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Resting 12-lead ECG tests performed by patients at home amid the COVID-19 pandemic — Results from the first 1000 patients

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ABSTRACT

Background: There were surges in the demand for telehealth and home care in the COVID-19 pandemic. A new home ECG testing model was developed and used in the real-world clinical practice.

Methods: Since June 2020, QT Medical, Inc. (Diamond Bard, California) has been providing home ECG testing service by mail. Upon receiving the order from a clinician, an ECG testing kit was sent to the patient by mail. The kit included an ECG recorder, a prepositioned electrode strip of proper size for the patient (determined by the ordering clinician), printed instructions for performing the test, and a return envelope. We reviewed and analyzed the de-identified administrative dataset of the first 1000 ECG tests ordered by 37 medical practices.

Results: Of the 1000 patients served by this mail delivery home ECG testing service, 77.3% were female and 22.7% were male. Their ages ranged from 1 year old to 96 years old, mean 49.5 ± 13.4 years (median 52). 92.9% patients completed their tests with clinical quality ECGs uploaded to their ordering clinician's online accounts. Of those who did not complete the tests, the main reason was they “no longer needed the test”. Failure to complete the test due to technical issues was 1.4%. Only one patient had to repeat the test due to inadequate ECG quality as judged by the ordering physician. The median turnaround time, from the kit being mailed out to the recorder being returned, was 10 days. Overall, 2.2% of the ECG devices were lost in shipping or unreturned by patients.

Conclusion: Of the first 1000 patients who had their ECG tests at homes, it was found that this home ECG testing platform and care model could be reliably used by patients with no training to acquire clinical grade ECG. The current study proved that medical standard, resting 12-lead ECG can be performed by the majority of patients at home.

Introduction

Resting 12-lead electrocardiogram (ECG) is the most commonly used test for the heart. Globally, it is estimated that over 300 million ECG tests are performed every year [1]. Conventionally, resting 12-lead ECG tests are performed by trained technicians in healthcare facilities. This is because the procedures for conducting an ECG test are complicated that require training, skills and experiences. For example, the technicians will have to identify several landmarks on the surface of the patient in order to properly place the electrodes. Furthermore, even highly trained, very experienced ECG technicians can make mistakes in conducting the tests. Common errors are limb leads reversal, which has been shown in 0.5% to 4% of ECG tests performed in the hospital [2], chest leads placed to limb leads [3], and chest leads misplacements occur around 1% [4,5].

Home ECG testing services have been available by mobile service

providers. These ECG tests are performed by technicians who bring ECG machines to patient's homes. Home 12-lead ECG tests conducted by patients themselves had not been available. For the ECG tests conducted by patients themselves or with help from their families to be possible, the ECG system has to be greatly simplified and the user interface has to be very user-friendly. Furthermore, since ECG machines are typically medical equipment for professional use, regulatory clearance for laypeople (patients) use is needed for home use. QT Medical (Diamond Bar, California) received regulatory clearance by the FDA and CE Mark for its 12-lead ECG called PCA 500, with an indication for use: “[PCA 500] is designed to be used by a patient or other layperson at home, or by healthcare workers in non-acute care clinical facilities...” [6]. This is the first medical grade 12-lead ECG system available for both professional use and patient use. In a study comparing PCA 500 with Philips Page-Writer TC70, it was shown that the two ECG systems were “equivalent”

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as determined by the ECG recordings of the same patients by the two systems interpreted by 3 blinded cardiologists [7]. In another study of 2582 newborns, it was shown that the majority of parents were able to use PCA 500 to conduct a full 12-lead ECG test on their own newborn babies with no need for training [8].

In a typical use case of preparing ECG for patient's home use, professional supervision and patient education may be needed before an ECG device is delivered to the patient. However, when the COVID-19 pandemic started in early 2020, the healthcare system was not properly prepared, and many clinical practices were temporarily closed. While the use of telehealth rose dramatically in the pandemic, patients who needed resting ECG tests still had to find a hospital or ECG lab to get their tests. In response to the sudden surge of demand for home ECG testing, an online order, mail delivery home ECG testing service was developed using the PCA 500 device.

In this study, we report the results from the first 1000 patients of this home ECG testing service.

Methods

When the mail order home ECG service was started in June 2020, it was offered to a very limited number of doctor's practices at first. Over time the number of practices grew, and the number of patients served each month increased. By December 2021, the home ECG tests were ordered by 37 physicians or institutions for over 1000 patients. The 37 physicians or institutions ranged very widely in the scope of their clinical practices, including medical weight loss, primary care, concierge medicine, telehealth, cardiology and electrophysiology.

