DEBATABLE ISSUES IN AUTOMATED ECG REPORTING

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Highlights

- Four areas of topical interest in automated ECG reporting were debated at the 2017 International Society of Computerized Electrocardiology (ISCE) conference.

- These included the value of automated ECG interpretation, real time ambulatory ECG monitoring, ECG imaging and single channel ECG rhythm interpretation

- Advantages and disadvantages were elaborated in each of the four topics.

Abstract

Although automated ECG analysis has been available for many years, there are some aspects which require to be re-assessed with respect to their value while newer techniques which are worthy of review are beginning to find their way into routine use. At the annual International Society of Computerized Electrocardiology conference held in April, 2017, four areas in particular were debated. These were a) automated 12 lead resting ECG analysis; b) real time out of hospital ECG monitoring; c) ECG imaging; and d) single channel ECG rhythm interpretation.

One speaker presented the positive aspects of each technique and another outlined the more negative aspects. Debate ensued. There were many positives set out for each technique but equally, more negative features were not in short supply, particularly for out of hospital ECG monitoring.

INTRODUCTION

There are many areas of automated electrocardiography where the value of the technique is taken for granted when it is debatable if this is the case. Several such issues were reviewed by experienced individuals at the 2017 International Society of Computerized Electrocardiology (ISCE) conference held in St Simon's Island, Georgia, USA in April and are summarized here.

There were two participants in each debate, one supporting the debatable topic and the other taking an opposite view. The speakers did not necessarily agree with the side of the argument which they were supporting but nevertheless they had to make a case for it!

The following commentaries essentially summarise the point of view of the speaker in each side of each debate.

Automated ECG interpretation is beneficial even in major hospitals with experienced over-readers

Pro: ***Jay W. Mason***

Measurement and interpretation of the ECG by computerized algorithms has been in clinical use since the work of Pipberger and Caceres in 1960. There is a debate over the value of these interpretations, especially in centers with experienced ECG over-readers, because the algorithms can make errors [1]. This brief statement offers support for the value of computerized ECG interpretation, even in the academic medical setting.

Algorithms are extremely accurate in detecting normal ECGs. This was known early on[2] and has been affirmed more recently[3]. Since most ECGs are normal, most computerized interpretations are correct and fully serve the need for an accurate ECG interpretation.

Though computer algorithms are imperfect, so are physicians, including cardiologists. Willems, et al[1] demonstrated that the overall performance of computers and cardiologists were very similar, though the cardiologists prevailed in a study comparing 8 cardiologists to 9 computer programs. But, specific algorithms actually out-performed specific cardiologists.

When algorithms err, the result is usually benign. That is because they rarely miss acute ischemia or infarction. Guglin and Thatai showed perfect sensitivity of computer programs for these diagnoses[3], while Min and coworkers found perfect sensitivity for detection of STEMI[4], allowing them to use computer algorithms in the ER to decide on transfer to the cardiac cath lab, without waiting for a physician's interpretation. They documented accelerated transfer as a result.

The one important diagnosis that challenges algorithms most of all is atrial fibrillation (AF), with only 76% sensitivity for the diagnosis demonstrated by Guglin and Thatai[3]. But, in a more recent study Mant and colleagues[5] found that interpretive software had greater sensitivity and specificity (83% and 99%, respectively) for detection of AF in comparison with general practitioners (80% and 92%) and nurse practitioners (77% and 85%). They also showed that the general practitioner using prompting from interpretive software further improved his/her detection of AF (92% sensitivity and 91% specificity).

Reader prompting is one of the greatest benefits of algorithmic interpretation. It helps the experienced over-reader inadvertently avoid missing diagnoses and it improves the less experienced reader's performance. This was nicely documented by Novotny, et al[6], who demonstrated that diagnostic prompting improved interpretive accuracy substantially by both cardiology and non-cardiology fellows. For example, when multiple correct and incorrect diagnostic statements were presented, the over-readers were able to distinguish well between correct and incorrect statements, and they improved their diagnostic accuracy over their interpretations without availability of automated diagnostic statements by approximately 30% (non-cardiology fellows) and 28% (cardiology fellows).

