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Wearable technology and the cardiovascular system: the future of patient assessment

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The past decade has seen a dramatic rise in consumer technologies able to monitor a variety of cardiovascular parameters. Such devices initially recorded markers of exercise, but now include physiological and health-care focused measurements. The public are keen to adopt these devices in the belief that they are useful to identify and monitor cardiovascular disease. Clinicians are therefore often presented with health app data accompanied by a diverse range of concerns and queries. Herein, we assess whether these devices are accurate, their outputs validated, and whether they are suitable for professionals to make management decisions. We review underpinning methods and technologies and explore the evidence supporting the use of these devices as diagnostic and monitoring tools in hypertension, arrhythmia, heart failure, coronary artery disease, pulmonary hypertension, and valvular heart disease. Used correctly, they might improve health care and support research.

Introduction

To predict, prevent, diagnose, and treat cardiovascular diseases, physicians require an assessment of symptoms, activity, comorbidity, and context before prescribing targeted investigations and recommendations for treatment. The patient also needs information on what the physician considers their state of health to be, the basis for this view, and the risks and benefits of any treatment. Here we examine the potential for wearable technologies to enhance care in all these areas of cardiovascular medicine. We review devices that are accessible to the public, the underlying sensor technologies, the data acquired, and their application, providing a perspective on where these tools could sit within cardiovascular health care, the challenges that need to be resolved, and the studies required to confirm their utility. We also discuss the incorporation of sensor technologies into wearable clothing, apparel, and cutaneous patches and how these have been applied to clinical research in cardiovascular medicine.

Devices, data, and apps

Wearable medical devices such as ambulatory blood pressure and Holter (GEHealthCare, Chicago, IL, US) electrocardiogram (ECG) monitors, have been used in health care for decades; nowadays, devices purchased by the public, including smartphones, wristbands, watches, scales, shirts, rings, and eyeglasses are equipped with this type of functionality (figure 1). Patients instinctively recognise the potential of these technologies, and often present their doctor with health app-derived data. Although doctors recognise their potential usefulness, they are uncertain about the evidence base and appropriate use of such data. Measurements range from established parameters such as heart rate, blood pressure, and oxygen saturation, to step counts, minutes of activity, heart rate variability, and intrathoracic impedance. Wireless technology allows multiple sensors to integrate different signals, enabling body area sensor networks that can augment measurement accuracy (eg, heart rate) or compute parameters indirectly by combining different signals (eg, blood pressure). WiFi connectivity permits near-constant data upload to cloud storage, enabling continuous and simultaneous monitoring of multiple parameters, which can alert clinicians to significant changes (figure 2). A summary of relevant wearable sensor technologies is shown in the table. Software apps are designed to process, curate, and present data from raw sensor signals into relevant information within a user-friendly graphical display, usually on a smartphone, smart watch, or linked to a personal computer. These data can be presented in familiar formats such as resting heart rate and daily step count, with multiple sensor signals combined by the app and displayed in device-specific formats (eg, the Apple Move Ring, the Garmin Fitness Age, or the Fitbit Sleep Score). Apps can also provide user functions, such as providing health advice based on physical activity

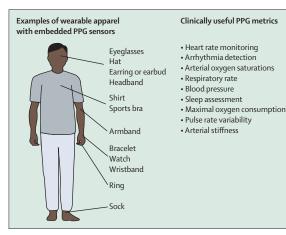


Figure 1: The use of PPG in wearable apparel and its application to cardiovascular health assessments

PPG has been adapted to a variety of wearable apparel in published literature (left panel) and how signals generated from this sensor can be applied to cardiovascular health assessments (right panel). PPG=photoplethysmography





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Correspondence to: Dr Paul D Morris, Department of Infection, Immunity and Cardiovascular Disease, University of Sheffield, Sheffield 5102RX, UK paul.morris@sheffield.ac.uk levels or forwarding relevant sensor data directly to health-care providers.