Workflow

To order a home ECG test, the doctor's office first established an online "Dashboard" account with QT Medical at www.dashboard.qtmedical.com. From the Dashboard, the doctor can order ECG tests and receive the ECGs uploaded from patients for review and management. When an ECG order was placed, QT Medical processed the order on the same day or the next business day. An online form was sent to the patient by SMS or email to verify the patient's contact information, and to ensure the patient had internet connection and compatible smart devices (e.g. phones and tablets using iOS or Android systems).

After the patient's responses to the verification form were received, an ECG kit was prepared with the following items: 1) a PCA 500 recorder; 2) an electrode strip of the size specified in the doctor's order; 3) a 1-page printed instructions (Fig. 1); and 4) a postage-paid return envelope. The kits were sent to patients via the postal service, which typically arrived at the delivering address in 2 to 5 days, depending on the destination. For patients who reported that they did not have a reliable internet connection or a compatible smart device, a Samsung A20 smartphone preloaded with the QT ECG app was included in the ECG kit for the patients to use.

When the patients received the kit, they followed the included instructions to download the mobile app, connect the recorder to the smart device via Bluetooth, enter the login information (shown on the 1-page instructions, Fig. 1), place the electrode strip properly, and make 3 ECG recordings. The only technical issue that would stop these processes was when there was a "leadoff alert". When one or more leads did not have adequate skin contact or showed poor signal quality, a "leadoff alert" with a diagram showing which leads were off would pop up in the app. Troubleshooting steps were provided in the pop-up alert for the user to follow. If the steps did not resolve the leadoff issue, the last step was to call the customer service line (with a phone number provided) where a customer service specialist could troubleshoot with the patient on the phone. After an ECG was recorded, it was automatically uploaded to the QT Medical cloud server immediately. The ordering doctor would receive an email notification that ECGs were successfully uploaded and ready for review. The doctor could then login to the dashboard using a

Capture your 10 seconds 12-Lead ECG Complete in 3 minutes

Check Your Kit

Recorder

Electrode Strip

Assigned Login Info

Account: X+@qtmedical.com
Password: []

1. Setup

- Download QT ECG App
- Login to QT ECG App with provided account
- Open app and connect to recorder by Bluetooth
- Attach Electrode Strip

2. Start Recording

- Click Record & wait for 10 second countdown
- See [] for a Successful Recording Upload
- Click "Record" and repeat the processes until 3 recordings are completed

3. Pack Up

- Turn off Recorder by holding the Power button for 5 seconds
- Place Recorder in Provided RETURN Envelope
- Place in Outgoing mail OR drop off at local Post Office (USPS)

For more detailed instruction please see user manual
OR contact our customer support line 855-722-6006

855-722-6006

QT Medical
www.qtmedical.com

Fig. 1. Home ECG test 1-page instructions.

web browser on a computer or a smart device to review the ECG and finalize the ECG report.

Instructions

The electrode strips come in 4 sizes—S, M, L and XL. An electrode template is available as a sizing guide to place on the patient's chest to determine the proper size, if the patient is in the doctor's office. For ordering ECG tests when the patients were not in the doctor's office, we provided a simple way to determine the size of electrode by the patient's sex and weight, using the chart shown in Fig. 2.

Instructions for patients to conduct their ECG test using the ECG kit were provided in 3 ways:

- Print**— One-page step-by-step instructions (Fig. 1) were included in the kit. If the patient wished to read more detailed instructions, he/she could use a smartphone to scan the QR code at the bottom of the 1-page instructions to read a detailed 6-page instructions in pdf online.
- Video**— A 3-min video on YouTube was provided for step-by-step instructions.
- App**— A series of cartoon illustrations of step-by-step instructions was built in the QT ECG app that the patients could view one step at a time, and progressed at his or her own pace by swiping to the next picture.

Customer service and technical support were provided by a phone line which covered 6 AM to 12 AM, Pacific Time, 7 days a week. The phone number was provided in the 1-page instruction and in the app.

