



The digital journey: 25 years of digital development in electrophysiology from an Europace perspective

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Aims

Over the past 25 years there has been a substantial development in the field of digital electrophysiology (EP) and in parallel a substantial increase in publications on digital cardiology. In this celebratory paper, we provide an overview of the digital field by highlighting publications from the field focusing on the EP Europace journal.

Results

In this journey across the past quarter of a century we follow the development of digital tools commonly used in the clinic spanning from the initiation of digital clinics through the early days of telemonitoring, to wearables, mobile applications, and the use of fully virtual clinics. We then provide a chronicle of the field of artificial intelligence, a regulatory perspective, and at the end of our journey provide a future outlook for digital EP.

Conclusion

Over the past 25 years Europace has published a substantial number of papers on digital EP, with a marked expansion in digital publications in recent years.

Keywords

Digital • Telemonitoring • Artificial intelligence

What's New?

- A comprehensive overview of the past 25 years within the field of digital electrophysiology with a particular focus on publications from the EP Europace journal.

Introduction

Digital technology has the potential to impact and transform healthcare by providing a platform for patient identification, risk stratification, management, patient interactivity, and education. In the past 25 years

there has been a substantial development within the field of digital cardiology, with electrophysiology (EP) in the forefront paralleled by an increase in publications within this field.

This paper seeks to provide an in-depth overview and chronology of the field of digital EP mirroring the substantial influence in this area that EP Europace has had in the past decades. Digital technologies can enable care for arrhythmia patients, and we aim to provide the reader with a brief overview of the digital toolbox, starting with a journey from the early days of telemonitoring, followed by an update on monitoring from a wearable perspective. From there we move forward to mobile applications and virtual clinics. In addition, a chronicle of the development within the field of artificial intelligence (AI), an

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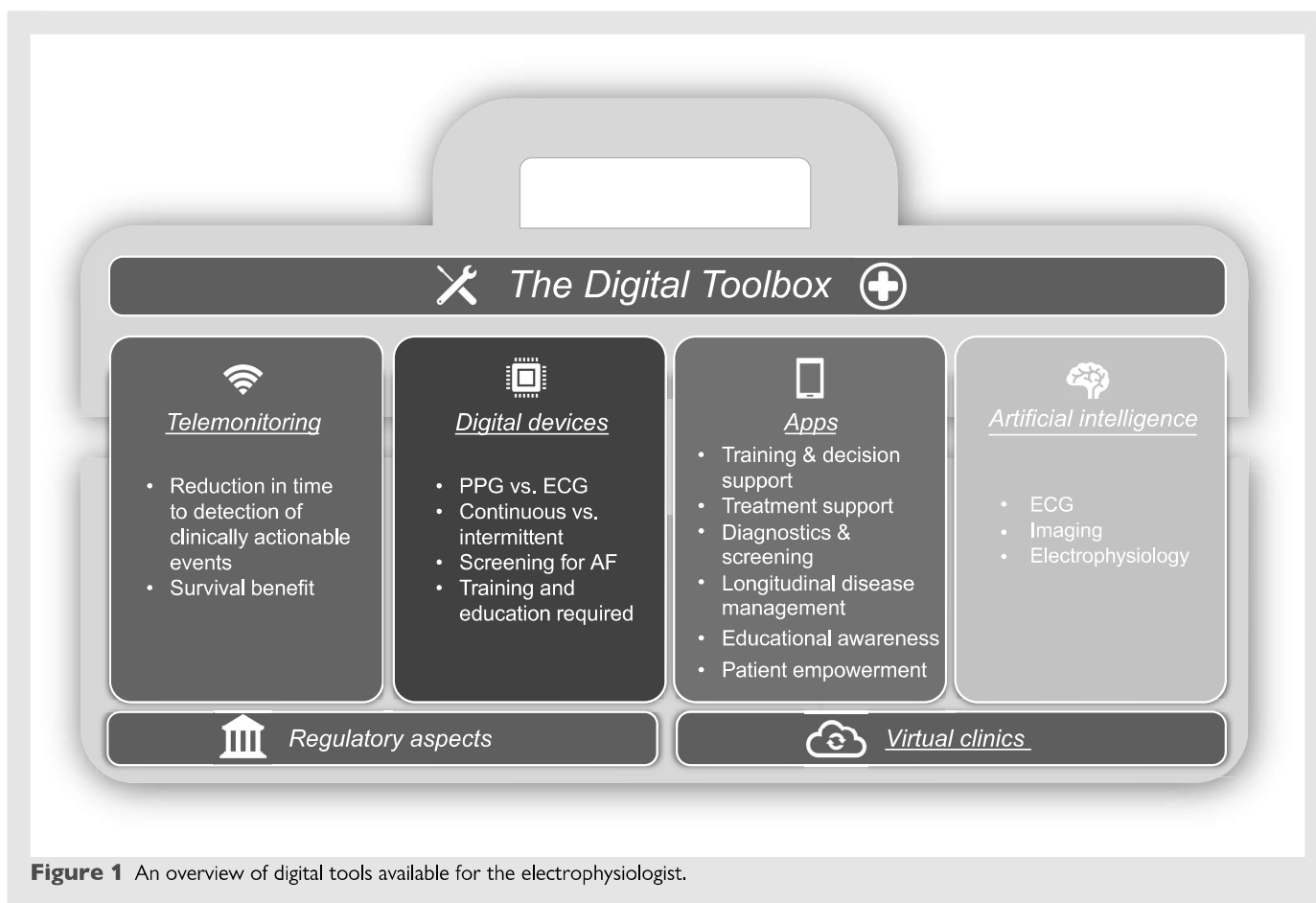


