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REVIEW

Improving the management of patients with chronic cardiac and respiratory diseases by extending pulse-oximeter uses: the dynamic pulse-oximetry

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ABSTRACT

Respiratory and cardio-vascular chronic diseases are among the most common noncommunicable diseases (NCDs) worldwide, accounting for a large portion of health-care costs in terms of mortality and disability. Their prevalence is expected to rise further in the coming years as the population ages. The current model of care for diagnosing and monitoring NCDs is out of date because it results in late medical interventions and/or an unfavourable cost-effectiveness balance based on reported symptoms and subsequent inpatient tests and treatments. Health projects and programs are being implemented in an attempt to move the time of an NCD's diagnosis, as well as its monitoring and follow up, out of hospital settings and as close to real life as possible, with the goal of benefiting both patients' quality of life and health system budgets. Following the SARS-CoV-2 pandemic, this implementation received additional impetus. Pulse-oximeters (POs) are currently used in a variety of clinical settings, but they can also aid in the telemonitoring of certain patients. POs that can measure activities as well as pulse rate and oxygen saturation as proxies of cardio-vascular and respiratory function are now being introduced to the market. To obtain these data, the devices must be absolutely reliable, that is, accurate and precise, and capable of recording for a long enough period of time to allow for diagnosis. This paper is a review of current pulse-oximetry (POy) use, with the goal of investigating how its current use can be expanded to manage not only cardio-respiratory NCDs, but also acute emergencies with telemonitoring when hospitalization is not required but the patients' situation is debatable. Newly designed devices, both "consumer" and "professional," will be scrutinized, particularly those capable of continuously recording vital parameters on a 24-hour basis and coupling them with daily activities, a practice known as dynamic pulse-oximetry.

Key words: cardio-vascular and respiratory NCDs; pulse-oximetry; pulse-oximeters; telemonitoring; dynamic pulse-oximetry.

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Introduction

The use of pulse-oximeters (POs) is well established (and actually a standard) in many clinical settings and is considered a reliable, affordable and user-friendly tool for diagnosis and monitoring of many acute and non-communicable disease (NCDs) [1]. In NCDs the needs are growing to get information about how patients perform in real life, aiming at both early diagnosis and follow up of these diseases which are more and more prevalent. New achievements in technology can widen the field of application and the possibilities of use of PO and fit them to new, unmet needs.

NCDs are the most prevalent diseases all over the world and the most frequent cause of death, even in non-developed countries [2]. The world situation emphasizes the burden of heart and respiratory among NCDs not only for mortality. Globally, in 2017, the five leading causes of disability-adjusted life year (DALY) were neonatal disorders, ischaemic heart disease, stroke, lower respiratory infections, and chronic obstructive pulmonary disease. Furthermore, between 1990 and 2017 global DALYs for non-communicable diseases increased by 40.1% (95% uncertainty interval 36.8-43.0) [3].

Facing this very high prevalence, some twenty years ago the World Health Organisation (WHO) produced a report about the issue, emphasizing that these health problems require ongoing management over a period of years or decades, highlighting the limits of a health system designed for acute diseases and proposing a new way of thinking about managing NCDs, by shifting from an acute to a chronic care model [4]. The transition from the old to the new model of care has been more difficult than expected and still today, when chronic disease symptoms exacerbate, patients seek preferentially medical advice for first aid and/or hospitalizations [5]. Frequently this is the time when the diagnosis is made, and this delay can limit the chances of intervention. Moreover, this unplanned and not-organized use of health resources in severe worsening or emergencies is not cost-effective (disregarding its negative effects on the patients' quality of life and the increased risk of infections linked to hospitalization). In fact, up to one half of the cost of health care for people with NCDs can be accounted for by the use of unscheduled care [6]. Conversely, scheduled follow up visits (usually every six, nine or twelve months) can be useless (since they can come when the patient is stable and feeling well) causing unnecessary use of health service resources [7].

One proposed solution is to "empower the patient" making him "a member of the health care team" [8].

In this model the patient is anyway the initiator (or the continuator) of the pathway and is not a passive party. On the contrary, if a patient is experiencing (or think he/she is experiencing) a non-normal situation or a worsening in his/her symptoms, he/she can phone a specialist nurse, who, after a triage has suggested its advisability, can arrange a consultant appointment in a short time [7]. In other words, instead of monitoring the patient with scheduled appointments or waiting that the health conditions deteriorate to the point of making hospitalization necessary, the patient is provided with the possibility of appreciating his/her health status and quickly contacting health staff when the situation is felt as non-normal or deteriorating. This approach can be enriched to include telemonitoring tools, as the recent COVID-19 pandemic has demonstrated. For instance, during the pandemic the use of telemedicine as part of diabetes care has been accelerated and proved to be not inferior to standard care pre-COVID [9].

Whatever the selected model, in the context described, a continuous recording of patient's situation and/or an early detection of its worsening is advisable and convenient, like the daily measure of glycemia in a person suffering from diabetes can prevent a hospitalization for diabetic ketoacidosis, hyperosmolar hyperglycaemic state, or coma. For these reasons, in the management of NCDs (not only diabetes) WHO gives - among other measures - the utmost importance to the empowerment of the patient and to his/her self-monitoring. Devices which can give the patient (and/or the physician) information about biological parameters can of course increase his/her capacity to self-manage the disease.

Looking at diabetes care as a benchmark for NCDs management, for continuous glucose monitoring there are not only commercially available platforms but also open-source software [10], whose function can be enhanced (or is indeed required) by monitoring tools.

Like glucose measurements can be looked at as a proxy of whole diabetes situation, in the same way some other biological parameters like heart rate (pulse) and oxygen content in blood (i.e. oxygen saturation) can be (and actually are) used and looked at as vital parameters, proxies of the situation of cardiac and respiratory conditions. And the search for devices able to *continuously* record PO in monitoring these chronic diseases has already reached some goals, going on toward new achievements, in addition to the well-known dynamic ECG "Holter" [11].