Quality control

All patients received a notification by a phone call, text or email upon shipping of the ECG kit. If the patient did not complete the ECG test

Size of Electrode	Men		Women	
	Body Weight (lb)	Body Weight (kg)	Body Weight (lb)	Body Weight (kg)
S	< 110	< 50	< 99	< 45
M	110 – 154	50 – 70	99 – 143	45 – 65
L	154 – 209	70 – 95	143 – 187	65 – 85
XL	> 209	> 95	> 187	> 85

Fig. 2. Table for selecting the appropriate size of electrodes.

within 14 days after receiving the kit, a phone call reminder would be made.

The following processes were in place to ensure good ECG quality as the patients conducted their own ECG tests:

1. Leadoff detection—Whenever there was 1 or more leads off, an alert would pop up in the app and the patient had to go through proper troubleshooting procedures to continue.
2. Bluetooth stability—When there were too many Bluetooth devices nearby, or when the recorder was close to large home electric appliances (such as microwave ovens, air conditioners), there might be interferences. The built-in algorithm of the app would detect such interferences and drop signals, and would reject the recording in such cases.
3. Artifacts—When there were excessive artifacts such as from movements, the data algorithm in the cloud would detect such cases. The algorithm checked for missing leads, dropped data from Bluetooth instability, and noises or artifacts that made the detection of R wave peaks unreliable. Based on the algorithm findings, an ECG signal quality rating of “good”, “fair” or “poor” was provided for each ECG recording.

The doctors, once received the email notifications of ECG uploads, would login to the dashboard to review and finalize the report typically the same day or the next day. When the doctor determined the ECG quality was inadequate for clinical interpretation, the doctor would request for a repeat-test.

Data analysis

We reviewed and analyzed the de-identified administrative dataset of the first 1000 ECG orders. Standard descriptive statistics were provided as means and standard deviations (SD), medians and ranges, where appropriate. Chi square test was used for comparison of proportions and Student t-test was used for comparisons of continuous variables. Statistical significance was determined by a *p* value <0.05.

Results

Of the 1000 ECG tests ordered, 773 were for female patients (77.3%) and 227 were for male patients (22.3%). The patient's ages ranged from 1 year old to 96 years old, mean 49.5 ± 13.4 years (median 52). The age distribution of patients is shown in Fig. 3. The sizes of the electrodes were 38 S, 125 M, 386 L and 450 XL, and 1 infant size electrode.