All devices that claim to provide measurements of human physiology need to show safety, accuracy, reliability, and reproducibility in a variety of settings. An example of this is blood pressure devices, for which stringent, overarching guidelines are offered by standards organisations such as the International Organization for Standardization.¹ These validating bodies approve and regulate the use of such devices to ensure that health app-derived data can be relied on by patients and health-care providers to accurately identify or exclude cardiovascular disorders. Here, there is a specific need for greater involvement of clinical bodies in the development of regulatory guidelines and evaluation methods.

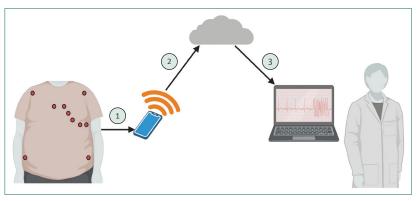


Figure 2: ECG data transmission from wearable technology

ECG data are sent via Bluetooth to a device with internet connectivity (eg, a mobile phone; step 1). Data are transferred to the cloud storage database from the device via internet connectivity (step 2). A local platform connects to the cloud storage database and the ECG recordings are reviewed by a health-care provider. ECG=electrocardiogram

Symptoms

Symptom context (duration, frequency, and association with physical activity, eating, sleeping stress, etc) is crucial to medical decision making. Traditionally, this information is obtained by asking patients to recall what they were doing when they had symptoms. This information is subjective and might be misleading, especially for patients with memory or communication difficulties. Mobile and wearable devices allow the user to record symptoms and physical parameters simultaneously and has been successfully applied to mental health and Parkinson's disease.2.3 The MyHeart Counts App study showed the feasibility of large-scale physical activity measurement through self-reported questionnaires, and smartphone and wearable movement data from accelerometer and gyroscope sensors with a global positioning system (GPS). This study recruited 48968 participants and discovered relationships between patterns of physical activity and self-reported health.⁴ The authors did, however, observe recording fatigue, limiting long-term effectiveness. Nevertheless, there is potential to discriminate cardiac from non-cardiac symptoms and identify patients warranting further assessment, investigations, or monitoring.

Activity

Cardiovascular diseases such as heart failure and angina are classified according to the level of physical activity a person reports; this, in turn, drives important treatment decisions. Although useful, this approach is subjective and imprecise. Wearable device data provide objective measurements over long periods of time. Physical activity can be quantified by accelerometers to measure parameters such as step count, or more sophisticated

	Sensor principle	Applications	Wearable device
Accelerometer	Force sensor to measure the acceleration in a single or multiple directions	Movement classification and recording: step counting, physical activity, and fall detection	
Ballistocardiography	Measures the body's mechanical recoil from ventricular contraction to quantify cardiac outputs and dynamics	Cardiac energetics and cuffless blood pressure measurement	Wristwatch or wristband
Electrocardiogram	Measurement of electrical activity of cardiac impulse	Heart rate monitoring, and heart rhythm assessment	Wristwatch or shirt or vest
Impedance- plethysmography (bioimpedance)	Detect changes in blood electrical conductivity to measure cardiovascular characteristics (radial pulse volume, and blood volume in ascending aorta)	Cuffless blood pressure measurement, and measurement of intrathoracic impedance in heart failure	Wristwatch, wristband, shirt, or vest
Magnetoplethysmography or giant magnetoelastic effect	Hall effect sensors track cardiovascular activity via movement of magnets, and giant magnetoresistance sensors use the diamagnetic property of water to detect magnetic flux created by pulsatile blood flow	Cuffless blood pressure measurement	Wristwatch or wristband
Phonocardiogram	Detects subaudible vibrations created through the opening and closing of heart valves	Heart rate	Patch
Photoplethysmography	Optical sensor to detect blood volume changes within the microvascular structure of perfused tissue	Heart rate and rhythm, blood oxygen saturation, VO ₂ max, and cuffless blood pressure measurement	Wristwatch, wrist band, or eyeglasses
Remote dielectric sensing	Quantifies the dielectric coefficient of tissues, which correlates with fluid concentration	Detection of pulmonary oedema	Shirt or vest

GPS-based measurements of speed, location, and terrain tracking over weeks or months. Ready access to such detailed and objective data at a patient-specific level will allow for a more personalised approach to medicine in terms of individually tailored exercise advice, as well as monitoring response to treatment, which is consistent with the concept of precision medicine.