Though there is no doubt that algorithmic misdiagnoses can cause and have caused real clinical harm, the net benefit seems to exceed the harm substantially. The risk of harm can and should be a specific focus in training of practitioners to read ECGs. They need to know what types of algorithmic statements they can rely on, as well as those that they should question. Research on this topic is spotty and insufficient to permit development of a rigorous curriculum of training in the optimal use of ECG algorithms in clinical practice. This area is ripe for exploration.

Contra: ***Paul Kligfield***

In a 1991 editorial in The New England Journal of Medicine, Mike Laks and Ron Startt Selvester concluded that "no ECG program available now or in the near future has sufficient accuracy in all diagnostic categories to stand alone. Consequently, every computerized ECG must be read and modified as needed by a competently trained physician."[7] Has anything changed over nearly three decades that would alter this comment in context of our current debate that automated interpretation of the ECG is beneficial in large hospitals with experienced over-readers?

In truth, the contrary position to this debate proposition, that automated interpretation of the ECG is *not* beneficial in large hospitals with experienced over-readers, is nearly untenable. Automated measurements and interpretations continue to improve. Everyone who reads ECGs will agree that automated intervals, amplitudes, and axes provide essential time-saving in large volume over-reading settings. Further, preliminary rhythm interpretations are generally correct, particularly when these are preponderantly normal. In addition, morphology diagnoses of abnormal waveforms are often correct. However, there are exceptions to these generalities.

But let us consider the concept of being "beneficial" as it applies to this debate. There will be little disagreement that automated interpretation is beneficial to the physician over-reader for the reasons outlined above, but how can this benefit be translated to direct benefit to the patient? Interestingly, the Latin root of the concept of being "beneficial" is associated with the ethical concept of "beneficence," an established medical research and clinical tenet that patient safety should come first in the doctor-patient relationship, as in the Hippocratic doctrine of "first, do no harm." Since clinicians with limited ECG interpretive skills increasingly rely on automated interpretations even when experienced over-readers provide confirmed diagnoses, patients may be harmed under some circumstances by automated interpretations that are neither directly beneficial nor beneficent.

So in the sense of "beneficence," let us reframe the debate proposition with acknowledgment that experienced over-readers certainly benefit from computerized ECG interpretations. However, that benefit is not uniquely patient-centered. A reframed debate might thus propose that automated interpretation of the ECG does no harm in large hospitals when primary caregivers rely entirely on computerized interpretations. This patient-centered reframed proposition is easily refuted, because there are several types of harm that may result in an era of generally declining ECG interpretive skills when automated algorithms are imperfect. Imperfection is common to all diagnostic algorithms.

Imperfect examples may be categorized by a simple two by two contingency table that relates automated ECG diagnoses with gold standard interpretive diagnoses (Figure 1). When the automated diagnosis is normal and the true diagnosis is normal, the physician benefits and no harm can accrue to the patient. However, when the automated diagnosis is normal but there is a diagnostic ECG abnormality, the "false normal" report has the potential to cause patient harm if not recognized. Although relatively rare, examples of false normal automated interpretations can be found (Figure 2).

Contingencies are also important when the automated ECG diagnosis suggests that an underlying abnormality exists. When the true diagnosis is normal, such a "false abnormal" statement may trigger treatment or additional clinical evaluation that is unwarranted, which may be potentially harmful to the patient. While also relatively rare, examples include inaccurate automated algorithm diagnoses of arrhythmias, including atrial fibrillation, and false abnormal diagnoses of acute coronary syndromes, such as acute ST elevation myocardial infarction. When acted upon without being critically reviewed, these diagnoses can cause harm. And finally, even when the automated diagnosis and true diagnosis are both abnormal, there may be discordance between diagnoses for findings relating to either abnormal rhythm or to abnormal waveform morphology.

Solutions to these problems are beyond the scope of the present debate, but continued improvement in automated algorithms and better training of clinicians in ECG interpretation are obvious suggestions. In 2017, the automated ECG still remains an adjunct to the clinician.