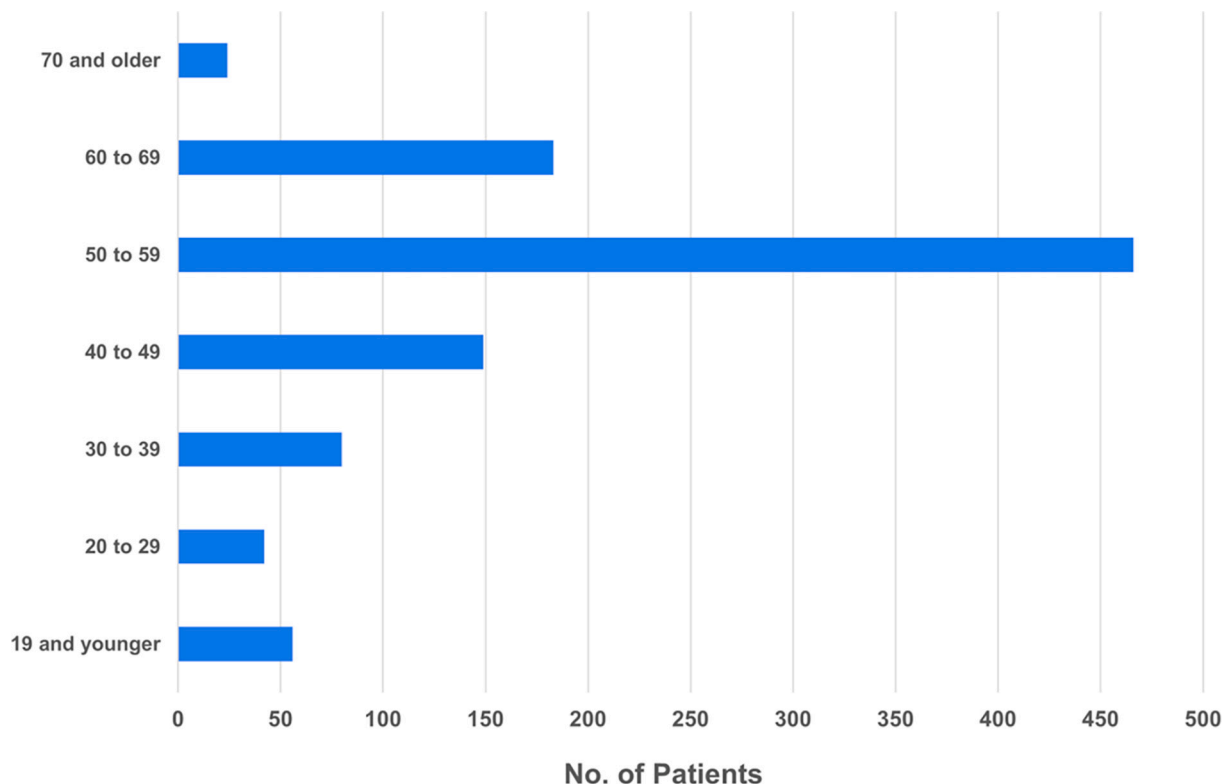


Fig. 3. Age distribution of patients.

Nine hundred twenty-nine (929) patients successfully completed their ECG tests and uploaded their ECGs to the cloud. The overall success rate for completing the test and unloading ECGs was 92.9%. Of the 929 patients who uploaded ECGs, 928 patient's ECGs were considered as the signal quality of clinically adequate for interpretation. One patient's ECG showed excessive noises and the ordering doctor requested for a repeat test. The repeat test was subsequently completed with good ECG quality.

Of the 71 patients who did not upload any ECGs, 27 were because they no longer needed ECG testing, 14 were due to technical issues, 13 due to loss of the ECG kit in shipping, and 17 did not specify the reasons. Therefore, the overall failure rate due to technical issues was 1.4%. When the failure to complete the tests from 27 patients who no longer needed the test, and 13 patients whose ECG kits were lost in shipping, the overall success rate of completing the test was calculated as 929 succeeded out of a total of 960 patients, thus 96.8%.

For the 14 patients who did not complete their ECG due to technical problems, we compared them with the group of remaining 929 patients who completed their tests successfully. Their mean age was 52.9 ± 12.2 years old, not significantly different from the group ($p = 0.35$). There were 4 males and 10 females, and the sex proportion was no different from the group ($p = 0.60$).

Of the 453 patients who reported the make and model of the smartphones or tablets they had, 362 reported to have iPhones, 12 reported iPads, 79 reported to have Android phones. Seventy-seven (7.7%) patients did not have compatible smartphones and requested QT Medical to send a provision phone (Samsung A20 preinstalled with QT ECG app) with the ECG kit. Of these patients who used provision phones to conduct their tests, all completed their tests and uploaded ECGs successfully.

Two hundred fifty-four (25.4%) patients called the customer service line, including 191 calls for general inquires (such as: Is my smartphone compatible? When is my ECG kit arriving? When should I do my test? Are my ECGs uploaded?), 34 calls for internet and mobile device issues (Bluetooth connection, internet connection), and 29 calls for issues relating to the electrodes and ECG recorders. Combining the connectivity and electrode/recorder issues, the overall call for technical issues was 63, or 6.3%.

Twenty-three (2.3%) patients reported electrode problem shown as "lead-off" alerts on the app, which could not be resolved by the troubleshooting instructions provided. These patients were sent with replacement electrodes and were subsequently all able to complete their tests successfully.

Of all the orders which were shipped out, 22 (2.2%) did not return the recorders back to QT Medical. Among these unreturned recorders, 13 patients stated that they never received the ECG kit and did not do their ECG test (no ECG uploaded to the cloud). Nine patients completed their ECG tests and claimed that ECG recorders were sent back to QT Medical in the included return envelope, but their recorders were never received.

The overall turnaround time, from the time the ECG kit was shipped out to the time the recorder returned to QT Medical, was mean 12.6 ± 12.7 days, median 10 days, and ranges from 2 days to 176 days. The longest turnaround of 176 days was because the patient thought the recorder was lost, but later found the recorder and returned, after almost 6 months.

Discussion

In this study, we found that medical standard resting 12-lead ECG tests could be performed by patients at home with no prior experience or training. The main findings of this study of the first 1000 patients who had their home ECG tests were: 1) the great majority of patients completed their tests at home with good quality ECGs; 2) <2% patients had technical problems that they could not complete their tests; 3) Home 12-lead ECG testing is feasible for both female and male patients of a very wide age range.