Heart rate

The relationship between heart rate and cardiovascular risk is well established, with long-term studies showing an association between a higher resting heart rate and cardiovascular disease and adverse clinical outcomes.5 Heart rate monitors using chest strap electrodes have been used in sports for decades. Photoplethysmographybased measurements from wrist-worn devices provide continuous monitoring with greater convenience. Although individual device accuracy varies, recent devices typically utilise peak detection algorithms which report median error ranges of less than 5% in comparison with telemetry in healthy individuals.6 Improvements in photoplethysmography sensor miniaturisation has enabled incorporation into other common apparel, including rings and eyeglasses (figure 3).^{7,8} Peak detection algorithms can be confounded by irregular rhythms-including atrial fibrillation and premature atrial or ventricular contractions-which produce photoplethysmography signals that vary from the underlying electrical activity. This can lead to incorrect measurements of heart rate. Sophisticated algorithms have been developed to reduce the errors of photoplethysmography signals in this context.9 Modern smartwatches can offer ECG recording functions alongside limited rate and rhythm analysis software.¹⁰ The development of self-powered wearable devices using triboelectric nanogenerator technology with pulsesensing capabilities also shows the potential for uninterrupted heart rate monitoring over prolonged periods.¹¹ By harvesting the biomechanical energy released by the radial artery pulse in the wrist, the selfsustaining sensor converts the mechanical movement into energy as well as a signal with a strong agreement with ECG ($R^20.98$).

Respiratory function

Commonly used respiratory parameters can also be measured by wearable devices. Photoplethysmography can be used to measure oxygen saturation. Many fitness devices also estimate maximal oxygen consumption during exercise (VO₂ max). Respiratory rate can be measured with smart clothing using accelerometer, gyroscopic, or magnetometer-based detection of chest wall movements, circumference, or impedance pneumography.¹² There has been a significant rise in the use of wearable devices to assess respiratory function since the COVID-19 pandemic.¹³

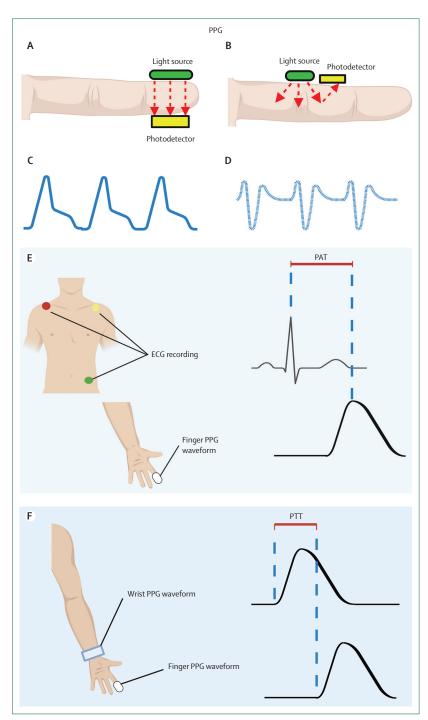


Figure 3: PPG sensor principles

The intensity of either transmitted (A) or reflected (B) non-absorbed light reflects variations in blood volume. A range of cardiovascular metrics can be calculated from the dynamic signal intensity (C). Analysis of derivatives of this signal (D) yield additional information about blood acceleration, pressure, and arterial stiffness. PPG signal analysis can be combined with other sensor modalities to generate parameters such as PAT (the time interval between the R wave and the PPG waveform) (E) and PTT (the time interval between the troughs of the proximal distal PPG waveforms) (F), which can be used to estimate blood pressure. ECG=electroardiogram. PPG=photoplethysmoorgaphy. PAT=pulse arrival time. PTT=pulse transit time.