Is 24/7 monitoring out of hospital a viable concept when nursing staff switch off alarms in hospitals?

Background

Mobile Cardiac Telemetry (MCT) devices have been introduced over the past 15 years [8] to provide real-time outpatient electrocardiographic (ECG) monitoring for up to 30 days. Proprietary arrhythmia algorithms automatically detect abnormal rhythms and transmit ECG data via cell phone to a diagnostic laboratory where monitor technicians analyze rhythms and notify physicians of significant arrhythmias. Ten devices are currently approved by the United States Food & Drug Administration (FDA). An industry-maintained website (www.cardiacmonitoring.com) describes features of each device. Most MCT devices utilize a torso-positioned 3-electrode lead configuration and provide for viewing 2-3 channels of bipolar leads (Mason Likar Leads I, II, and/or III). [9]

Pro: ***Claire E. Sommargren***

MCT is a portable, simple, non-invasive, and relatively inexpensive technique that provides long-term real-time ECG monitoring. It is used when short term monitoring modalities, such as inpatient ECG telemetry, Holter monitoring, or other ambulatory monitoring devices have failed to detect arrhythmia. Because of the long-term nature of the monitoring, the diagnostic yield of MCT is significantly higher than other ambulatory monitoring methods[10,11]. MCT does not require patient involvement in the transmission of ECG data to the diagnostic lab, making it particularly useful with cognitively impaired patients and in the detection of asymptomatic arrhythmia. Because data is transmitted in real time and reported to the physician immediately after arrhythmia occurrence, therapeutic intervention can begin in a timely fashion when indicated.

In the diagnostic laboratory, the certified technicians' sole responsibility is to monitor and report ECG data, unlike hospital nurses who have numerous distracting patient care duties in addition to cardiac monitoring. These labs are maintained by the manufacturers of the devices and require to be accredited for round the clock operation throughout the year. Little in the way of detail is available on the internal operation of these labs. Protocols are in place in the labs to ensure continued alertness of the technicians; for example, an auditory alarm signals technicians to stand up and walk every ten minutes. In addition to routine ECG data analysis and reporting to physicians per prescribed protocols, technicians also follow standardized procedures for notification of the physician and/or patient in situations in which emergency assistance is needed. Technicians assist patients as needed in troubleshooting transmission problems.

The general purpose of MCT is to uncover the etiology of unexplained prior or recurrent symptomatic event, or capture arrhythmic events that aid in assessing patient prognosis or effect of medication/treatment. It is used in the diagnosis of new atrial fibrillation (AF), particularly after cryptogenic stroke or when there are unexplained symptoms suggestive of AF. The AHA/ASA stroke prevention guidelines recommend 30 days of cardiac monitoring for patients with cryptogenic stroke or transient ischemic attack.[12] MCT is well-suited for this purpose, and many centers have adopted MCT as the first line in prolonged cardiac monitoring after cryptogenic stroke.[11] In patients with known AF, MCT is useful to a) distinguish paroxysmal from sustained AF, b) determine the pattern of AF onset and termination, c) assess the adequacy of ventricular rate control, and d) evaluate the efficacy of ablation procedures. MCT is also useful in the diagnosis of syncope or pre-syncope by determining whether the cause is arrhythmic or non-arrhythmic in nature.[13] In addition, it is used to uncover the cause of palpitations, recurrent unexplained falls, arrhythmia evaluation in obstructive sleep apnea, and for post-cardiac surgery arrhythmia evaluation. In addition, there is emerging evidence for MCT advantage in both time to initiation of drug therapy and inpatient cardiovascular patient costs.[14]

Contra: ***Barbara J. Drew***

The pioneer device (Cardionet, now Biotelemetry, Inc., Malvern, PA) that has been most successful was developed by specialists in invasive cardiac electrophysiology and approved by the FDA in 2002. In an inaugural publication,[15] 100 patients were reported as having worn the device and as a result of monitoring, 5 had pacemakers implanted, 1 received an implantable cardioverter defibrillator, and 1 had ablation therapy. The investigators considered success as "the results of the monitoring led to a change in treatment." One could argue that a better measure of success would be better patient outcomes such as more timely treatment, fewer atrial fibrillation-related strokes, or better survival.