Although mail order 1-lead ECG or Holter monitor testing for patients at home has been reported [9], in an extensive search of the medical literature and internet, there has not been a mail order standard 12-lead ECG home testing service reported, or available as a clinical service. Home ECG testing by patients with very limited involvement of healthcare professionals requires the new ECG technology that makes the test itself very simple, user-friendly, and reliable. Using only printed materials, as-needed access to a short video, step-by-step instructions in the app, patients can receive, apply, and record and upload clinical grade data for standard resting 12-lead ECG.

This study shows that using pre-positioned and preconnected electrodes in a single piece, together with 3 pull-out limb leads, the chance of having leads misplacements or wrong connections, even by patients who had no training, could be greatly reduced. This much simplified way of performing an ECG test using prepositioned electrodes, combined with a super compact ECG recorder that could be easily mailed to the patients and mailed back after use, made it possible for this new clinical use model of ECG testing at home by patients. Furthermore, all ECGs were collected centrally in a HIPAA-compliant cloud server, thus there would be no risk of misplacement or loss of the ECG copies, and the results could be viewed instantly and remotely.

Previous studies have shown that Holter monitors could be mailed to patients to self-apply the tests at home [9,10]. There has been no studies or clinical practice on mail delivery home 12-lead ECG testing. With the accelerated adoption of telehealth, home testing and remote monitoring in the COVID-19 pandemic, we found that 12-lead ECG can also be offered as a test for patients to complete at home. The current study provides the evidence that the great majority of patients, with a very wide age range, could complete their ECG tests with good quality data for clinical interpretation.

Single-lead ECG devices, such as Apple Watch, has been widely accepted for personal or home use [11]. These wearable or portal ECG devices have been shown to be useful for screening or detecting arrhythmias, such as atrial fibrillation [12]. However, medical standard resting 12-lead ECG has not been used as a diagnostic or screening test for home use. It would be important to know why home 12-lead ECG tests were ordered for these patients, but we did not collect data on the clinical indications for the tests. From our general discussions with the ordering physicians, we learned that primary care physicians used the home tests for pre-operative evaluation, and for some patients who did not want to come to office or go to a hospital or medical office to get an ECG test. Medical weight loss practice physicians used home ECG tests for general assessment and prior to initiation of certain medications. Telehealth physicians used home ECG tests for patients who were seen by video visits. Cardiologists and electrophysiologists used home ECG tests for post-procedure follow up, initiation of new therapy, or between scheduled visits.

If it weren't for the pandemic, the needs for home ECG testing might not have been so clear. In the pandemic, not only ECG testing is going to homes, many patients are now hospitalized at home (the so called "Hospital at Home" now offered by over 200 hospitals) [13]. Many changes occurred in healthcare in response to the pandemic, such as telehealth and remote patient monitoring, are expected to continue beyond the pandemic. By introducing 12-lead ECG to home users, this useful medical test can be made more available and accessible to patients. Many home medical tests, when first introduced, received resistance and skepticism. Glucometers, blood pressure measures, genetic tests and HIV tests are some examples of home testing now routinely by patients in their homes.

It is too early to tell if home 12-lead ECG testing will be used only because of the restrictions caused by the pandemic, for its convenience, or there will be additional clinical and economic values to such practice. Single-lead ECG has demonstrated its clinical usefulness for arrhythmia detection [12]. Whether home 12-lead ECG tests can be an alternative to ECG tests in hospitals and medical offices requires further investigation. From an economic standpoint, because the reimbursement of an ECG

test by the existing CPT codes is low, home ECG testing may seem to be more costly than an office ECG test at the first glance. However, the costs of the patient's time, travel, parking, etc. should also be considered. Therefore, more studies on the impact on clinical outcomes and cost-effectiveness of home ECG testing are needed.

The current study had a large sample size of 1000 patients from 37 medical practices. The patient population was very diverse, with ages ranging from 1 to 96 years old. Furthermore, the physician practices were diverse as well, ranging from medical weight loss, children's hospitals, cardiology offices, primary care practices, telehealth providers and home care agencies.

Limitations

We did not examine each of the ECGs for their signal quality. However, the doctors were all aware that they should contact QT Medical to have a repeat ECG for those with signals of inadequate quality. Requests for repeat ECG due to inadequate ECG quality occurred in only 1 patient (0.1%). In a subset of the 1000 patients cohort reported in the current study, Stanford Cardiology group reported their results of 146 ECG recordings from 31 patients. The ECG quality was independently rated by 2 cardiologists. They reported that all patients had recordings suitable for clinical decision-making, including 68% of 'excellent' recording and 32% of 'good recording' [14].