As mentioned before, another reason which enforces the search for devices for continuous recording of vital parameters is the need of anticipating the diagnosis of a NCD, i.e. when symptoms are non-specific and subtly presenting and can be disregarded by the person, so retarding the diagnosis to a later stage of the disease, when disability is more severe, and costs of assistance are higher. A person made aware of the first symptoms of NCDs by media campaign - aimed at raising awareness about the disease like for instance for smoking or obesity [12], or by opportunities in general practice [13] can be addressed to a screening which will be more welcome the more simple and minimally invasive will be the procedure.

Finally, there is a need which has been felt for years in Emergency Departments (ED) but has been exacerbated by the COVID-19 pandemic [14] beyond the already cited possibility of early diagnosing a disease so far ignored. It pertains the prognosis of patients who are not clearly eligible for hospitalization but are "*on the edge*" - i.e. not so severe to be hospitalized and in condition to be discharged to home but with a doubtful prognosis - which leads to advise the patient to access again a triage in the ED if feeling worse. In this case a monitoring of his/her situation could help the physician and health staff to understand what was (and is) going on at home.

This paper will review the current use of POs and examine how the use of POs of new generation can help the proper management not only of some acute conditions, but also in early diagnosis and follow up of some chronic ones (namely cardiac and respiratory ones), through a careful monitoring of some vital parameters with a look at the newest technologies developed in devices useful to a continuous monitoring.

Pulse-oximetry: generality in acute situations and pitfalls

The pulse oximeter is a non-invasive tool that estimates the O_2 saturation of haemoglobin (pulse oximeter oxygen saturation or SpO_2) and is widely used to monitor patient oxygenation in clinical situations, even outside the hospital, thanks to portable battery-powered devices.

The principle of operation of the pulse oximeter is based on the fact that the transmission of red and infrared light through the capillary bed generates variable signals throughout the cardiac cycle, that are related to the variable absorption of the transmitted

light by the tissues or arterial and venous blood. The sensor of the pulse oximeter contains two diodes that emit monochromatic light at 660 and 940 nm, respectively. The light passes through the body tissues and is sensed by a photodetector. Light waves are analyzed by an alternating-current amplifier, that amplifies pulsatile light waves (caused by inflow of arterial blood), while blocking non-pulsatile waves. From these signals it is possible to derive an estimate (SpO_2) of the quantity of oxyhaemoglobin (SaO_2) in percentage ratio to the total haemoglobin ($O_2Hb/(O_2Hb+HHb)$) [15]. It goes without saying that SaO_2 is not comparable to the PaO_2 (partial pressure of 0_2) in blood, as PaO_2 and SaO_2 are related nonlinearly to each other through the haemoglobin dissociation curve [16]. Other types of haemoglobin (COHb or MetHb) can also be detected, adding diodes for additional wavelengths (multi-wave-lengths sensors) [17-18]. In the clinical range of SaO_2 >70%, measured SpO_2 differs from real SaO_2 by less than 3% [19,20].

Interestingly enough a further mode of use of POs is also available, useful as an add to it: in anaesthesiology (or anyway in emergency medicine) especially in particular populations of patients like patients in an advanced stage of COPD, there is a definite danger when too much oxygen therapy is administered and PaO_2 reaches very high levels; in this case oxygen saturation goes over 100% and no information can be obtained about PaO_2 without an invasive blood gas analysis. In order to prevent dangerous levels of hyperoxia an interesting add-on information about the arterial partial pressure of O_2 (SpO_2) can be non-invasively obtained by coupling two devices produced by Masimo Corp. (Irvine, CA, USA). The first device (Masimo Radical-7- https://www.masimo. com/products/continuous/radical-7/) is described as a platform connectable with a multi-wave-lengths sensor and able to measure in a non-invasive way not only pulse- and oxygen saturation but also different types of haemoglobin as well as perfusion index and respiration rate and other additional parameters. The second device is another platform (Root® Platform- https://www.masimo. com/products/continuous/root/), Connecting Root® with Radical-7®Pulse CO-Oximeter®. The obtained parameter is called the *oxygen reserve index* (ORi) an index measured using a *non-unit* scale between 0.00 and 1.00, which can be related to different levels of moderate hyperoxia (PaO_2 roughly between 100 and 200 mmHg) [18].

Oximetry probes can be applied to fingers, big toes, earlobes, forehead, lower lip, or any skin surface where a reliable signal can be obtained. Several factors can affect reliability of pulse oximetry and must be kept in mind in clinical use. Since the pulse oximeter uses the fluctuating light wave absorption due to the arterial blood volume increasing during systole and decreasing during diastole, if the device cannot detect a change in light wave absorption it will not be able to measure SpO_2. If the pulse oximeter shows a heart rate significantly different from that measured on the wrist or with an ECG, SpO_2 will be unreliable. The most common cause is arterial hypoperfusion, which may be due to local causes (among others, peripheral vascular disease, sphygmomanometer use, external low temperature), or to systemic causes such as hypovolemic or distributive shock, hypothermia, poor cardiac output due to pump failure or arrythmias. Excessive movement such as tremor or convulsion, surgical cautery, poor probe position, and ambient light interference can also cause erratic SpO_2 [15]. Falsely low SpO_2 can occur with methylene blue, indocyanine green, indigo carmine, isosulfan blue, or fingernail polish. Falsely high SpO_2 can be seen in presence of carboxyhaemoglobin, or sickle cell anaemia vaso-occlusive crises or finally very dark skin at low O_2 saturation [15,21].

On the other side, sometimes the pulse oximeter could be more reliable than the CO-oximeter (from a blood sample, in blood gas analysis). In some CO-oximeters, severe hyperbilirubinemia (≥30 mg/dL), could make measurements of fractional O_2Hb falsely low by measuring a factitious increase of MetHb and COHb [15]. Also foetal Hb (HbF) can deceive some CO-oximeters, as HbF may be misread as COHb, while it does not alter the pulse oximeter reading [15].

Since many years pulse oximeter monitoring use has been mandatory not only in the operating room and in Post Anaesthesia Care Units (PACU) [22,23], but also in ED [24], on ambulances [25], and in intensive care units (ICU) [26]. Furthermore, its use is now widespread in all acute care wards dealing with patients with (or potentially at risk for) respiratory or heart failure [27].