Figure 1 An overview of digital tools available for the electrophysiologist.

outlook on the future as well as a regulatory perspective, is provided (Figure 1).

Telemonitoring of cardiac implantable electronic devices

The digital journey in EP begins with cardiac implantable electronic devices (CIEDs). A significant evolution has been seen over the last decade, with novel technologies allowing complex programming and wireless remote monitoring (RM) of device function and patient health status.^{1–6} Telemonitoring of CIEDs has now evolved to a fully automated system to complement in-office follow-up⁷ and has gained even more importance during the COVID-19 pandemic.⁸

Previous studies have demonstrated a reduction in time to detection of clinically actionable events, prompting earlier intervention with the implementation of RM compared to standard in-person follow-up care.^{9–14} In the multicenter RIONI study, in 619 patients with an implantable cardioverter-defibrillator (ICD) it was shown that home monitoring could provide an accurate evaluation of events by experts.^{5,15} The PREFER study evaluated 980 pacemaker patients with RM providing earlier and more frequent detection of clinically relevant events.⁹ The TRUST study showed a median time to evaluation after an arrhythmic event of less than 2 days, compared to 36 days in the control group.^{16,17} Access to continuous RM data has resulted in fewer in-person evaluations, a reduction in emergent and unscheduled hospital visits with a decrease in overall healthcare utilization.^{6,16,18–22} However, apart from the COMPAS trial, most of these studies were conducted only in ICD patients. Prompt arrhythmia detection coupled with early recognition of fluid accumulation²³ with an in-built algorithm reduced

emergency department and urgent in-office visits by 35% in the remote arm, as demonstrated by the EVOLVO study.¹⁸ Other large-scale studies have shown the potential cost saving associated with RM strategy.^{21,22,24–30}

More importantly, a pooled analysis of three randomized controlled trials (TRUST, ECOST, and IN-TIME) involving 2405 patients with ICDs showed a significant reduction of all-cause mortality with RM.³¹ Another meta-analysis of nine randomised controlled trials (RCTs) demonstrated non-inferiority of RM and in-office follow-up with RCTs utilizing daily transmission verification, proving significant survival benefit.³² Large real-world registries have further established the survival benefit of RM also emphasizing the impact of adherence to RM in improving patient outcomes.^{29,33–35}

Despite its various proven clinical benefits, RM implementation and uptake have been modest.³⁶ Barriers to RM implementation are multifactorial and include patient factors such as health literacy, preference and access, lack of healthcare infrastructure, and inadequate reimbursement.³⁷ The Altitude Survival Study found that more than 60% of patients with RM-capable devices did not participate in RM.³⁵ Real-world population studies also revealed poor compliance to RM, with one study reporting 53% of patients without a single RM transmission over the follow-up period, and another with 21% non-compliance rate.^{33,38}

On the other hand, the increasing volume of RM transmissions has reached a staggering proportion and increased the clinic workloads. In a study involving more than 26 000 patients, the number of transmissions and alert burden was quantified, resulting in a total of 205 804 transmissions, 40% of which were alert with only 4.8% requiring urgent clinical response.³⁹ This data deluge, which includes a high rate of false positives, particularly with the increasing use of implantable loop

recorders, leads to an increased burden on clinical staff, and delays in the evaluation of actionable alerts.^{40,41} Early studies suggested how this may be partially overcome using AI to better identify actionable alerts.⁴² However, critical for improved patient outcomes are the clinic-level pathways to manage actionable alerts. Evidence suggests this may pose a significant threat to the success of RM.⁴³ Ultimately, patient education, streamlined alert settings and clinic workflow, adequate trained staffing, and attractive reimbursement policies must be in place to ensure successful adoption of the RM approach for CIEDs.^{44,45} Recently, a query has been raised if smartwatches can provide a replacement for CIEDs, which will be addressed in the next section.⁴⁶