Ultrasonography

Ultrasound is central to cardiovascular assessment in secondary care but is not widely available in primary care. Patch-based ultrasound devices now enable continuous haemodynamic measurements of arterial Doppler waveforms and can detect changes in stroke volume.¹⁴ Obtaining such data in the community without the need for constant specialist oversight and interval hospital visits might enhance early detection of haemodynamic deterioration, particularly in valvular and ventricular disease.

Promoting physical activity to reduce cardiovascular disease

Physical inactivity is considered the fourth leading risk factor for global mortality, associated with 6% of deaths and 30% of ischaemic heart disease worldwide.¹⁵ In patients with symptomatic disease, activity improves event-free survival and might delay disease progression.¹⁶ Despite these messages, global estimates suggest more than 25% of people do not achieve recommended activity levels.¹⁷ Multiple smartphone apps have been developed to reinforce healthy behaviours. One example is Active 10, which records activity levels.¹⁸ Analysis of 129010 users showed a significant improvement in physical activity, including those with a very low initial baseline activity levels. There are many other similar initiatives, including the Smart Walk and MyHeart Counts apps.

Wearable technology lends itself to personalised feedback and guidance. The Personal Activity Intelligence (PAI) system personalises activity targets using maximal heart rate data, questionnaires, and clinical data, as opposed to standard generic targets (10 mins brisk walking, 10000 steps, etc).¹⁹ In 39298 participants, obtaining 100 PAI points per week was associated with a 23% reduction in cardiovascular disease mortality in women and 17% in men when compared with those achieving zero PAI points per week.¹⁹ A systematic review of studies investigating the effect of personalised mobile health interventions in older adults showed the potential to improve step count and sedentary time, although none achieved statistical significance.²⁰

Hypertension

Hypertension is the leading preventable cause of death worldwide.²¹ Manufacturers have sought to incorporate blood pressure measurements into commercially available wearable devices. Several sensor modalities have been assessed and developed in preclinical and clinical stages (table). Devices are now available to the public with the purpose of providing validated measurements of blood pressure from the wrist. The Omron HeartGuide, the first clinically validated wristwatch blood pressure device, uses an inflation cuff within the strap to measure blood pressure (Omron Healthcare, Kyoto, Japan).²² It compared well with office-based sphygmomanometer measurements (difference in systolic blood pressure <5mm Hg [SD 8]), but less well against simultaneous ambulatory blood pressure monitoring outside the office $(3 \cdot 2 \text{ mm Hg [SD 17]})$.²³ More recently, Huawei have released an inflatable cuff-based blood pressure wristwatch that has also shown sufficient accuracy to meet the Association for the Advancement of Medical Instrumentation, European Society of Hypertension, and International Organization for Standardization universal standards (differences between test and reference systolic and diastolic blood pressure -1.4 mm Hg [SD 6.47] and -0.2 mm Hg [SD 5.85], respectively);²⁴ however, the manufacturer states that the data obtained by the device should not be used for medical research, diagnostic, or treatment purposes and are for reference use only. Both products are listed as validated blood pressure devices by Science and Technology for Regional Innovation and Development in Europe, an international organisation associated with the European Society of Hypertension, International Society of Hypertension and World Hypertension League that aims to improve the accuracy of hypertension assessment, diagnosis, and management by providing guidance and practice tools along with the latest scientific and validation evidence.25 The Aktiia bracelet (Aktiia, Neuchâtel, Switzerland) is a cuffless blood pressure device that derives measurements from an optical photoplethysmography sensor. It requires an initial calibration step against a separate sphygmomanometer device, and this must be repeated intermittently. Given that there are currently no guidelines for the validation of cuffless blood pressure devices, the Aktiia bracelet was validated against an adapted international standard (difference between test and reference systolic and diastolic blood pressure 0.46 mm Hg [SD 7.75] and 0.39 mm Hg [SD 6.86], respectively).²⁶

These developments highlight the willingness of the commercial sector to generate and make available validation data in response to calls for better regulation.27 Although these wearable devices might be more comfortable and practical for home use, and are likely to avoid white coat hypertension due to the stress of the clinical environment, they do present new challenges for validation; body position (particularly the position of the wrist and arm relative to the heart) and activity have been shown to influence the blood pressure measurement.^{23,28} Because of this, and the fact that these devices are validated against traditional office-based measurements, the instructions for use advise only recording blood pressure while in an upright, seated, relaxed position. This is an important point for physicians to consider when interpreting blood pressure recordings from wearable devices. As the use of these devices expands it might be beneficial for international organisations to develop and adapt standards to consider validation of wearable sensors in the ambulant patient.