The main aims of monitoring SpO_2 in the acute setting are the prompt identification of hypoxia, and oxygen therapy and/or supported ventilation adjustment; monitoring can be either continuous, or intermittent [21,25]. Pulse oximetry has been shown to be helpful in pre-hospital setting in titrating low dose oxygen therapy in COPD patients [21], and in mechanically ventilated patients in ICU [28]. Moreover, its use proved to be cost-effective in reducing number of arterial blood gas sample (ABG) in ICU, and in lowering ABGs in emergency department [28,29].

Unfortunately, it has been very difficult to confirm in randomized trials the efficacy of the pulse oximeter in improving patient outcomes, probably due to the very small signal-to-noise ratio: because the outcomes under study (death, ICU readmission, or myocardial infarction) are (fortunately) very rare, a huge number of patients would be needed to show a significant reduction in these events [28-30].

Pulse-oximetry in clinical practice

POy in neonatology

Apart from adult conditions which will be fully treated in the next chapter, POy find a wide use of capital importance in new-borns and children. In fact, it can help in the detection of congenital heart disease (CHD) which is one of the most common birth defects, with an incidence of nine out of every 1,000 live births: its mortality has decreased over the past decades, but significant morbidity and mortality continue to occur when undiagnosed shortly after birth.

PO was recommended as a screening tool to detect critical CHD (CCHD) in 2011 by the American Academy of Pediatrics and the American Heart Association [31]. If CCHD is detected, surgery or cardiac catheterization within the first month (or within the first year by different definitions) of life is mandatory to prevent death or severe end organ damage. Unfortunately, delayed diagnosis of CCHD is all too common, with up to 25% of infants with these defects being missed in neonatal period if identification is based on clinical symptoms or signs of heart disease even in settings with routine prenatal sonograms [32-34].

Studies in Europe and the USA have suggested that new-born screening with PO testing prior to discharge from the nursery can decrease the number of missed diagnoses by 30% [31,35]. In 2011, PO screening for CCHD was added to the Recommended Uniform Screening Panel by the Health and Human Services Secretary [36] and a recent study has shown the association of State implementation of PO policies with a significant reduction in early infant cardiac deaths [37].

PO is used in all aspects of new-born care, including resuscitation of new-borns in the delivery room to routine monitoring in the operating room. A study by Levesque *et al.* in 2000 described the normal range of oxygen saturations in term new-borns in the first days of life. PO measurements were taken upon admission to the new-born nursery, at 24 hours of life, and at discharge. Infant's activity affects oxygen saturation over time, with SpO_2 values obtained while the infant was crying, fussy, or awake being

significantly lower than the values obtained while sleeping [38]. As told before, a substantial proportion, some two out of three, of infants with CCHD are typically missed by physical examination alone. Addition of PO screening raises the diagnosis rate.

In a systematic review and meta-analysis of PO screening for CCHD in the new-born nursery, which included 13 studies with 229,421 infants, sensitivity of pulse oximetry for the detection of CHD was 76.5% (95% CI 67.7-83.5) and specificity was 99.9% (95% CI 99.7-99.9) with the average false-positive rate for these infants being 0.14% (95% CI 0.16-0.33) [39]. With the average PO value being 97.2% during the first days of life for all new-borns, PO is an excellent tool to evaluate subclinical hypoxemia, that occurs during transitioning physiology of certain CHD, such as transposition of the great arteries, *truncus arteriosus communis*, hypoplastic left heart syndrome, total anomalous pulmonary venous connection, tricuspid atresia, tetralogy of Fallot, and pulmonary atresia. These lesions are usually associated with hypoxemia in the new-born period and can cause significant morbidity and mortality if the diagnosis is delayed.

The Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) of the U.S. Department of Health and Human Services (HHS) approved a protocol about CCHD screening: an infant would have a positive (failing) screen if at ≥24 hours of life: i) a PO reading was <90% in either the right hand (preductal) or either foot (postductal); ii) both readings from the right hand and either foot were <95% on three measurements each separated by 1 hour; iii) a persistent >3% difference in the right hand and either foot measurement on three different measurements, each separated by 1 hour. An infant who had ≥95% in either extremity with ≤3% difference in the pre- and postductal oxygen saturation would have a negative screen and no further work-up is needed [39].

PO in anaesthesiology and critical care practice

PO is universally used for monitoring respiratory status of patients in the critical care setting.

POs may lead to a quicker treatment of serious hypoxemia and possibly circumvent serious complications. Any type of PO can be used: sensors are suitable for use on the finger, toe, or earlobe; when tested under conditions of low perfusion, finger probes performed better than other probes [40] while ear probes respond quicker to a change in O_2 saturation than finger probes [41].

A study compared the response time of the conventional finger probe with the reflectance forehead probe in patients undergoing general anaesthesia [42]. The lengths of time it took to detect a decrease in SpO_2 to 90% after apnoea was induced (desaturation response time) were 94 seconds for the forehead probe and 100 seconds for the finger probe. After mask ventilation was started, the lengths of time it took to detect an increase in SpO_2 to 100% (re-saturation response time) were 23.2 seconds for the forehead probe and 28.9 seconds for the finger probes. The investigators speculated that the shorter response time with the reflectance forehead probe was most likely due to the location of the probe rather than to the workings of the reflectance technology. The forehead probe monitors O_2 saturation from the supraorbital artery in which blood flow is abundant and is less likely to be affected by vasoconstriction than is a peripheral artery [43].

In addition to its known clinical usefulness, PO may serve as an adequate substitute for in-line oximetry during extracorporeal life support. In a tertiary care neonatal ICU the accuracy of the oximeters was determined in sixty-five consecutive neonates with severe cardiorespiratory failure undergoing extracorporeal life support by simultaneously comparing the saturation displayed by the POs with the measured fractional venous oxygen saturation obtained at regular intervals from the extracorporeal circuit. Authors concluded that PO, despite some variability between the various instruments tested, has proved to be an adequate tool for monitoring this condition [44].

Monitoring with PO continues to be a critical component of standard of care of critically ill patients despite the paucity of data that such devices improve outcome [45,46].