Digital devices

In concordance with telemonitoring, cardiac rhythm monitoring has also markedly evolved in the past 25 years, progressing from the initial Holter monitors to event recorders, mobile cardiac telemetry, implantable cardiac monitors to increasingly 'smart' multipurpose sensing and monitoring instruments.^{47,48}

Wearable devices have become central for cardiac rhythm monitoring. In 1994, the first wrist-worn heart rhythm monitor was introduced. This device was capable of transmitting an analogue transtelephonic signal that was converted into a digitized single-lead ECG tracing. Unfortunately, adoption was limited as patients found the device more difficult to use than traditional Holter monitors.⁴⁹ Several other wrist-worn devices and simple textile-based heart rate monitors soon followed.⁵⁰ While they provided some insight into a patient's HR, they were not accurate enough for clinical use and were primarily used by fitness enthusiasts. In the last decade, advances in wearable technology have led to more accurate and reliable devices for cardiac rhythm monitoring.⁵¹ Most of these devices, such as smartwatches, rings, and fitness trackers, use optical sensors to detect the patient's HR and rhythm using photoplethysmography, providing real-time monitoring and analysis.⁵²

More modern wearable devices, such as smartwatches, use either photoplethysmography and/or ECG-based HR and rhythm monitoring providing single-lead ECGs or even multiple lead ECGs. These devices can also track other metrics such as physical activity, sleep, and stress levels, providing a more holistic view of the patient's health.

Digital devices offer new possibilities for continuous or intermittent monitoring and have been increasingly used for screening for atrial fibrillation (AF).^{53,54} Large-scale studies in different settings and populations have shown that screening for AF using digital devices identifies patients at risk,^{55–59} has the potential to reduce relevant outcomes⁶⁰ and reduce costs.⁶¹ Screening for AF using new digital devices is recommended in guidelines and consensus documents.^{51,62,63}

Clinical usage and acceptance of digital devices have increased in the last few years. The true advantages of digital care were seen during the time of the COVID-19 pandemic when digital devices still allowed specific and dedicated remote patient care for arrhythmia management, as shown in the international TELECHECK-AF project.^{64–68} Healthcare providers have since started to recognize the potential benefits of these devices for patient care, and digitally advanced centres are using them as a tool for remote patient monitoring.

While wearable devices have shown promise in cardiac rhythm monitoring, there are still challenges that need to be addressed. In particular, the accuracy and reliability of wearable devices for cardiac rhythm and rate monitoring have been a subject of debate.^{69,70} Recent studies have shown that although some wearable devices can provide reliable measurements of HR and rhythm, variations due to the manufacturer's algorithms and the patient population are common.⁷¹ Another challenge is the interpretation of the data generated by these devices, which can be complex and requires specialized knowledge.^{72,73} As recently shown in an European Heart Rhythm Association (EHRA) survey, digital

devices are widely used, but reimbursement for usage and interpretation is a problem to solve in most countries.⁷⁴ In the future, we can expect to see further advances in wearable technology for cardiac rhythm monitoring.⁷⁵ These devices may become more accurate, reliable, and personalized to the patient's needs, and advances in AI may enable more efficient and accurate interpretation of the generated data.⁷⁶ In addition, patient involvement remains an important aspect of digital care.^{77,78}

In conclusion, wearable devices have evolved significantly in the last 25 years and have the potential to revolutionize cardiac rhythm monitoring. While there are still some challenges that need to be addressed, they have shown promise in improving patient outcomes through earlier detection and treatment of cardiac conditions. As technology continues to advance, we can expect to see further improvements in cardiac rhythm monitoring. Many wearables are connected to mobile health applications, which will be discussed in the coming section.