To date, there have been no prospective randomized clinical trials showing evidence that treatment guided by mobile cardiac telemetry monitoring results in improved patient outcomes for any subgroup (palpitations, atrial fibrillation, syncope). In addition, there is little to no data reported on the technical challenges of this type of outpatient monitoring. For example, it is unclear what percentage of the 30-day monitoring recordings is unanalyzable due to poor signal quality or missing data due to cell phone, battery, or electrode issues. Also unclear are the device algorithm's false alarm rate and the patient work load of the central laboratory technicians who may become desensitized to alarms because of alarm fatigue. It has been documented in the hospital environment that there are a huge number of false positive alarms, e.g. in one study, 91% of 6196 ST alarms were considered to be false positive[16]. Also unreported are the delay times for physician notification and response for clinically important arrhythmias. Patients who are at risk for arrhythmias are usually elders who are likely to have cognitive and physical limitations that make it challenging to follow directions for maintaining electrodes and trouble-shooting device issues. There is little data reported on skin break-down and compliance with the protocol over the 30-day monitoring period. Also unreported are the costs associated with providing real-time Mobile Cardiac Telemetry Monitoring. With an aging population, there is justifiable concern about unsustainable health care expenditures. Future research is required to determine whether a similar diagnostic yield and patient outcome could be achieved with non-real time monitoring before this technology is adopted into routine care for patients at risk for arrhythmia.

ECG Imaging is a superb, clinically cost-effective diagnostic tool

Pro: ***Peter van Dam***

The technological development of the ECG dates back to the work of Einthoven at the beginning of the 20th century[17]. In 1934, Wilson introduced the common reference, the so called Wilson central terminal, which allowed the recording of unipolar precordial leads and limb leads (VR, VL and VF). As the lead strength and hence amplitude of the unipolar limb leads was less than the bipolar limb leads, Goldberger introduced new circuitry for deriving the extremity leads, effectively multiplying these leads by 1.5[17]. In 1949, Holter introduced long term ECG monitoring. Although the ECG recorders have become better in terms of signal quality and data storage capacity, the ECG measurement has not fundamentally changed since that time.

Although the diagnostic potential of the ECG is enormous, the last decades have shown that the diagnostic value of the ECG cannot be improved by solely analyzing the ECG due to the inter-individual variability of the patient's body build[18]. To improve the diagnostic value of the ECG for the individual patient, additional clinical information should be incorporated. The combination of different clinical data modalities to enhance the ECG diagnosis is traditionally the cardiac modeling world in which many scientists have been working on solving the ill-posed inverse problem in electrocardiography.

The inverse ECG (*i*ECG) field has a history that also dates back to the early days of Einthoven, who used a dipole model to represent the cardiac electrical activity[19]. More advanced models came into the field with increasing computer power. So after about 5 decades of research, the solution to the inverse problem in electrocardiography (*i*ECG) has reached a stage where some practical clinical applications seem feasible. The first commercially available *i*ECG system manufactured by CardioInsight has been applied to mapping AF, but also to the localization of ventricular arrhythmias. These commercial *i*ECG systems are complex and therefore sensitive to parameter selection. They involve the need for an MRI scan for determining heart geometry of the model for each patient. Consequently, these systems often require a lot of user experience and knowledge of the system, which reduce their clinical applicability. On the other hand, the *i*ECG technology offers an infrastructure to combine multi-modal information through modeling, such as the combination of cardiac imaging data and the ECG, but also the localization of scar tissue, fiber direction, genetic background, etc.

An example of such multi-modality data combination is the use of a 3D camera to localize the 12 lead ECG electrodes[20]. This not only detects the accurate lead placement, thus enabling the correction of the lead placemen[21], but also the body dimensions of the patient can be obtained (Figure 3). These body dimensions can be used to select a model from a database with torso/heart model combinations. The selection of a torso/heart model will enable the ECG correction for heart orientation, a major source of variation in the ECG. Patients with a more narrow ribcage will be more likely have a vertical heart than patients with a wide ribcage. Also, patients with a large chest circumference will probably be overweight, and consequently have a more horizontal heart. Using such estimated heart orientation allows the vector cardiogram

(VCG) to be related to the cardiac anatomy instead of to the body. Such a direct relation enables the visualization of a PVC origin as is shown in Figure 4.