Data analyzed in the current study were de-identified records of ECG orders fulfilled by QT Medical. Information on race/ethnicity, weight, and medical history were not collected thus could not be analyzed or reported in the current study.

Conclusion

In the early phase of the COVID-19 pandemic, a new resting 12-lead ECG test delivery model was developed and tested in the real-world clinical practice. Of the first 1000 patients served by this mail delivery home ECG testing service, 92.9% patients completed their tests with good quality ECGs, and the technical failure rate was under 2%. The current study proved that medical standard, resting 12-lead ECG can be performed by patients at home, even with no training. This service delivery model will be extremely instrumental as telehealth practice continues to play an increasingly important role, remote patient monitoring becomes the accepted norm for chronic disease management, and hospital at home emerges as the alternative for care of acute illnesses.

Author contribution

Ruey-Kang Chang, MD is the only author of this paper. Dr. Chang is responsible for the entire study, and all the contents presented in the paper.

Informed consent and patient details

This study was deemed a performance review, quality improvement study with no generalizable information by the Chair of IRB at The Lundquist Institute at Harbor-UCLA. It is not a "research study", thus is exempt for a full IRB review.

Submission declaration and verification

This paper or any of its contents have not been published previously. The paper is not currently under review or consideration for publication by other medical journals.

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Disclosure

Dr. Chang is founder and CEO of QT Medical, Inc.

Declaration of Competing Interest

Ruey-Kang Chang, MD is the founder and CEO of QT Medical. This is stated in the author affiliation, and Disclosure sections of the manuscript.

References

- [1] J-m Kwon, Cho Y, Jeon K-H, Cho S, Kim K-H, Baek SD, et al. A deep learning algorithm to detect anaemia with ECGs: a retrospective, multicentre study. *Lancet Digital Health* 2020;2:e358–67.
- [2] Rudiger A, Hellermann JP, Mukherjee R, Follath F, Turina J. Electrocardiographic artifacts due to electrode misplacement and their frequency in different clinical settings. *Am J Emerg Med* 2007;25:174–8.
- [3] Pastor JA, Castellanos A, Myerburg RJ, Pallares DS. Apparent misplacement of chest electrode on left leg: a unique example of electrode confusion. *Am J Cardiol* 2001;88:829–30.
- [4] Zatuchni J, Elko PP. "Switched" Precordial leads. *Circulation* 2001;103:E90–e90.
- [5] Rehman M, Rehman NU. Precordial ECG lead mispositioning: its incidence and estimated cost to healthcare. *Cureus*. 2020;12:e9040.
- [6] 510(k) Summary of QT ECG. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180157pdf;2018.
- [7] Roy SK, Shah SU, Villa-Lopez E, Murillo M, Arenas N, Oshima K, et al. Comparison of electrocardiogram quality and clinical interpretations using prepositioned ECG electrodes and conventional individual electrodes. *J Electrocardiol* 2020;59:126–33.
- [8] Lin HJ, Lan YT, Silka MJ, Halnon NJ, Villa-Lopez E, Arenas N, et al. Home use of a compact, 12-lead ECG recording system for newborns. *J Electrocardiol* 2019;53:89–94.
- [9] Benjamin H, Bischof M, Goldshtein D, Fecteau P, Newman D. A pandemic response to home delivery for ambulatory ECG monitoring: development and validation. *J Electrocardiol* 2021;64:72–5.
- [10] Steinhubl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS, et al. Effect of a home-based wearable continuous ECG monitoring patch on detection of undiagnosed atrial fibrillation: the mSToPS randomized clinical trial. *Jama*. 2018;320:146–55.
- [11] Raja JM, Elsagr C, Roman S, Cave B, Pour-Ghaz I, Nanda A, et al. Apple watch, wearables, and heart rhythm: where do we stand? *Ann Transl Med* 2019;7(417–417).
- [12] Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, et al. Large-scale assessment of a smartwatch to identify atrial fibrillation. *N Engl J Med* 2019;381:1909–17.
- [13] Achanta A, Velasquez DE, Grabowski DC. Hospital at home: paying for what it's worth. *Am J Manag Care* 2021;27:369–71.
- [14] Chubb H, Motonaga K, Goodyer WR, Trela A, Hanisch D, Boramanand N, et al. Abstract 11134: the feasibility of a mail-out 12-Lead ECG in a pediatric cardiac electrophysiology telemedicine environment. *Circulation*. 2021;144 (A11134–A11134).