Mobile health applications (apps)

The introduction of novel generations of smartphones using computer-like built-in features and sensors on the market in 2007, allowed for customization of the devices by downloading apps from central stores. This feature, combined with the high-grade adoption of smartphone technology in the population (i.e. 86% penetration rate in Europe in 2021) increases the possible applications in the EP field.⁷⁹

In EP, the initial interest with regards to smartphones was focused on safety, in particular by determining the potential interference of smartphones with implantable cardioverter defibrillators.⁸⁰

More recently, evaluation studies comparing the accuracy of handheld connected devices and smartphone apps have gained a lot of attention.⁸¹ The use of apps within healthcare has manifold opportunities when implemented in a structured pathway, as described in multiple publications (Figure 2).

- (1) **Training of healthcare providers and decision support.** Providing care that conforms to the guidelines is of pivotal importance to optimize patient outcomes, but adherence to the guidelines is often suboptimal. The availability of interactive clinical practice guidelines through an app, such as the 'ESC Pocket Guidelines' app, could facilitate their uptake. On top of this, for AF the CATCH ME Consortium developed the 'AF Manager' app as a tool in which healthcare professionals can incorporate patient data to suggest treatment options that conform to the guidelines.^{82,83}
- (2) **Treatment support.** To support patients in their daily treatment and to promote a healthy lifestyle, mHealth apps can enhance adherence to medication, increase adherence to hospital appointments, support patients in rehabilitation and physical activity and assist in tackling of comorbidities.^{84–88}
- (3) **Diagnostics and screening.** Various apps can be used to screen for arrhythmias making use of different sensors embedded in the smartphone or connected to it.^{51,71}
- (4) **Longitudinal disease management.** mHealth opens a large spectrum for the (remote) follow-up of various clinical parameters to fill in the gaps between the in-person consultation visits, including HR, heart rhythm, symptoms, weight, and blood pressure.^{51,67,68,83,84,87,89–91} Apps can also connect with wearables, or with implanted devices to collect valuable clinical information on the patient's status.^{84,92–94}
- (5) **Education and awareness.** To engage patients in their own care and allow shared decision-making, mHealth apps can assist in delivering validated information and tailored education to patients to increase health literacy.^{82,87,95,96}
- (6) **Empowering patients to own their health data and directly contact healthcare providers.** Apps can allow patients to get informed about their healthcare data and contact their healthcare providers in case of questions about their management. Moreover, many hospitals have their own applications allowing patients to counsel their health data.

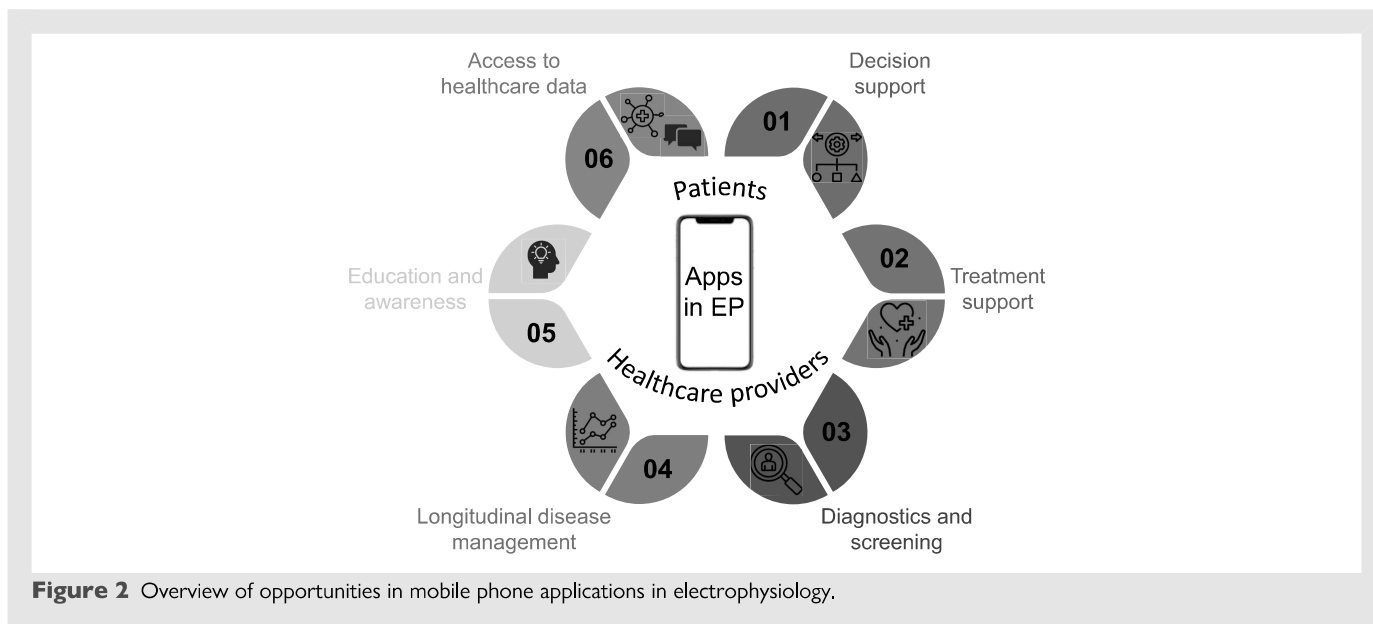


Figure 2 Overview of opportunities in mobile phone applications in electrophysiology.