Pulse-oximetry in respiratory practice

Pulse-oximetry in hospital wards

After decades of use of POy in perioperative monitoring and intensive care units the device is now widely used in medical wards and particularly in Pulmonology wards, (not only at bedside but also during invasive procedures (*e.g.*, bronchoscopy). POy's use has skyrocketed during the COVID-19 period and has widened to include the whole spectrum of situations from home to hospital. In practice, besides the well-established use in ICU and Medical wards the device has been proposed (and was actually used) to monitor patients at home [47]. This is the most promising field for the new pulse-oximetry devices (Table 1).

For many years pulse-oximetry (POy) has been used to monitor respiratory function and detect early its deterioration. This use of PO was particularly recommended to nurses in general wards because in this settings physicians can be farther away from patient's bed than in ICU [48-50]. The accuracy of PO is so reliable that official guidelines about the management of patients at the beginning of the SARS CoV2 pandemic suggested that unless the clinician suspect a CO_2 retention, blood gas analysis can be avoided and replaced by PO [51]. Even when retrospectively analysed and compared with blood gas analysis in a subsets of 30 COVID-19 patients recovering from severe COVID-19, PO showed an agreement with blood gas analysis that was slightly suboptimal but within acceptable levels for Food and Drug Administration (FDA) approval [52].

Pulse-oximetry in screening and monitoring of sleep apnoea

PO has been shown to be effective in both screening as well as treatment monitoring sleep disordered breathing [53,54], not only in adults but also in children [55]. Since sleep apnoea is particularly frequent in obese and metabolic syndrome patients (35-94%), PO can be recommended - besides the above mentioned settings - for

Table 1. Use of pulse-oximetry during SARS-CoV-2.

Well-established use		New use
Hospital		Home
Wards	ICU	
Quick detection of clinical distress	Continuous monitoring	Self-monitoring (checking clinical stability or deterioration, if perceived)
Continuous control of oxygen therapy	While under observation or during (mechanical) ventilation	Communicating data to health staff by phone or *via* tele-medicine devices (see paragraphs above)

continuously monitoring patients in bariatric surgery in the immediate and late post-operative management [56].

Pulse-oximetry in the 6-minute walking test

After many years of informal, non-standardized and raw use, since some twenty years the walk test has been recommended in an official guideline [57]. Since then, the so-standardized 6-minute walking test (6MWT) has affirmed itself as a safe, well tolerated, easy to be carried out test for essaying cardiac and respiratory function. It also reflects activities of daily living better than other tests [58]. Consequently, it has a lot of indications, particularly in respiratory clinics and in pulmonary rehabilitation, but also in cardio-vascular patients, as widely explained in the following paragraph, above all in a context of heart failure and post-cardiac surgery rehabilitation [59]. It proved to be a good prognostic indicator even in the subsets of elderly hospitalised patients [60]. Although the use of POy during the test was not initially recommended [58,59], continuous POy has been currently adopted not only because it enhances patients' safety, particularly for those suffering from heart diseases, but also because it adds crucial information like the qualification of dyspnoea [61] or the calculation of the distance-desaturation product (DSP) [62].

Pulse-oximetry in chronic respiratory diseases

In chronic respiratory diseases (CRD) the role of PO is important today and, in the future, can become essential (a wider discussion of the burden and consequences of CRD is available in Appendix 1).

Chronic obstructive pulmonary disease (COPD) as well as idiopathic pulmonary fibrosis (IPF), other interstitial lung diseases (ILD) and other conditions included by the World Health Organization in the Global Alliance against Chronic Respiratory Diseases (GARD) [63] can cause respiratory symptoms and even cardiac complications gradually leading to respiratory insufficiency and failure. The more advanced the disease the more severe is the prognosis, despite the currently available pharmacological treatments. Consequently, an early diagnosis is advisable whenever possible [64,65]. In CRD patients, especially in the first stages, an objective measure like PO can help the diagnosis and staging of the disease, besides the only evaluation of symptoms. The prescription of long term oxygen therapy (LTOT) is an example (see below). But patients' situation can vary significantly from day to day or even within the same day, so they should be strictly monitored with repeated control of various vital parameters such as: the level of oxygenation, respiratory rate, heart rate and rhythm and others, both during the day while the subject carries out normal daily activities, and during the night. In summary, a careful and continuous surveillance of patients' health status could promptly detect clinical and functional signs of deterioration and indicate adequate treatment, thus decreasing the need for emergency consultations and hospitalization, as demonstrated in many studies [66-69]. Non-invasive monitoring of vital parameters allows also to identify the need for LTOT and to verify its persistent need over time [70,71]. Moreover, clinical-functional monitoring throughout the day, while the patient carries out his/her normal activities or is at rest, appears invaluable for a correct definition of the causes of dyspnoea, especially when it appears disproportionate to the clinical and functional state [72,73]. The continuous measurement of vital parameters with PO, days and nights, is essential for the identification of possible respiratory alterations also during sleep such as in already cited OSAS [54,74].

Today the measure of the cited vital parameters with POs is usually carried out in a single shot manner, at pre-settled time points and using devices not always easy to use, and often in a hospital setting, possibly limiting activity and mobility of the individual. The utility of a PO easy to use, wearable, unobtrusive, and able to record not only vital parameters continuously, but also measure the patient daily activities, rest and sleep can only be fancied. As regards the latter point, some experiences in the past had emphasized the importance of a continuous monitoring of PO, what we define the "dynamic pulse-oximetry". In the first [75] the role of the so-called ambulatory oximetry monitoring (AOM) was investigated to clarify if the compensation of chronic hypoxemia obtained with LTOT after a single static measurement is maintained during normal activities of daily living. Among 27 severe COPD patients in LTOT, followed up for 18 hours, there was a high frequency of desaturations below 90%, for approximately 25% of AOM recording time. A subsequent study [76] not only confirmed these results, but also demonstrated a significant decrease in the amount of oxygen prescribed due to the detection of overprescribing.

In another study [77], 88 patients with stable COPD with a PaO_2 between 60 and 70 mm/Hg (*i.e.* non requiring LTOT) were studied with 24 hours of ambulatory oximetry; 38% of patients showed desaturations: mainly nocturnal (50%) but also during daytime (22%). Similar results were also achieved in a pulmonary rehabilitation setting by another group from Portugal and the Netherlands [78].

Given the latest developments of technology of POs and their future evolutions a substantial change in the CRD management outside hospitals can be easily forecast, in a way similar to what we have seen in Cardiology in the last decade.