Arrhythmia

Prolonged ECG monitoring devices such as Holter monitors are cumbersome, can only be worn for short

periods, and might miss paroxysmal arrhythmias. Furthermore, implantable devices (loop recorders) are invasive and require specialist training to insert and analyse. Wearable technology can be advantageous for arrhythmia detection; several modern smartwatches use photoplethysmography sensors, and more recently ECG technology, to detect heart rate and rhythm. Photoplethysmography sensors can detect atrial fibrillation, the most common significant arrhythmia, with a sensitivity and specificity of 91-100% in comparison with ECG.29,30 The Apple Heart study investigated the use of smartwatchbased arrhythmia detection in 419297 participants (Apple. Cupertino, CA, USA).³¹ Through the watch's photoplethysmography sensor, if an irregular cardiac rhythm was detected, a notification advised a telemedicine consultation and to wear an ECG recording patch for 7 days. Within a median monitoring period of 117 days, 2161 participants received an irregular pulse notification (0.52%). After exclusions, 450 participants returned usable ECG data, 34% of which were confirmed to have atrial fibrillation. Although undergoing simultaneous ECG monitoring, the positive predictive value of subsequent irregular pulse notifications was 84%. In a similar study performed across China, 246541 people downloaded a mobile atrial fibrillation app that used data from a photoplethysmography wristband or watch. Of these, 187912 people used the app via their smartphone and 0.23% received a notification of a suspected atrial fibrillation. After follow-up, the positive predictive value of the photoplethysmography detected signal was 91.6%.³² These studies were the first demonstration of a general population-wide approach to arrhythmia screening using a commercially available wearable device with telemedicine. Given that atrial fibrillation was diagnosed in asymptomatic participants, future research should consider whether major sequelae such as the incidence of stroke can be reduced by this approach in adequately powered prospective controlled trials.

Heart rate-sensing wearable technology has also been applied to multiple types of apparel, leading to a variety of potential arrhythmia detection modalities. The smart shirt design Cardioskin (BioSerenity, Paris, France) can record a 15 lead ECG continuously with quality comparable to Holter monitors.33 ECG vests or chest straps worn for 28 days were investigated in the assessment of 146 patients with a diagnosis of cryptogenic stroke.³⁴ Atrial fibrillation was detected in 21.9% of patients, with the number needed to screen to detect one incidence of atrial fibrillation being 4.8 patients. Smart eyewear might also provide additional opportunities. A smartphone camerabased program can detect atrial fibrillation through facial photoplethysmography using variations detected in skin colour, with a sensitivity of 95% and specificity of 96% in discriminating atrial fibrillation from sinus rhythm.³⁵ This introduces the potential for facial photoplethysmography to be developed for eyeglasses.8 Miniaturisation of photoplethysmography has led to a heart rate monitoring ring (Oura Health, Oulu, Finland), but it has only been tested in sinus rhythm to date.⁷ A variety of wearable designs might soon become available for consumer-driven arrhythmia monitoring, allowing device selection that best suits patient preference and comfort.