Despite the fact that mHealth apps are widely available, several barriers^{93,97,98} still exist. These include in particular, lack of validation, sparse data on effectiveness and impact on clinically relevant endpoints, poor data integration with electronic health record systems, lack of clear guidance on care pathways to make use of these apps in daily clinical practice, and lack of reimbursement.

Studies formally evaluating the impact of mHealth apps on healthcare professional's behaviour are scarce and larger-scale studies with representative patient cohorts, appropriate comparators, and longer-term assessment of the impact of mHealth apps are warranted, also in view of the new requirements for conformity assessment introduced by the EU Medical Device Regulation.^{87,99} As a result, apps are rarely prescribed to patients by healthcare providers in daily clinical practice.

The use of apps for medical purposes could further expand in the future when current barriers in the development, security, validation, cost-effectiveness, interoperability, implementation, and reimbursement of mHealth in daily clinical practice will be solved, and it is an integral part of virtual clinics.^{97,98}

Virtual clinics

As highlighted in the previous sections the publication of 'Transtelephone Pacemaker Clinic' in 1971 and the subsequent rise of RM of CIEDs established cardiac EP as leaders in providing virtual care for patients.¹⁰⁰ The rapid transition to virtual modalities to provide safe, uninterrupted arrhythmia care during the COVID-19 pandemic led to an exponential adoption of digital care by EP.^{101–103} This cemented the view of EPs as one of the highest adopters of virtual care (>95% in some systems), and a high rate of virtual care is maintained even after the pandemic has largely subsided.^{65,66,104}

EP is particularly conducive to the adoption of virtual clinics as most consultations can be performed entirely virtually. Cardiac rhythm tracings can all be reviewed and analysed online. Discussions, including shared decision-making, can be performed via video or telephone contact.¹⁰² HR and rhythm data from direct-to-consumer digital devices continue to be integrated, helping to enrich arrhythmia patient virtual care.^{51,65,93,105}

Real-world studies have shown feasibility, safety, and efficacy of virtual arrhythmia clinics, with similar outcomes, quality metrics, and patient satisfaction when compared to in-person visits.^{106–108} Virtual AF management has

shown particular promise. One of the largest endeavours has been the TELECHECK-AF virtual clinic.^{68,91} Here, teleconsultation, use of a CE-certified, clinically validated smartphone photoplethysmography HR and rhythm monitoring App (FibriCheck, Flanders, Belgium), and virtual education were combined to support comprehensive AF management.^{68,109} Patients used the app to check HR/rhythm three times a day for one week, and data was uploaded to the cloud for clinician review before teleconsultation.⁶⁸ In 20 days after launch, 9 countries/23 European centers adopted this virtual clinic model; by 6 months nearly 1700 patients were enrolled.^{52,110} Patients have found the app easy to use (94%), providing them a sense of reassurance (74%); clinicians have given high ratings for on-boarding, cloud access, and reliability.⁶⁷ Currently, over 6000 AF patients have received care via this virtual clinic model. The TeleVVAS-AF 'wait-and-see' programme for patients with recently diagnosed AF uses this same virtual care strategy to help avoid unnecessary cardioversions.⁶⁷ A randomized trial, RACE 9 OBSERVE-AF, assessing this virtual care pathway is currently underway (clinicaltrials.gov NCT04612335). In the UK, an 'AF virtual ward' has recently been piloted to manage hemodynamically stable AF patients in an ambulatory setting by using digital tools for vital signs monitoring (hand-held daily ECGs, BP monitoring, and O₂ saturations), twice daily 'virtual' rounds, and medication adjustments via a clinical pharmacy. This proof-of-concept study recently showed potential for decreasing AF hospital admissions and re-admissions.¹¹¹