Both the model database as well as the rules to select the model need to be determined, but ultimately this will offer an *i*ECG method to improve the diagnostic value of the ECG without the cardiac imaging (MRI/CT) required in many of the iECG systems.

Contra: *Roger Abächerli*

The 12-lead electrocardiogram (ECG) has become the most frequently performed cardiovascular test, and approximately 200 million ECGs are recorded worldwide each year. It is an essential diagnostic tool in clinical cardiology and critical for evidence-based management of patients with most cardiovascular conditions including patients with acute myocardial infarction, suspected chronic cardiac ischaemia, cardiac arrhythmias, heart failure and implantable cardiac devices. In contrast to many other techniques in cardiology, the ECG is simple, small, mobile, universally available and cheap, all of which make the ECG a particularly attractive diagnostic tool. The progress in biomedical computing and signal processing, and the available computational power of microcontrollers and processors offer fascinating new options for ECG analysis, including improved filtering effects, morphology feature analysis, frequency content analysis, vectorcardiography analysis and ECG imaging[22]. Regardless, the look of the standard 12-lead ECG has remained the same and the interpretation still relies mainly on direct visual assessment. The criteria for ECG interpretation have hardly changed over the past 25 years. However, the use of these conventional criteria expose relevant limitations of the ECG which leave significant unmet clinical needs in various field of cardiology[22].

Further, the ECG is still the only non-invasive diagnostic tool for assessing the electrical activity of the heart at a low cost. It is clinically established, simple to apply, mobile, proven to be cost-effective and much more.

ECG imaging (ECGI)[23] needs an imaging modality (i.e. CT, MRI) to extract the anatomy of the thorax and makes assumptions over the electrical properties of the tissue. This additional process is not for free. If the ECGI is not adding any additional value to the diagnosis that can be made with a standard 12-lead ECG, it cannot be cost-efficient compared to the ECG. Further, in most cases, only the thorax is used for ECG lead recording. A standard 12-lead ECG therefore is not possible and the so called Mason-Likar positions for the arm and leg electrode placement are used. This introduces some errors.

Nevertheless, we might have to become a bit more self-critical; the ECGI might have some potential with a different focus and the coexistence of the ECG and ECGI might become a fruitful partnership where both sides profit from each other. A possible compromise might be to use ECGI only in research in order to learn how the ECG can be improved. Another possibility might be that a surface image for the thorax only is taken. This easily can be achieved at a low additional cost and might add a corrective value for the often wrongly placed electrodes in standard 12 lead ECG. Moreover, if the ECG market (including the device manufacturers, the device buyer and users) allows the ECG device to become more modern, there will be a future for that innovative product. This may include some new striking technologies pushed by the

ECG manufacturers. The ECG buyers and users are in charge of accepting its evolutional step. In such a positive environment, the ECG might rebuild itself to keep its role as the most important cardiac diagnostic test in clinics.

Over-the-Counter ECG Devices Are Very Beneficial

Pro: ***David E. Albert***

In his recent book [24], Dr. Eric Topol has stated that the age of paternalism in medicine needs to be over! He goes on to state that the smartphones in every pocket represent the power for people to control their own healthcare.

My company, AliveCor, introduced the first smartphone-based ECG rhythm strip recorder in the US that gained FDA clearance as over-the-counter in 2013. Since that time, the company has sold hundreds of thousands of devices. While over half of those were sold on the prescription or recommendation of a physician (usually a cardiologist or cardiac electrophysiologist) or by a physician for his/her own use, a significant number were purchased by patient-consumers (the average age is around 60) of their own accord. In these four years, the company has received exactly one formal complaint that the device increased the anxiety of a patient and that was from a patient who stated up front that he had an anxiety disorder. To the contrary, we have received hundreds of accolades from both patients and physicians as to the value of our solution and the “peace of mind” it provides.