Heart failure

In the management of congestive heart failure (CHF), reduced activity levels are predictive of worse outcomes, including mortality.36 Wearable actigraphy devices have been validated against patient diaries and physical activity during cardiac rehabilitation.37 Wrist-based actigraphy enabled the dichotomisation of 50 patients with CHF into higher and lower physical activity groups, with the lower physical activity group having a five times higher rate of hospital admission.³⁸ A systematic review of wearable actigraphy monitoring in patients with CHF revealed reduced physical activity was associated with poor clinical outcomes, mortality, and morbidity.39 The AWAKE-HF study, which assessed the effect of combination sacubitril and valsartan versus enalapril on quality of life in patients with heart failure with reduced ejection fraction, used wearable actigraphy to detect physical activity. The study showed no significant difference in activity between either treatment group, despite an improvement in patientreported quality of life in the group who received sacubitril and valsartan, suggesting a divergence between objectively gathered patient data and subjective outcomes.40 A band electrode design integrated in shirts or vests can measure and detect changes in intrathoracic impedance which correlates with weight reduction secondary to diuresis (figure 4). Monitoring this parameter might predict hospital admission more reliably than change in weight alone.41,42 One study investigated heart failure patients wearing such a vest for only 5 min a day after discharge from hospital, with data transmitted via Bluetooth and mobile phone.43 For 106 participants, there were 64 heart failure events (18 readmissions and 46 up-titrations of diuretic medication). An algorithm analysing intrathoracic impedance was consequently developed, which showed 87% sensitivity and 70% specificity in identifying patients with recurrent admissions due to decompensated heart failure. Remote dielectric sensing (ReDS) uses electromagnetic signals emitted across the chest. It correlates well with pulmonary congestion and has been developed for home monitoring and wearable apps.4445 Daily ReDS monitoring in 50 patients with CHF for 90 days, with appropriate medication changes, resulted in an 87% reduction in admissions compared with the premonitoring period, and 79% reduction compared with the post-monitoring period.46 Retrospective studies corroborate these findings.47,48

Ischaemic heart disease

Despite the evidence supporting physical activity and cardiac rehabilitation after acute coronary syndrome (ACS) and revascularisation, studies using activity-monitoring

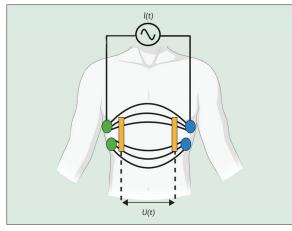


Figure 4: Intrathoracic impedance measurement technique Electrodes on both sides of the chest (green and blue) pass a constant current across the chest, *I*(*t*), with an impedance detection circuit (yellow) measuring the voltage drop caused by intrathoracic blood volume *U*(*t*).

devices report daytime sedentary periods in excess of 9 h within the first month of recovery.49,50 A prospective study of 72 patients with stable ischaemic heart disease taking optimal medical therapy demonstrated an improvement in exercise time following a 6-week cardiac rehabilitation programme over a 12 month follow-up period; however, the proportion of patients who met guideline recommendations of physical activity targets did not change significantly and sedentary time remained high throughout.51 Patients with the lowest level of sedentary time made the most improvement in physical activity, with the reverse also being true. A study of 330 patients who provided wristwatch-based accelerometer data following discharge after an ACS revealed that only 16% conformed to exercise guidelines.⁵² Simply wearing an activity monitor might encourage physical activity. Small randomised controlled studies of patients attending cardiac rehabilitation demonstrate that wearable pedometers improved adherence with physical activity advice, with improvements in psychosocial health and self-reported function;53,54 however, these studies also included support from specialist staff which might have contributed to the results. The UP-STEP ACS study utilising the Fitbit Charge 2 (Fitbit, San Francisco, CA, USA) will be the first to assess the effect of wearable physical activity monitoring in improving exercise capacity and modifying cardiovascular risk factors in a randomised setting in recovering patients with ACS.55