Virtual clinics for the management of anticoagulation have been well-established.^{112,113} Virtual clinics for outpatient antiarrhythmic drug loading have been less explored. In an initial feasibility study, three patients with CIEDs requiring sotalol initiation during the COVID-19 pandemic were monitored from home via CIED remote transmissions, mobile cardiac telemetry, a hand-held 6L ECG device Food and Drug Administration-cleared for QTc monitoring (KardiaMobile® 6L, Alivecor, Mountainview, CA), as well as video-telehealth. Successful outpatient initiation of sotalol initiation was performed without any adverse events.¹¹⁴ A pharmacist-driven virtual clinic for outpatient sotalol loading and monitoring has since been safely piloted using online ECG and lab review, telephone contact, and remote QTc monitoring via the KardiaMobile® 6L.¹¹⁵

Virtual clinics for post-AF ablation patients show potential. One study on 46 AF patients from the UK replaced the 3-month post-ablation in-person visit with a video visit coupled with a proprietary vital sign tracking mApp. This virtual clinic showed high overall patient satisfaction (84%) and patient cost and time savings (80%).¹¹⁶ The Cleveland Clinic 'Atrial Fibrillation Future Clinic' randomized 100

post-ablation patients to traditional in-person care vs. virtual care enhanced with a hand-held ECG monitor and follow-up at 6 months. Hospitalization, ER, and clinic visits, as well as anxiety, were similar between groups. In addition, the virtual care group had less use of ambulatory ECGs.¹¹⁷

As virtual clinics and digital devices are further integrated into EP, patient perspectives—preferences, readiness, digital access, availability, and literacy, as well as cost—must be considered.^{51,75} Canadian studies have shown that arrhythmia patient virtual care may be well received for quality of life, cost and time savings, and opportunities for participation from caregivers and family members.^{118,119} However, it may be less preferred for new patients or complex issues requiring nuanced discussions. Fit (or non-fit) of virtual clinics has been found to be dependent on clinician and medical staff's ability to communicate via these channels effectively and comprehensively.¹¹⁹ Hybrid models combining in-person with virtual clinics may be an effective middle-ground for both patients and clinicians. Also, AI might have a future role in virtual clinics, by ECG interpretation and prediction of outcomes.

Artificial intelligence

AI and machine learning (ML) are rapidly evolving disciplines within data science that can classify complex data, and thus 'interpret them' to predict future patterns or risk of events.¹²⁰ Studies published in *Europace* within the field of AI provide an exciting chronology of our field aimed at better-managing patients with cardiac electrophysiologic disorders.

Europace published its first AI study in 2003, well before its 25th birthday, in which Kappenberger *et al.*¹²¹ identified ventricular tachycardia (VT)/ventricular fibrillation (VF) with a c-statistic >0.90 by leveraging sensed voltage alterations from sinus rhythm in ICD recipients. This early study incorporated elements that remain foundational to this day, most notably separating the cohorts used for algorithm development from cohorts used for testing to improve the generalizability of results. Studies in 2008 used AI of electrogram shapes to discriminate VT with such high accuracy (c-statistic > 0.95)¹²² that an accompanying editorial¹²³ posed a question that still resonates: '[will] automated analysis ... replace the electrophysiologist?'

Of numerous studies using AI to predict VT/VF, Shakibfar *et al* used random forests to classify daily ICD interrogation summaries in 19 935 patients, providing a c-statistic of 0.80 for imminent electrical storm in an independent test cohort.¹²⁴ When explaining their results, the authors found that the most predictive features were percentage of ventricular pacing and level of daytime activity. This use of AI to analyse near continuous ICD data has stimulated much interest and further studies.¹²⁵ In an intriguing study by Sammani *et al.*, deep neural networks were used to develop an autoencoder to represent key features of 1 million ECGs in a latent space; when applied to 695 patients with dilated cardiomyopathy, this interpretable AI predicted long-term VT/VF and found that P wave features, right bundle branch delay and reduced QRS-T voltages were the most predictive.¹²⁶ Several studies applied AI to imaging data. Balaban *et al.* reported that remodelling of LV end-diastolic shape in 156 patients was the strongest multivariate predictor of VT/VF over an extended follow-up of 7.7 years.¹²⁷

A remarkable achievement of AI has been to dramatically alter clinical care using simple data. Pioneering work by Attia *et al.* showed that the 'AI-enabled 12-lead ECG' in sinus rhythm can reveal left ventricular dysfunction¹²⁸ and patients with paroxysmal AF.¹²⁹ This is an exciting field, although further studies are needed since some others suggest that the AI-ECG may not add to traditional risk factors,¹³⁰ or may not apply to single ECG leads⁷⁶ in ambulatory monitors. AI may effectively 'learn' other ECG waveform patterns, for example AI of T-wave morphology was reported to identify gene-positive long QT syndrome patients from controls with a c-statistic of 0.901, better than QTc estimates.¹³¹ Convolutional neural networks applied to the ECG were shown to identify echocardiographic LV hypertrophy better than

clinicians in 21 286 patients, with a c-statistic of 0.868 in an external validation set.¹³²

