Telemonitoring of Home Oxygen Therapy: A Review of the State of the Art and Introduction of a New Cloud-based System

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ABSTRACT

Home oxygen therapy allows patients requiring longterm oxygen therapy to receive care at home and helps improve the prognosis of patients with chronic respiratory failure. The usage conditions of oxygen concentrators, which are used to supply gaseous oxygen, and the effects of oxygen inhaled at a prescribed flow rate have not been confirmed in adequate detail. As a result of advances in information and communications technology, internet communication functions can now be incorporated into medical devices installed in patients' homes. This allows time-series data on oxygen concentrator usage and biological variables to be stored on a server and accessed remotely by health care providers, enabling them to check the validity of home oxygen therapy and intervene appropriately. In Japan, telemonitoring of home oxygen therapy is covered by social insurance systems and is recognized as a new medical technology. This article reviews the usefulness of telemonitoring of home oxygen therapy and describes the cloud-based analytical system we have developed.

Key words arterial blood oxygen saturation; chronic respiratory failure; health-related quality of life; home oxygen therapy; telemonitoring

Home oxygen therapy (HOT) plays an important role in home medical care and provides long-term oxygen therapy to improve patients' quality of life (QOL) and prognosis. HOT has been covered by social insurance programs in Japan since 1985 and is administered to many patients. In Japan, indications for HOT include

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Abbreviations: COPD, chronic obstructive pulmonary disease; EQ-5D, EuroQol 5-dimension questionnaire; HADS, Hospital Anxiety and Depression Scale; HOT, home oxygen therapy; HRQOL, health-related quality of life; ICT, information and communications technology; IoT, Internet of Things; QOL, quality of life; SF-36, Medical Outcome Study 36-Item Short Form Health Survey; SGRQ-C; St George's Respiratory Questionnaire for COPD patients; SpO₂, percutaneous arterial blood oxygen saturations

chronic respiratory failure, chronic heart failure with Cheyne-Stokes respiration, pulmonary hypertension, and cyanotic congenital heart diseases. The vast majority of patients with chronic respiratory failure require HOT, and it improves the prognosis in these patients. 1-3 Regarding the duration of oxygen inhalation, a study in patients with chronic obstructive pulmonary disease (COPD) with chronic respiratory failure reported that the prognosis was better in the group that received continuous, 24-hour oxygen inhalation than in the group that received nocturnal oxygen inhalation.⁴ A costeffectiveness study also found better cost-effectiveness in the continuous oxygen inhalation group than in the nocturnal oxygen inhalation group.⁵ Health economic study has shown the importance of inhaling oxygen over long periods of time; however, some patients did not use oxygen inhalation long enough and setting of oxygen flow rate was not optimal.

Telemonitoring is a new medical tool that has emerged from developments in information and communications technology (ICT). For example, the use of cardiac pacemakers and implantable cardiac defibrillators compatible with telemonitoring has been reported to reduce mortality, the number of hospitalizations, and the frequency of face-to-face clinical consultations. 6–8 In cardiac diseases, telemonitoring improves patients' QOL and prognosis. 6–8

Recently, social insurance programs in Japan started covering the cost of telemonitoring of HOT. To request social insurance reimbursement for telemonitoring of HOT, a care provider is required to remotely monitor pulse rates, percutaneous arterial blood oxygen saturation (SpO₂) levels⁹ (measured with a pulse oximeter), and the usage conditions of an oxygen concentrator and also needs to provide the patient with instructions based on the monitoring. This article describes the usefulness of telemonitoring of HOT and introduces an analytical system that we have developed to enable health care providers to use their own computers to analyze integrated time-series data from telemonitoring.

USEFULNESS OF TELEMONITORING OF HOT

Below, studies are discussed that have examined the ability of telemonitoring of HOT to improve

Table 1. Characteristics of studies investigating the usefulness of telemonitoring of home oxygen therapy