POy in cardiology

Arrhythmias

As for cardiovascular NCDs, POy can help in the diagnosis (essentially as a screening tool) and monitoring of arrhythmias and chronic heart failure. Fingertip POy has been since a long time a low-cost and non-invasive modality for home monitoring of heart rate and rhythm evaluation, *e.g.* oligosymptomatic symptomatic atrial fibrillation (AF) cases, patients with occasionally occurring palpitations of unknown origin.

An irregular rhythm notification in a patient must be taken seriously. A series of investigations should be started and subjective complaints should be coupled - as we will see - with data obtained with monitoring devices designed to record PO and physical activity in real life. If the heart rhythm is an appropriate sinus tachycardia, then no further arrhythmia evaluation may be needed. Otherwise, the physician could decide to perform an ambulatory ECG monitoring of 7-14 days, or event recording of up to 30 days. AF is the most common arrhythmia (estimated lifetime risk, 22-26%) causing impaired quality of life and heralding complications (e.g., stroke or heart failure) leading to hospitalization and sometimes death. So far, only personal digital devices -referred at in the following paragraphs as 'fitness'- type devices- can be used. They are designed for health and wellness and clinical features are not reviewed or regulated by the FDA (although some of their functions are so far FDA approved). These devices are directly marketed to the public by manufacturers and may be purchased and used without clinician oversight -or any direct interaction with the medical community. Patients may approach clinicians about using personal digital devices, but clinicians may not have solid scientific research available to guide them [79]. Among them Apple Watch is widely advertised and now exceeds 30 million units in annual sales. It can be considered a sort of "medical alert system" because it can -besides the usual measurements of heart rate and oxygen saturation and, using with special apps- detect falls, give a notification of irregular cardiac rhythm and provide ECG features; however, it needs an

iPhone to work. Currently, there are limited data on the impact of those commonly used features on patient quality of life and some worries have arisen in the medical community [80]. A detailed discussion of the current state of these devices is in the last paragraph.

A virtual ambulatory AF ward providing multidisciplinary care with remote hospital-level monitoring has been implemented in UK in a tertiary care centre, and could reshape the future model of AF management. This can give us a glimpse of the future. Patients admitted with a primary diagnosis of AF satisfying the AF virtual ward (AFVW) entry criteria (*i.e.*, haemodynamically stable, HR <140 bpm with other acute conditions excluded) were given access to a single lead ECG recording device, a Bluetooth integrated blood pressure measuring machine and POy with instruction to record daily ECGs, blood pressure readings, oxygen saturations and fill an online AF symptom questionnaire via a smart phone or electronic tablet. Data were uploaded to an integrated digital platform for review by the clinical team who undertook twice daily virtual ward rounds. Over the 6-week period a total of 14 patients were enrolled. All patients were in AF with a mean heart rate of 122±24 bpm, and 38.5% (n=5) were discharged from the virtual ward in sinus rhythm. One patient was onboarded directly from pacemaker clinic and hence hospital admission was completely avoided, and 5 re-admissions were avoided for 3 patients. One patient required brief readmission due to persistent tachycardia requiring acute cardioversion. Patients' satisfaction assessed using the NHS family and friends' test yielded 100% positive responses among patients [81].

Pulse rate data are simple to obtain with POy and may also be useful to assess ventricular response in AF. However, POy may significantly and unpredictably underestimate (or overestimate) ventricular rate, especially during rapid AF or in the presence of structural disease such as aortic stenosis. Although POy has proven to be a simple and good alternative to ECG for ambulatory real-time detection of arrhythmias like sinus tachycardia, premature ectopic beats and AF, there are obvious limitations in its use, including the impossibility of recording detected parameters and letting more sophisticated investigations.

Wearable devices powered by sophisticated algorithms offering precise and continuous AF detection will provide an excellent opportunity to screen AF at scale, as demonstrated in the recent Apple and Huawei studies [82-87]. More recent smartwatch models *(Apple Watch Series 4 or higher, Samsung Galaxy Watch 3)*have FDA-cleared single-lead ECG capability. The user actively records a 30-second lead I (right arm [−] to left arm [+]) ECG on the watch by pressing the crown with a finger of the hand opposite the hand with the watch body electrode. A new six-lead consumer version is now available that uses the right leg for additional limb and derived ECG leads. However, despite recent technological progression, consumer-based ECG devices entail some limitations (see below).

Heart failure

Heart failure (HF) is a common syndrome associated with substantial morbidity, mortality, and healthcare expenditures. Currently, the prevalence of HF appears to be 1-2% of adults (https://doi.org/10.1093/eurheartj/ehab368), as studies only usually include recognized/diagnosed HF cases, but the true prevalence is likely to be higher. These statistics emphasize - like for respiratory NCDs - the need to develop and implement more effective strategies to early assess, monitor, and treat HF.

The potential for home monitoring to improve the management of patients with HF is substantial: earlier identification and treatment of congestion together with improved care coordination, management of comorbid conditions, and enhanced patient self-management may help to prevent hospitalizations in patients with chronic HF. Such home monitoring extends from the promotion of self-care and home visits to telemedicine and remote monitoring of external or implantable devices [88].

Telemonitoring involves the transfer of physiological data such as blood pressure, weight, electrocardiographic signals, or oxygen saturation through technologies such as telephone lines, broadband, satellite, or wireless networks. Similar to structured telephone support, this strategy of Home telemonitoring (HTM) may lift some of the burden of geographic or funding barriers limiting in-home visits, reduce patient travel costs, minimize the frequency of clinic visits and facilitate rapid access to care when needed [88,89] as the next paragraph will analyse.

Systems that focus on continuous optimization of care (a health maintenance approach) rather than trying to anticipate and manage episodes of worsening (a strategy that is plagued by a large number of false-positive alerts), appear more successful [90]. By incorporating more data, especially about the physical activity of the patient telemonitoring also promises to detect HF deterioration earlier, allowing for more prompt and effective intervention. Important alerts may get lost if an appropriate triage system is not in place. Any successful approach will likely need to be multipronged. Monitoring alone, without adequate follow up and feedback to the patient, is unlikely to be the solution that prevents HF readmissions or decompensation.