The ESC-EHRA AF ablation long-term registry recently used AI of multimodal data to predict outcomes after AF ablation in 3128 patients with a c-statistic of 0.72, making the tool available online and outperforming clinical risk scores.¹³³ AI has been applied to electronic health records to reduce spurious AF alerts, using natural language processing and CHA2DS2-VASc elements, providing 98% accuracy and reducing workload by 84%.¹³⁴ AI of clinical data predicted sinus rhythm after electrical cardioversion of AF,¹³⁵ and after guideline-directed medical therapy¹³⁶ in secondary analyses of the Flec-SL-AFNET 3 and ANTIPAF-AFNET 2 trials, respectively. Neural network classifiers can predict recurrent syncope from patients in the emergency room using the history and ECG with accuracies from 67 to 95%.¹³⁷

AI has been used to improve body surface potential mapping,¹³⁸ and even to generate 3D maps of ventricular activation from the 12-lead ECG.¹³⁹ AI of the ECG can separate typical from atypical atrial flutter mechanisms.¹⁴⁰ A consensus document discussed the use of AI to better understand and map AF.⁷⁰ Bhatia *et al.* applied AI to intracardiac electrograms in AF to identify patterns of organization associated with recurrence after ablation,^{141,142} and such tools have been incorporated into clinical mapping systems.^{143,144} Corrado *et al* recently applied AI to reveal tissue conduction slowing and atrial surface area that may predispose to re-entry during AF.¹⁴⁵ Toprak reported that AI of NT-pro BNP and other circulating biomarkers improved upon traditional clinical variables in predicting incident AF.¹⁴⁶

Europace has also taken the lead in reporting some of the challenges for AI. A notable editorial by Loring and Piccini in 2019 entitled 'Machine Learning in Big Data: Handle with care'¹⁴⁷ discussed how AI is not immune to bias in study design. These authors also showed that AI did not improve AF outcome predictions in the large ORBIT-AF and GARFIELD registries over traditional statistical predictors.¹⁴⁸

In summary, AI is an extremely promising discipline to better understand and treat patients with heart rhythm disorders, and future work should focus on defining disease states, patient groups, and algorithmic approaches which will enable the greatest benefit. However, it is vital that the regulatory process is in balance with the development of novel models.

A regulatory perspective

Although our journey through digital arrhythmia care over the past decades has shown remarkable progress, there is also a need to be careful when introducing novel technologies. Medical devices are becoming smarter by using software that is increasingly 'intelligent', taking advantage of the steep rise in capabilities of AI and ML. As data is the cornerstone of AI learning, testing, and validation, this means that such novel devices need to comply (already or in the near future) with several regulations from the EU: besides the General Data Protection Regulation (GDPR) also the Medical Device Regulation (MDR), Data Governance Act, and the upcoming AI Act, and the European Health Data Space regulation. While this is already a significant challenge for small and even large manufacturing companies, for non-profit hospitals, and academic institutions it has become a major hurdle for the implementation of their innovations. Politicians and regulators across Europe have become aware of this issue, which is pushing innovation to other markets like the USA and China. Finding the proper balance between safety and innovation is still ongoing.^{94,149,150}

One must weigh in that zero risk does not exist, and one always must consider the balance between benefit and risk for the individual patient and for society. Presently the balance seems to have swung towards risk aversity, which inadvertently creates risks of with-holding potentially beneficial devices from patients in need of them.^{151,152} There is also a disconnect between the regulatory requirements from GDPR and MDR and the scientific evidence on which clinicians base their decision

to use certain devices in specific circumstances for a given patient. Scientific guidelines and the clinical requirements from GDPR and MDR aim towards the same goals at the highest level, but in their practical implementation, they do not coincide and sometimes only marginally overlap. The regulatory requirements focus on avoiding risk (which is further enhanced by the status of the notified bodies) and are subject to a variable interpretation of the GDPR in the EU Member States and of the MDR by the notified bodies. Scientific guidelines focus more on the benefit-risk balance but are not available for all clinical decisions and are often based on inconclusive or incomplete evidence and only on expert opinion with the inevitable (but mostly not intentional) bias.¹⁵³

To bring the two requirement systems closer together and to avoid the high costs of duplicated clinical trials, registries, and studies, one could consider aligning them to their intrinsic purpose, which is allowing the patient/family to make the decisions about diagnostic and treatment options together with their health care provider based on the best available information, for example about benefits, risks, alternatives, and refraining from active therapy. Depending on the clinical situation of the patient, the severity of the pathology, and potential benefit of the intervention a lower or higher risk or uncertainty might be acceptable. It is the core of co-decision making to weigh these factors and come to an informed, balanced conclusion. The information needed to make these choices can vary and that must be reflected in the regulatory framework.