The cost and complexity of modern medicine in the US is out of control. Implantable ECG monitoring solutions costing tens of thousands of dollars are utilized with minimal to no proof that they improve outcomes but they do generate huge amounts of revenue and profit (ignore the pain and potential complications). The patients are never given a view of their own data while it clearly belongs to them. As deductibles and co-pays continue their inexorable upward path, the medical community *must* better engage patients in their own care. It is clear that many cardiac afflictions need the patient to lose weight and exercise more. Only by encouraging the patient to take control can these goals be achieved. Having access to their own cardiac rhythm, like providing them access to their weight and blood pressure, brings patients into the treatment. That engagement is the future of medicine. Partnership and not paternalism is the hallmark of that future. Over the counter ECG devices are a part of that future.

Contra: *Morrison Hodges*

While it cannot be denied that the availability of a small ECG recorder can be helpful, it can be misleading in some situations. Such devices tend to record a single lead I though other leads can be recorded by a trained individual[25]. A single lead I can often present normal appearances when other leads are abnormal. This can be the case with ST elevation in leads II and III possibly due to an acute inferior myocardial infarction where the frontal plane ST vector is oriented at 90°. A well meaning but inexperienced medical practitioner might wrongly conclude from a single channel recording that the cause of chest pain is non cardiac.

If such devices are bought over the counter by the worried well, they could also be misled into thinking that a report of Normal ECG on a single channel ECG means that their heart is normal. However, a well-trained medical student will know that a normal ECG does not imply a normal, heart.

The answer here is “horses for courses”. If a patient is thought to have a cardiac arrhythmia, then he or she could be advised to use a single channel hand held device to make a recording during symptomatic episodes. This could be valuable. If a trained practitioner uses the device to look for an arrhythmia, that is also acceptable. However, in the vast majority of cases, a patient will make a recording which will be reported as normal when in some cases a full 12 lead ECG might reveal an abnormality such as a Brugada pattern.

In summary, although over the counter ECG recording devices can be beneficial, they have the potential to be misleading in a way that may rarely be detected.

CONCLUSION

Those who spoke in favor of a proposition generally had many positive factors to back up their case. On the other hand, those who opposed a motion had a more difficult argument to make. However, the negative aspects cannot be ignored and many points which were raised are worthy of further research.

For basic automated resting ECG analysis, further work to minimize false positive and negative diagnoses of cardiac arrhythmias remains essential while false positive and negative reports of ST elevation myocardial infarction are equally in need of being reduced.

Real time out of hospital monitoring is currently labor intensive despite automated assistance which, to be objective, is essential. The value of real time monitoring of an increasing number of individuals awaits a proper clinical trial to determine if the technique is of clinical value in most cases.

ECG imaging is in its infancy after many years of research but is now a commercially available technique of unique value. It does require a routine CT or MRI scan for maximum effectiveness so it will remain a specialist investigation for a small number of cardiac patients meantime. Other imaging approaches which do not require scans may be of more widespread value in due course.

Single channel ECG interpretation is of value in many situations where an assessment of cardiac rhythm is required and is readily available for those who can afford to buy electrodes. On the other hand, this technique has an undocumented capacity to advise that an ECG is normal when there may be abnormalities not seen in a single lead.

In summary, automated ECG interpretation is a technique of considerable value but which is still worthy of further research.

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Figure 1. Two by two contingency table illustrating the relationship of automated ECG diagnoses to true diagnoses. False normal and false abnormal interpretations have potential for patient harm in the absence of critical over-reading.

Figure 2. Digitized ECG with automated diagnostic statement “Normal Sinus Rhythm, Normal ECG.” Important T wave inversion is present in the lateral frontal plane leads. Erroneous computer-based diagnoses of “normal” are not limited to the automated algorithm of any single electrocardiograph.

Figure 3. A 3D photo (left panel) can be used to select a torso/heart model from a database (middle panel) with many torso/heart models such that a close fit between 3D model and torso model is found (right panel).