Pulse-oximetry, tele-medicine and tele-monitoring

There are in scientific literature a few studies about POy and telemonitoring. The perspective to use "remotely" POy data, in the context of tele-medicine, is of course very appealing. However, to devise this use we should, first of all, understand what tele-medicine and tele-monitoring can be (a comprehensive review of telehealth in respiratory and cardiac disease is available in Appendix 2). The term "tele-health" or "tele-medicine" literally means- as told before- the transmission of clinical data to a distant receiver and can refer in different experiences to very different methodology and devices. It spans from the simple communication of data collected by the patient via telephone line to a central management unit, to Information and Communications Technology (ICT) platforms connecting with call centres and to contacts between the patient and the clinical centre *via* a personal computer with webcam and microphone. The described differences in the use of the term "tele-medicine" can probably account for the conflicting results obtained in the field. Even if diabetes is the forerunner in tele-health also the cardiovascular diseases are promising "competitors". Tele-health in emergency cardiology can be of great help, reducing the time to diagnosis in acute conditions, for example in differentiating an acute coronary syndrome from an acute pulmonary embolism, therefore shortening the time to the most appropriate treatment, angioplasty or fibrinolysis. The possibility of transmitting remotely ECG coupled with a "hub and spoke" organised network, can really reduce mortality and morbidity and guidelines about it has been published since 2004 [91,92].

In the context of tele-medicine, tele-monitoring defines the use of ICT to monitor outpatients, even, whenever possible, in their real life. For instance, a study on 21 patients at a high risk oncology surgery evaluated the feasibility of such a study before and after surgery. Patients use a pedometer and recorded vital parameters, included pulse-oximetry, through a tele-health platform and electronically completed a survey about their outcomes. The adherence was very good (95% before surgery) for vital sings and survey, gradually reducing itself over the days, after surgery. The

study proved to be feasible and, as expected, showed that mobility, self-care and usual daily activities deteriorated after discharge [93].

Another paper studied the feasibility of remotely telemonitoring a population of patients with systemic sclerosis while undergoing iloprost infusion. The device used was a disposable single-use ultra-thin, non-invasive digital patch to be placed on the chest. This device was able to collect and analyse ECG, respiratory rate, body temperature, systolic blood pressure and physical activity. Patients received the iloprost infusion in the day-hospital setting and were free to move within the hospital premises; data were transmitted in real-time *via* Bluetooth to an accessory App installed on a smartphone or tablet. The App transferred data *via* the Internet or Wi-Fi to a dashboard, making data available to clinicians. Authors confirmed the feasibility and acceptability of this kind of telemonitoring even if the measurement of body temperature was not reliable [94].

In domiciliary non invasive ventilation (NIV)- frequently used not only in advanced stages of COPD but also in OSA, hypoventilation-obesity syndrome and neuromuscular diseases- there is room for tele-monitoring for both initial assessment and follow up of patients. Pulse oximetry can be carried out during ventilation, using a stand-alone POs or a POs connected to the ventilator. Anyway, it adds a lot of useful information for clinicians [95]. Currently, almost all ventilators used for treating OSA has a built-in hardware and software (built-in software - BIS stored data) which usually measure and record in own memory card among other parameters: the pressure used by the machine, the AHI as well as air leaks [95]. The same built-in software can also be used to record data from home auto-titrating machine which finds the best therapeutic pressure [96] to start the treatment. These data can then be downloaded in the outpatient clinic for follow up, but some machines can also transmit data remotely. Tele-medicine could be used in this context to reduce the patient's access to the sleep clinic, as recommended during the COVID-19 pandemic [97]. Recently a real-life prospective study in patients with OSA was carried out to compare two methods of evaluating the final residual severity of OSAS patients in home positive airway pressure titration: built-in software remote-controlled data *versus* nocturnal portable multichannel monitoring data. The two measurement methods were equivalent [98].

As already mentioned, cardiology can easily benefit from the wide use of smartwatches and their implementation in fitness market. As we will see some smartwatches are already -at least partially- FDA approved devices for heart rate and beyond. In a prospective study volunteers equipped with smartwatches, were recruited to evaluate the feasibility and reliability of data transmission via smartphones. The study uses a digital platform with 3 different applications. These applications were able to record and analyse sleep quality, heart rate, oxygen saturation and blood pressure [99].

Devices for monitoring continuously pulse-oximetry for extended periods of time

In understanding the information given in the following paragraph one has to bear in mind that the differences between a consumer-market oriented device, intended for the everyday life, and a medical device designed for health staff needs are not only the functions which the device offers, but also the design itself, which in the second case starts from the very medical needs. In other words, the data collected may be the same ones but the data processing and the way to use data are from the beginning designed for supporting medical decision.

For any medical device aimed at managing chronic respiratory conditions there are, as already pointed out, two levels of intervention. The first one is to substantiate a suspicion of latent respiratory insufficiency of undiagnosed respiratory or cardiac conditions (the best established example is the Holter-ECG), and the second one to monitor an already diagnosed disease and its treatment (*e.g.*, LTOT).

Generally speaking, a physician looking for answers to the mentioned needs in prevention and care has in mind an "ideal" device. This device would be able (without any intervention by the patient) to record pulse, oxygen saturation, movements and body position, skids, falls and even cough, sneezes, in an accurate and consistent way, with a high sampling frequency (ideally less than five seconds). The device should give precise and consistent data, available both in real time and Holter-like way. It should be easy and comfortably wearable by the patient. Of course, it should be a medical fully certified device (FDA and/or CE). Besides, the device should be connectable to a system of infrastructures and networks of experts which can analyse data and provide a diagnosis even remotely. All components of the system should be classified as medical device in order to be applied in clinical scenarios and to this aim any device should have reliability (i.e., consistency, precision, and accuracy) and endurance enough to allow the diagnosis. Finally, it is a choice of the designer to provide the device with a display for the patient since it could be a plus for the patient, informing her/him about the current situation but, on the other side, it can affect and change patient behaviour and life.

The present

Recently following a continuous technological development, many wearable sensors have been designed and produced for acquisition of physiological parameters [100-102].