Similarly, the evidence to be provided by a manufacturer before the release of a product into the market should be based on the risk-benefit balance with a larger or smaller emphasis on post-release requirements. Regulators are presently hesitant to allow this because post-release obligations are often more difficult to define and enforce. For medical device software, this might possibly be the only way to address the difficulties with (self-)learning AI software and with the drift in the use of such devices in clinical real life.

In conclusion, the reality of medical device software, with its variable possibility of extensive pre-release clinical testing and potential drift in use and impact, will necessitate a more balanced risk-benefit evaluation and alignment of the regulatory and clinical scientific standards in the future.

The future digital aspects for electrophysiology Europace

As described in the previous sections, EP has a history of utilizing advanced digital solutions and tools. With the current rapid advancement of digital technologies, commonly referred to as digital transformation, including AI using ML and deep learning, RM, wearables, and advanced imaging, we can expect even greater progress in the field. Some potential future aspects for digital in cardiovascular EP follow.

Telemedicine and RM, as discussed in the section on virtual clinics and telemonitoring, have become increasingly important topics in cardiology,⁷⁵ especially with the acceleration brought on by the COVID-19 pandemic. We could expect to see improved capabilities and infrastructures for RM,⁶⁸ as well as advancements in wearable technologies. With ongoing developments in device miniaturization and wearable tech, monitoring, and treatment options should become more convenient and patient friendly. For instance, implantable sensors or wearable patches may provide continuous monitoring of heart rhythm and other relevant data, enabling early detection and intervention in case of abnormalities. This should lead to better patient outcomes and satisfaction, as well as a reduced workload for healthcare staff and lower healthcare costs.

ML and AI algorithms have the potential to transform EP by enabling automated and precise analysis of vast amounts of data.^{63,154,155} These technologies can aid in predicting, diagnosing, and providing

personalized treatment for heart rhythm disorders. The rapid development of digital technologies is expected to lead to significant improvements in imaging and mapping techniques, resulting in better visualization and characterization of the heart's electrical activity. This could include the widespread adoption of high-resolution imaging and three-dimensional mapping technologies, which would enable more precise diagnosis and treatment planning for patients. In addition, ML-powered algorithms can optimize the outcomes of catheter ablations by providing real-time guidance and feedback.

Advanced imaging using virtual reality and augmented reality has the potential to revolutionize EP training and procedural planning. Virtual reality can provide a safe and controlled environment for simulating ablation procedures, reducing the learning curve and improving safety. Additionally, augmented reality can offer real-time visual guidance during procedures by overlaying relevant information, such as anatomical landmarks or electrode placement, onto the patient's body. These technologies could ultimately lead to better patient outcomes. Moreover, virtual reality can also be utilized to reduce patient anxiety by aiding in teaching and preparing patients for procedures, as well as assisting in post-procedural rehabilitation.¹⁵⁶

One of the most challenging yet promising areas where AI could have a significant impact is personalized medicine. AI-based algorithms that incorporate individual patient characteristics, such as genetics, lifestyle, and medical history, can provide advanced analytics and computational modelling to predict the optimal treatment approach for each patient. This approach can lead to more targeted and effective treatments with improved outcomes.¹⁵⁷

In conclusion, the future of cardiovascular EP will be shaped by rapid advancements in digital technologies, such as advanced imaging and mapping, AI and ML, telemedicine and RM, virtual and augmented reality, miniaturization and wearable devices, and personalized medicine. These advancements have the potential to significantly improve diagnosis, treatment, and patient outcomes in cardiovascular EP, and represent an exciting time for the field. With this reflection on the past quarter of a century in EP, we can now cast our eyes forward, envisioning that the journey ahead will likely accelerate our digital knowledge. In the coming 25 years in the EP Europace journal, we will continue to provide you with novel digital tools to improve the management of arrhythmia patients and steadfastly aim to increase our coverage of digital topics, using a scientific approach to enable better patient management.

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