.5 hours the following times were spent directly next to the patient: Catheter placement and transseptal puncture - approximately 10 minutes, mapping time - approximately 8-11 minutes, removal of catheters and care of the puncture site - approximately 10 minutes, therefore approximately 28-31 minutes in total. The remaining time was spent in the control room. It can be assumed that without the use of an RMN system the total procedure time of approximately 1.5 hours would have been spent directly next to the patient vs. with the use of a RMN system only approximately 28-31 minutes. In post-intervention, there were no unusual events, and the patient was able to be discharged the day after the procedure.

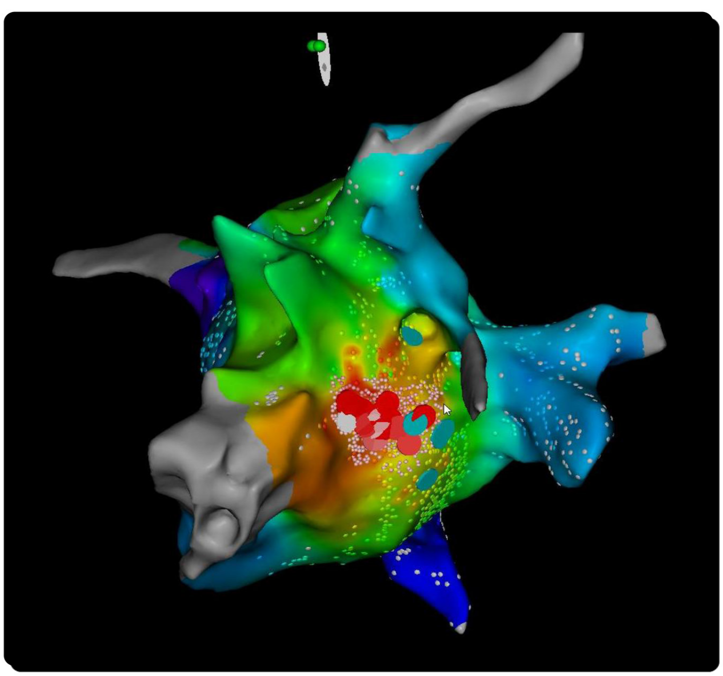

Figure 7 CARTO HD map and oblique left lateral ablation of the accessory pathway

Prospects for the future

The European Commission is already focusing on the future with the initiative "Join the AI-ROBOTICS versus COVID-19" - European AI Alliance. The goal is to find solutions to combat COVID-19 in the field of AI and robotics, including, for example, voice-activated robot-assisted contact avoidance with potentially infected surfaces, instruments, or humans, as well as telepresence/ telemedicine using remotely controlled robots to support medical protocols up to instrumental controls.[16]

Telemedicine showcases itself as a key technology of the future. Patients can receive high-level medical care and at the same time, robotic ablation helps to reduce infection spread. A study concerning e.g., user acceptance and perception, evaluation of current implementation, as well as the evaluation of possible regulatory obstacles was conducted with German physicians online. In line with other studies, telemedicine solutions are highly valued across all professional categories. In the present of a crisis, this perception of high value is significantly higher for the in-patient vs. out-patient sector. A fifth of respondents saw regulatory and technical obstacles to telemedicine in routine care. If regulators and governments can prioritize and overcome the removal of technological, organizational, and infrastructural barriers, telemedicine has a chance to emerge as a global care structure in the future. [20]

Conclusion

Globally, the healthcare system has been confronted with numerous new challenges. The return to the new reality of healthcare, along with the resumption of elective procedures, requires innovative approaches. The first publications on this topic considered (tele-) robotics as the answer across various fields in medicine. In parallel to the intense testing and personal protective equipment, robotics

Figure 8 ECG: Tachycardia - Visible potential on "MAP" catheter

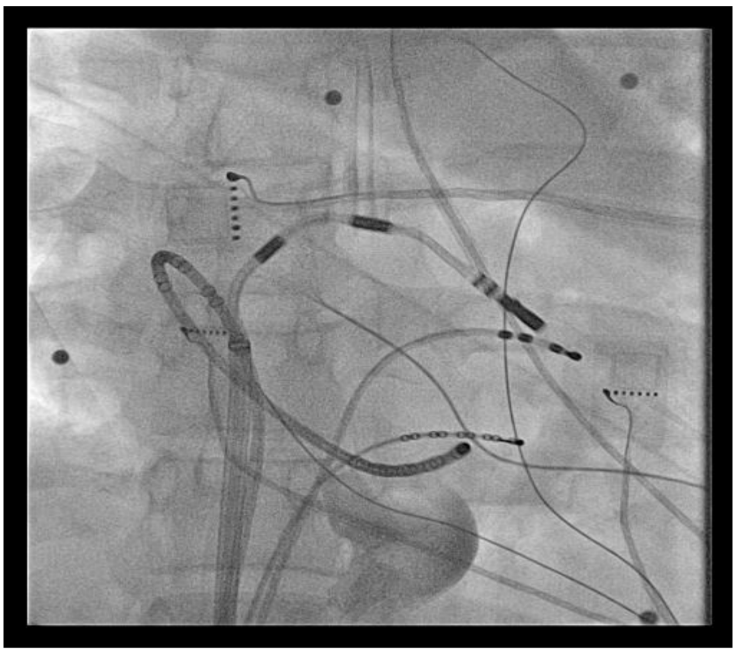

Figure 9 X-ray thorax: RMT ablation catheter in the LA, aligned left laterally

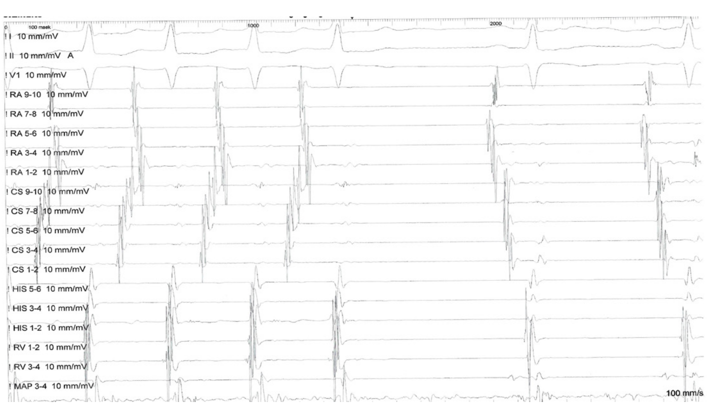

Figure 10 ECG: termination of tachycardia during ablation

serves as an additional layer of protection against potential exposure to COVID-19. Moreover, it allows for more efficient use of limited resources, such as fewer medical staff required or prevention of prolonged bed occupancy by tending to lower complication rates, for example. Particularly for the field of electrophysiology, we can agree with the positive results of the successful robotic implementation of an RMN system in our center and we can also report further advantages.

Especially in the clinical field, telemedicine presents itself with great acceptance as a future key technology. The clearing of technological, administrative, and infrastructural obstacles is necessary to prepare the path for the establishment of a global care structure.

Conflict of interest

Dr.Bjorn Buchter – No potential conflict of interest

Margarita Kreuzer: Stereotaxis Inc employee, Stock shareholder – Stereotaxis Inc

Stefan Mirazchiyski: Stock shareholder – Stereotaxis Inc

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