There are two different types of POs: the first and more widely used have already been described; it operates by transmission (where light source and photo detector are on opposing sides) while the second ones operate by reflection (light source and detectors are on the same side). SpO_2 with wrist-wearable device can be typically measured using the second type of transmission [103]: among them we can differentiate two different types.

'Fitness'-type devices (for example, Apple Watch, Garmin, Fitbit, *etc*.). All these devices measure POs by reflection [103]. One of the feature most common in commercial devices is ECG (electrocardiogram) feature (monitored via single channel or multiple channels): they record or monitor HR, some of them measure (instantly) also SpO_2 and activity however they don't correlate all these vital signs in a unique vision or report, they don't filter measurements in order to offer to clinician a complete set of data and a detailed definition of patient health situation and a vital sign continuous tracking cleaned by recording artifacts. Since the first series of smartwatches there have been great improvements in their performance and now they are confounding the border between leisure and medical device, especially for cardiovascular use (heart rate, ECG and arterial pressure). In this field they proved to be faithful, as pointed out in another paragraph of this paper and for some of their functions they received the FDA clearance. The Apple Watch series 6 proved to be reliable enough to detect hypoxemia like medical device (104). However, the reliability was not absolute and the Apple Watch frequently measured SpO_2 values outside the normal range (above 95%) even in healthy individuals (105).

Therefore, some of these fitness devices can be used to check for irregular heart rhythms or AF through an ECG reading of some seconds (frequently 30 seconds – *e.g.* Garmin Venu devices). Some of them like the Withings ScanWatch can track multiple parameters as sleep, activity, blood oxygen, heart rate and take a medical-grade

ECG. In all cases these device can record and monitor parameter instantly or for a short period (frequently about 30 seconds) and they don't offer a continuous (24 h) recording and monitoring in a "Holter-like" scenario.

Medically certified devices. There are currently a few devices in this class. It is important to highlight that SpO_2 (independently by their mode of operation, transmission or reflection) can be measured in three ways:

- Instantaneously: this is their universally established use, carried out by placing the tip of a finger on a sensor, while the hand of the patient is at rest. The display of the device shows the values of pulse and oximetry.
- Over extended periods of time, Holter-like: this is obtained by using either conventional finger probe pulse-oximeters operating by transmission (if connected to a memory support they can be used for extended periods of time (*e.g.*, during night sleep) or really wearable sensors, on the wrist of the patient (or on the chest, or on the ear lobe). The data recorded, often for a period up to 24 hours, are then transmitted to a personal computer for data processing and analysis. This is the most suitable and less expensive way to monitor chronic patients in stable conditions in real life. A devices like these can carry out what we call "dynamic pulse-oximetry".
- Real-time, remote monitoring: this seems today to be the most suitable way to look at unstable chronic situations, to check if the conditions are getting worse for quickly arranging a hospitalization [106] or (and this is particularly important in pandemic periods) to confirm stability, thus avoiding unnecessary hospitalizations [107] or allowing early discharges. We have seen the importance of this kind of clinical data collection during the COVID-19 pandemic in the paragraph "Pulse-oximetry in the respiratory ward". Such a monitoring is usually obtained by using many clinical sensors in the same patients to measure blood pressure, weight, oxygen saturation and motion sensor [108] but also with a single wearable sensor (able to measure POy and activity) normally placed on the wrist of the patient to avoid restriction of movement or cause discomfort. The measures can be transmitted remotely in real time and can be evaluated by trained health staff in a sort of control room. This method of collecting multi-parametric data is more complex and costly and so far, is supported by far less scientific literature. We compare in the next paragraph different devices which are full package medical-grade classified (non-only single features inside) and suitable for cardio-respiratory use.

As we will see in some of the "future" devices, workflow starts from vital signs recording and ends with medical reporting in a integrate technological system composed by several components: wearable device, data processing and filtering algorithms (designed and patented to offer to the clinicians the best quality and precision of recordings, isolating and avoiding artifacts due e.g., to patient movement in real life) and a full medical reporting suite compliant to medical international standards and needs.

The future

In cardiac and vascular conditions, it has been possible since last century to record both ECG and arterial pressure on a 24 hour basis. Norman Holter invented his recording device in 1961. Some decades thereafter the arterial blood pressure monitor (ABPM) was invented, and today it is possible to record continuously blood pressure for 24 hours. Both devices allow to record vital parameters in real life, even if with some discomfort for the patient and requiring his/her full involvement in the management of the device (for instance for ABPM the patient is asked to stand still when he/she feels the band inflation).

This paper has reviewed so far the reliability and usefulness of pulse-oximeters, confirmed by decades of use in many different settings. However reliable measurements of oxygen saturation and heart rate currently are generally obtained at certain predetermined times and with the use of equipment that is not always easy to use, possibly burdensome for the patient and is usually obtained in a hospital or outpatient setting, imposing a limitation in subject mobility and activity. Clearly the next step- fostered by the already mentioned needs of the new model of health care [4,5] should be a non-invasive and easy to use (*i.e.* "wearable") instrument. It should be able to provide the clinician with reliable measurements of oxygen saturation and heart rate, recorded outside health facilities, in real life, similarly to what Holter ECG or ABPM perform, correlating data with daily activities, in order to easily get follow up of chronic patients. This is now made possible by the Photopletismography (PPG) technology. This technology is widely used by fitness devices (see over) but is currently being implemented also for medical use. A few of such devices are now available: they do not perform to the same standard than traditional finger POs [109] and not all can record continuously both during the day, while the subject carries out his/her normal activities, and/or during the night sleep period. Generally, this kind of measurements are very reliable even if some inconsistencies are detected with a saturation < 90%, which is a well-known problem of all the pulse-oximeters [110]. Here are reported the available devices to the best of our knowledge according to their description on websites at the time we are writing our review. They can be considered as for their wearability as well as for their use (cardio-respiratory use or cardiac only use). The latter is usually best wearable.