Pulmonary hypertension

Pulmonary hypertension is a debilitating condition with significant morbidity and mortality, and high levels of fatigue and reduced physical activity. Accelerometer-based sensors detected reduced daily step counts, distance walked, and time spent in moderate to vigorous physical activity, with good correlations with established clinical parameters of physical activity (eg, 6 min walk test and quality-of-life questionnaires).56-58 This does not always correlate with right heart catheter measurements and echocardiographic changes, suggesting that fatigue and reduced physical activity might be the result of a complex multi-system response.59 The FIT-PH study aims to evaluate the correlation of Fitbit wristband activity data with implanted pulmonary artery pressure monitoring devices and their relationship to the patient's clinical condition and quality of life (NCT04078243). When used to monitor response to a physical training intervention, a study using wrist-based accelerometers showed an increase in physical activity in the intervention group. along with an improvement in 6 min walk distance (6MWD).60 Using armband accelerometers, inspiratory muscle training failed to show an increase in daily physical activity levels, 6MWD, or questionnaire responses against controls.61 Drug and device trials in pulmonary hypertension have incorporated activity monitoring as outcomes. Inhaled nitric oxide therapy was assessed in a randomised, double-blind, placebo-controlled trial.62 Using armband accelerometers, 23% of the people in the treatment group showed a significant improvement in physical activity following an 8 week treatment period, whereas no improvement was observed in the placebo group; 71% of people in the placebo group had a significant decrease in physical activity versus 39% in the treatment group.⁶² The TROPHY1 feasibility study, investigating the use of pulmonary artery denervation, showed an improvement in physical activity monitored through wearable accelerometery alongside conventional metrics.63 Other recent trials in pulmonary hypertension such as VENTASTEP,64 which investigated inhaled iloprost, and TRACE,65 which investigated selective prostacyclin receptor therapy, used wearable technology to measure parameters of daily physical activity as primary outcome measures.64,65

Aortic valve disease

Data from wearable devices are surprisingly sparse in aortic valve disease, considering their potential to track progression and optimally time intervention. In a study of 52 patients with severe aortic stenosis, there was little correlation between wrist-based accelerometer measurements of daytime physical activity and conventional performance assessments and self-reported activity questionnaires.⁶⁶ Wrist-mounted accelerometer-based daily activity monitoring in 25 patients undergoing transcatheter aortic valve implantation showed a recovery to pre-transcatheter aortic valve implantation levels of physical activity by 5 weeks.⁶⁷ Further studies are required to explore the relationship between activity level and other physiological biomarkers with prognosis and intervention.

Computational and predictive modelling

By combining the various sources of information from wearable technology into personal representations,

computer modelling could substantially enhance the information that can be extracted from such data.68 Modern medicine is guided by randomised controlled trials, which report relatively small overall effect sizes in large, heterogeneous patient groups. The results are then applied, often by extrapolation, as a generic remedy. Even if an individual patient in the clinic would have met the inclusion criteria of the key randomised control trial, would they have been one of the few positive responders? The individual's personal circumstances, comorbidities, socioeconomic status, genetics, activity levels, ethnicity, age, frailty, and other factors might be relevant. Computational modelling can analyse complex datasets to determine relevant factors and associations, offering the goal of tailored, or personalised care, rather than a one-size-fits-all approach.69 Wearable technology has the potential to obtain patient-specific data to tune these models in an individualised manner. Continuous assimilation of physiological data over prolonged periods will allow computational models to develop and age with the patient; the so called digital twin.70 It is anticipated that such models will incorporate artificial intelligence technology to characterise and delineate patient-specific physiological relationships that will be used to predict the likelihood of a new diagnosis, disease decompensation, or response to an intervention.71 In the All of Us research programme, which includes more than 400000 participants, data from wearable devices are combined with surveys, electronic health records, and clinical and laboratory samples to advance precision diagnosis on a large scale.72

Handling data from wearable technology in the clinic

Incorporating data from wearable devices into clinical decision making appears intuitive, plausible, and attractive. Patients are already presenting to their doctors with data from their wearable device as a new, patient-driven initiative. The collection of relevant health data before the first clinical consultation has the potential to revolutionise the traditional doctor–patient interaction (figure 5). Patients might be anxious about what they consider abnormal data, even without symptoms, and might (paradoxically) curtail their exercise as a result. At this early stage, doctors should ensure that data have been obtained within the manufacturer's stated intended use and do not exceed its evidence base or breach its regulatory approval. Off-label use might transfer responsibility from the manufacturer to the end user.