Figure 4. Three orthogonal views on the cardiac anatomy (LAO, RAO, and four chamber) are used to visualize the vector path of a PVC originating from the anterior RVOT region as can be easily deduced from the combination of the LAO with either the RAO or 4 chamber view. The view of the cardiac anatomy can be standardized when the heart orientation is properly estimated.

Figure 1

		Automated ECG Diagnosis	
		Normal	Not Normal
True Diagnosis	Normal	True Normal	False Abnormal
	Not Normal	False Normal *(Small but not 0)*	True Abnormal *(May be incorrect abnormal dx)*

Figure 2

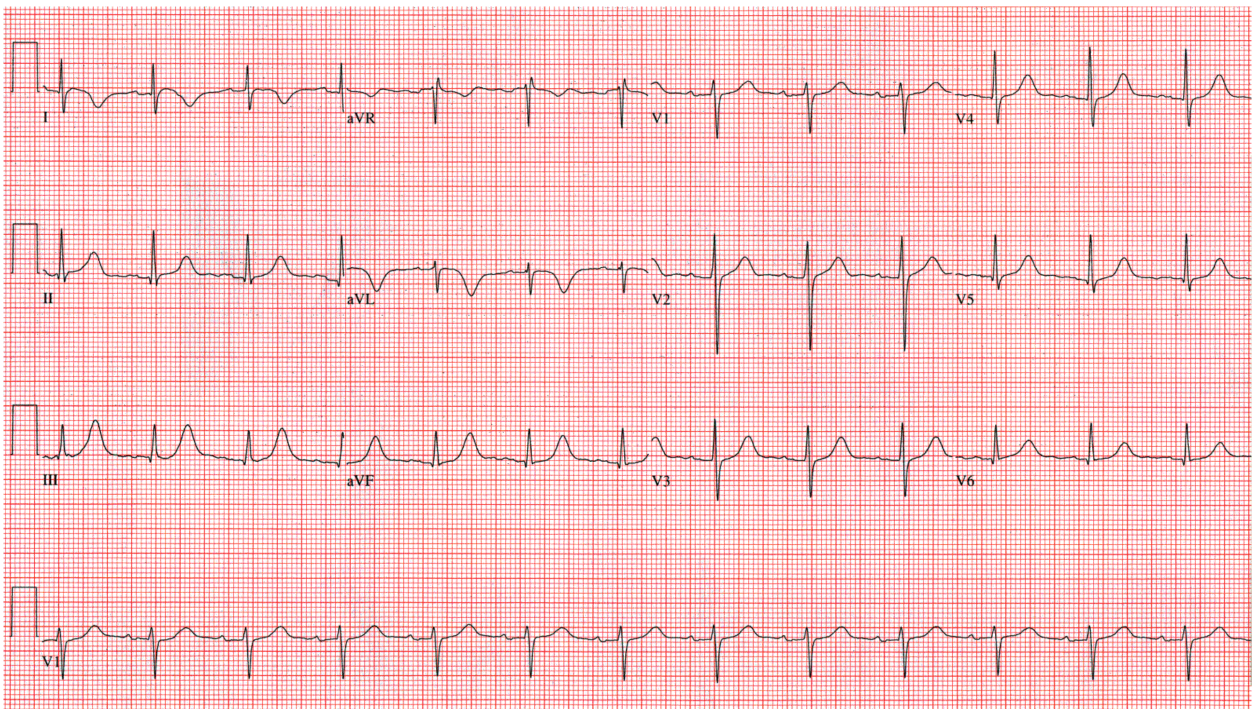


Figure 3

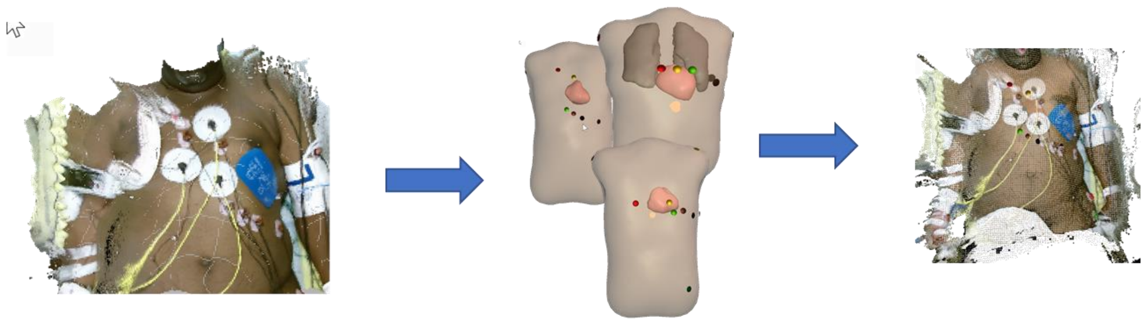
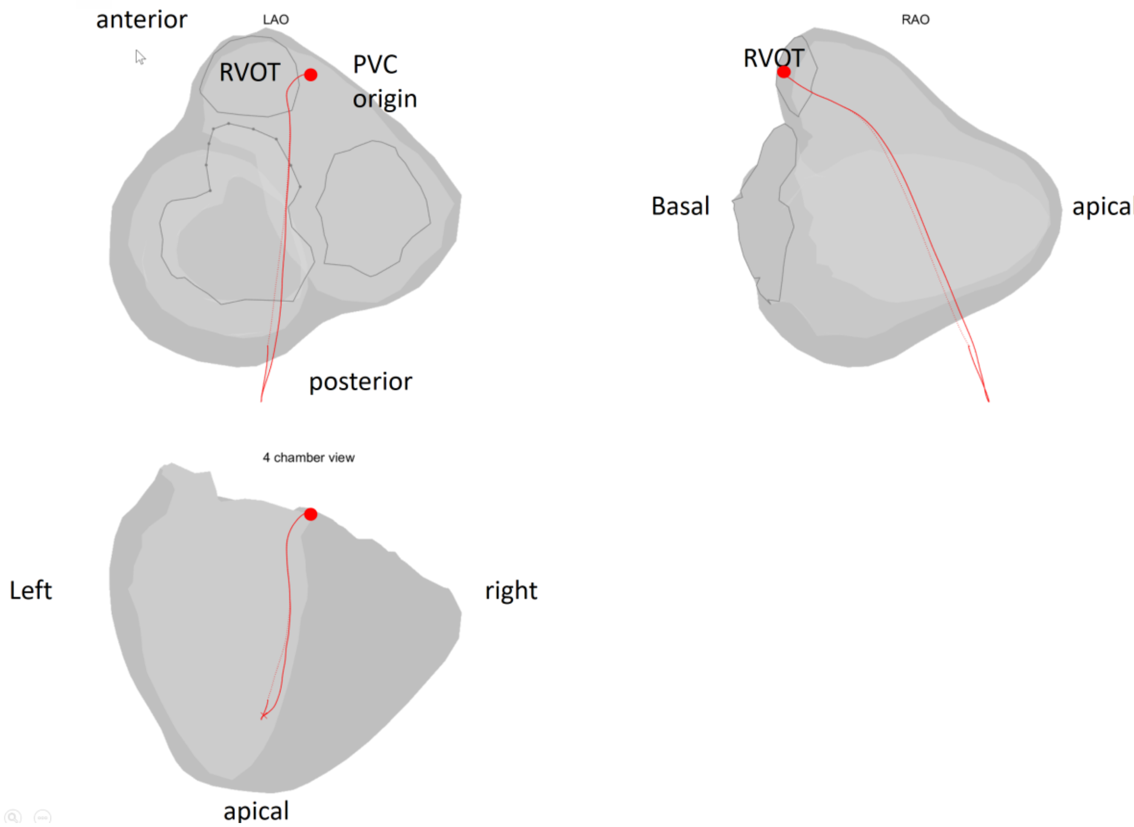


Figure 4


anterior
LAO
RVOT
PVC
origin
posterior
RAO
RVOT
Basal
apical
4 chamber view
Left
right
apical