Bio-Beat Medical Smartmonitoring

This is a Holter-like device, designed according to manufacturer, for lasting (the battery life is supposed to last up to 5 days) and repeated use. It records not only oxygen saturation and pulse rate, but also respiratory rate and blood pressure. It is possible to upload data to the cloud if the device is paired with a proprietary app (Biobeat App) while an internal memory can store temporarily data if the device is not using the app. Its wearability is a possible drawback because it includes not only a wrist monitor in shape of a bracelet but also a chest monitor in shape of a smart patch on patient chest. It is equipped with a web management platform. This device has FDA, CE, Australian Department of Health, Canadian Health certification (https://www.bio-beat.com/)

Chronisense Medical (also known as Polso)

It is a medical grade, Holter-like, multiparameter monitoring device in an easy-to-wear wrist band able to measure pulse oximetry, pulse rate, blood pressure, respiration rate, ECG, temperature, heart rate variability, activity. However, it is FDA cleared only for pulse oximetry, pulse rate, and respiration rate. It uses the radial artery in the wrist as a source of physiologic information in real time. It can also send data to the cloud if paired to an app installed on a connected smart device (https://polsowatch.com/). In scientific literature there is a paper published in 2019 introducing a validation study presenting protocol and study design to measure vital signs in hospitalised patients, comparing Chronisense with the traditional monitoring carried out manually by nurses [111].

Cardiacsense

It is a Holter-like watch specifically designed for cardiac use which can monitor Heart Rate with medical accuracy. Its algorithm can accurately distinguish atrial fibrillation from sinus rhythm.

Future developments will include other heart arrhythmia. The watch has the CE Mark. It is useful both for initial atrial fibrillation detection when symptoms or risk factors suggest this diagnosis and for non-invasive monitoring of atrial fibrillation recurrence after ablation [112-114]. In addition to AF, recording of additional vital signs such as continuous respiratory rate, oxygen saturation, temperature, and blood pressure will be added in the near future. Also this device requires to be paired to an app installed on a connected smart device to upload data in cloud.

Oxitone 1000M

This device is a real time remote monitoring wrist-sensor pulse oximetry monitor without fingertip probe which provides POy, skin temperature, pulse rate and heart rate variability, pedometer, motion and time. Fall detection and respiratory rate are, according to the website, under development. It is wearable, easy to use and FDA and CE certified. It uses a patented trans-illumination optical technology for real-time SpO_2 and pulse rate reading. It warrants 1-second resolution data and vibrational alert, has a long life rechargeable battery with a fast charging and connects *via* Bluetooth (https://www.oxitone.com/).

BrOxy-M

BrOxy-M is another Holter-like patented pulse oximeter wearable like a watch (https://www.lifemetersrl.com/). It is CE marked, can record in real life and store clinical data which can be analysed afterwards, including oxygen saturation and heart rate over a 24-hour period, while the subject carries out his/her daily physical activity and at night. Its accuracy can be considered very high because it has a peculiar exclusive calibration system, protected by two patent families which can record by its sensor an "unmistakable patient's fingerprint" (https://www.lifemetersrl.com/). It consists of three components: i) a bracelet with built-in SpO_2, heart rate monitor and accelerometer to record and store data; ii) a charger with an interface for uploading data/information to the cloud; and iii) a software containing a proprietor patented analysis algorithm which interprets the data. These can be given to the user as raw data or as a medical report, i.e. with data analysed and interpreted by a specialist, even operating remotely. In the scientific literature this device has been tested with a standard [115] reference, medical pulse oximeter (Nellcor PM 1000N). SpO_2 and HR readings by the two devices resulted significantly correlated ($r=0.91$ and 0.96, $p<0.001$, respectively) and analyses excluded the presence of proportional bias.

Bora Care

Bora Care is a real time remote monitoring device, a good answer to the "ideal device" description. It works with a bracelet (Bora-band), a connecting device (Bora-Box, a portable telephone), an on-line platform (Bora connect, which allows the visualization for the clinician of vital sign data as well as of respiratory devices used by the patient). Clinical data are collected intermittently and not continuously. According to the productor's site (https://biosency.com/en/solution/), Bora Care is an integrated solution for the tele-monitoring of patients, even at home, requiring no intervention from the user, aimed at optimising the patients care pathways and improving their quality of life. The system, of which the device is a component, is described as a disruptive digital solution capable of integrating clinical data analysis and facilitating collaboration among various health professionals.

Conclusions

Respiratory and cardiovascular NCDs are very common and account for a large portion of community health expenditures. Their prevalence is expected to rise further as the population ages. However, the current model of care for diagnosing and monitoring these conditions, which is based on reported symptoms and subsequent inpatient tests and treatments (often in hospitals), results in late medical interventions and a poor cost-effectiveness balance. Telemonitoring projects and programs are a way to get earlier diagnosis and more cost-effective management of chronic diseases by moving management outside of hospital settings.

Since decades, POs have been a cornerstone in reliably measuring vital parameters in a wide range of clinical settings, including telemonitoring. Looking for a new use of POs that can address the aforementioned challenges while improving patient quality of life and health-care budgets, new devices based on this well-known technology are now being developed or made available. Some of them can telemonitor patients' vital parameters in real time (in a "Holter-like" mode), correlating them to daily activities even 24 hours a day. This clinical practice has been dubbed "dynamic pulse-oximetry," and its application promises to improve chronic disease management.

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Abbreviations

6MWT: 6-minute walking test;
ABPM: arterial blood pressure monitor:
AF: atrial fibrillation;
AFVW: AF virtual ward;
AOM: ambulatory oximetry monitoring;
CCHD: critical congenital heart disease;
CHD: congenital heart disease;
COPD: chronic obstructive pulmonary disease;
DALY: disability-adjusted life year;
ECG: electrocardiogram;
ED: emergency department;
ERS: European Respiratory Society;
GARD: Global Alliance against Chronic Respiratory Diseases;
HF: heart failure;
HTM: home telemonitoring;
ICT: information and communications technology;
ILD: interstitial lung diseases;
IPF: idiopathic pulmonary fibrosis;
LTOT: long-term continuous oxygen therapy;
NCDs: non-communicable disease;
NIV: non-invasive mechanical ventilation;
OSA: obstructive sleep apnoea;
OSAS: obstructive sleep apnoea syndrome;
POs: pulse-oximeters, both finger and pulse ones;
POy: pulse-oximetry;
PPG: photopletismography;
SGRQ: St. George's Respiratory questionnaire;
TF: telemonitoring follow up;
TI: telemonitoring interventions;
YLL: years of life lost.

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