Challenges and future perspectives

The ubiquity of wearable devices risks that they will be used in clinical decision making, irrespective of validation. Despite a wide range of studies, they have not yet been shown to improve defined medical outcomes, necessitating studies to identify risks and benefits to the patient and health-care systems. Medical training will need to address these risks and benefits as the evidence base grows, as well as navigate the difficulties posed by volumes of disparate device data. Cardiologists, who are familiar with assessing traditional cardiovascular symptoms such as chest pain, palpitations, and shortness of breath, based on a patient's subjective description, will need to assimilate these new data sources and, in time,

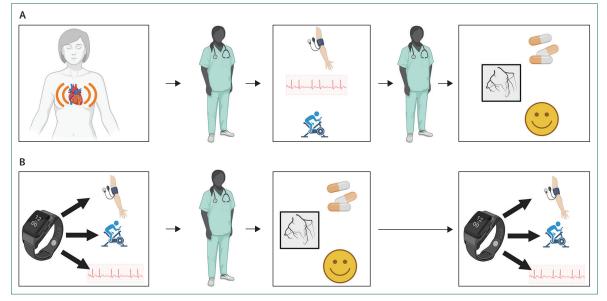


Figure 5: How wearable devices can disrupt the traditional doctor-patient interaction

(Å) The traditional model of healthcare is initiated by symptoms, leading to a patient-clinician consultation. The clinician then requests investigations that document objective cardiovascular parameters under resting and stress conditions that leads to reassurance or diagnosis and treatment. (B) Patients present to their doctor with objective cardiovascular measurements under resting and physical exercise conditions, as measured and alerted by their wearable device. This process might lead to earlier initiation of treatment or reassurance and might facilitate monitoring the response to treatment.

Search strategy and selection criteria

The Web of Science and PubMed databases were used to search for relevant journal articles, including clinical trials, meta-analyses, and randomised controlled trials. The search terms used were "wearable", "sensors", "cardiovascular", "blood pressure", "cuffless", "heart disease", and "physical activity". Publications accessible from the database inception up to Nov 1, 2022 were considered for inclusion based on their relevance to consumer-led wearable devices in cardiovascular medicine. Articles were not included or excluded according to language.

use them to monitor the response to treatment. Parallel developments in machine learning and artificial intelligence might also be applied to data from wearable devices to identify novel associations in terms of diagnosis, risk prediction, and treatment choices.⁷¹ It is also likely that sensor technology will advance beyond traditional methods such as photoplethysmography with the emergence of smart fabrics. These incorporate novel sensing methods, including soft magnetoelastic generators and hierarchical in situ filling porous piezoresistive sensors capable of transducing pressure displacement. Such fabrics provide new ways of integrating biomedical sensing technology into clothing and wearable devices.73,74 The regulatory landscape for digital health care will need to develop rapidly. Public trust and acceptance will also be required. One hope is that wearables might help to reduce inequalities in health care, provided they are inexpensive, and do not discriminate against individuals who may struggle to engage with the technology (eg, due to a lack of familiarity with electronic devices or health conditions which may make using small devices challenging). The combination of wearables with telemedicine might also lead to a revolution in community care, as well as a reduction in both acute hospital admission and health spending.

Conclusion

Wearable technology has the potential to elevate the routine clinical consultation from a subjective discussion based on patient recollection to a standardised series of objective parameters of both health and quality of life gathered over months or years. Wearable devices have shown some potential application in many cardiovascular diseases, either through disease screening or monitoring; however, the evidence base and the integration of wearable data into clinical cardiology is still in its infancy. Such data could soon help personalise and improve the management of cardiovascular diseases on multiple levels, ultimately resulting in better outcomes on both an individual and a population-wide scale.

Contributors

PDM, GJW, JPG, TJAC, and DRH conceived the idea for this Review. PDM, GJW, and JPG contributed to the original manuscript draft. PDM and GJW designed the figures used. All authors contributed to subsequent drafting and editing of the manuscript.

Declaration of interests

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