Author	Type of study	No. of patients	Variables monitored	Significant improvements found
Kamei et al. (27)	RCT	37	Blood pressure, pulse rate, SpO ₂ , symptoms, body weight	Number of acute exacerbations, hospitalizations, length of hospital stay
Segrelles Calvo et al. (28)	Non-RCT	59	Blood pressure, pulse rate, SpO ₂ , peak flow, temperature	Number of acute exacerbations, emergency department visits, hospitalizations, length of hospital stay
Faria et al. (33)	Non-RCT	35	Heart rate, SpO ₂ , METS (measured with an accelerometer)	Adequate oxygen prescription
Ancochea et al. (29)	RCT	240	Blood pressure, pulse rate, SpO ₂ , spirometry data, respiratory rate, usage time of oxygen concentrator	
Burioka et al. (22)	Non-RCT	12	Pulse rate, SpO ₂ , usage time of oxygen concentrator	SF-36 scores of vitality and mental health

METS, metabolic equivalents; RCT, randomized controlled trial; SF-36, Medical Outcome Study 36-Item Short Form Health Survey; SpO₂, percutaneous arterial blood oxygen saturation.

health-related QOL (HRQOL), prevent acute exacerbations, and reduce the number of emergency department visits and hospitalizations in patients with chronic respiratory failure. The efficacy of telemonitoring in patients receiving HOT for other diseases remains unclear and further research is needed.

Effects on HRQOL

A limited number of studies examined patients receiving HOT for chronic respiratory failure (Table 1), and many studies compared HRQOL scores before and after patients with COPD started receiving telemonitoring without HOT.¹⁰ Long-term oxygen therapy is often required when COPD worsens to its most severe level.^{11, 12}

A meta-analysis of reports on telemonitoring in patients with COPD showed significant improvements in mental health-related QOL scores, ¹³ and an intervention involving telemonitoring of blood pressure, heart rate, and SpO₂ in patients with COPD demonstrated improvements in HRQOL scores measured with the St George's Respiratory Questionnaire for patients with COPD (SGRQ-C),14 the EuroQol 5-dimension questionnaire (EQ-5D), 15 and the Hospital Anxiety and Depression Scale (HADS). 16, 17 Another intervention involving telemonitoring of symptoms, spirometer readouts, and SpO₂ levels in patients with COPD showed an improvement in HRQOL measured with the 15D QoL questionnaire. 18, 19 Additional studies showed that various telemonitoring interventions improved the HRQOL of patients with COPD.^{20, 21} An interventional guidance based on telemonitoring of oxygen concentrator usage conditions, pulse rates, and SpO2 levels in patients receiving HOT for chronic respiratory failure was reported to improve vitality and mental health scores assessed with the Medical Outcome Study 36-Item Short Form Health Survey (SF-36).²² In contrast, some studies have found that telemonitoring does not improve HRQOL in patients with COPD.^{10, 23, 24} A systematic review attributed this finding to differences between studies in the methods used for telemonitoring in patients with COPD; specifically, some studies involved simple telemonitoring of biological variables, whereas others used the telemonitoring data to intervene.¹⁰ The usefulness of telemonitoring of HOT may depend on the different types of biological variables and instrument-related information being monitored and the way health care providers intervene. Thus, future studies should evaluate which variables provide the most useful information.

Effects on the number of acute exacerbations, emergency department visits, and hospitalizations

Telemonitoring has been used mainly in patients with COPD who are not receiving HOT. A meta-analysis of reported studies involving telemonitoring and intervention in patients with COPD found significant improvements in the number of emergency department visits and hospitalizations, ¹³ and a systemic review of telenursing of patients with COPD also found that telemonitoring of blood pressure, symptoms, SpO₂ levels, and pulse rate decreased the number of hospitalizations, emergency department visits, and acute exacerbations. ²⁵ However, a systematic review of studies on telemonitoring and intervention in patients with COPD suggested that telemonitoring and intervention did not help prevent exacerbations. ²⁶

Only a small number of reports have described the effectiveness of telemonitoring of HOT in preventing

acute exacerbations and reducing the number of emergency department visits and hospitalizations. A few studies have evaluated the effects of telemonitoring in patients receiving HOT for chronic respiratory failure (Table 1). A study conducted in Japan showed that telenursing by telemonitoring patients with COPD receiving HOT (including assessing blood pressure, symptoms, SpO₂, pulse rates, and body weight) resulted in significant decreases in the number of hospitalizations, the duration of hospital stays, and the number of acute exacerbations.²⁷ Describing the findings of the PROMETE study, in which patients with severe COPD receiving HOT were advised to visit a hospital when telemonitoring detected a possible exacerbation of COPD, Segrelles Calvo et al. reported that telemonitoring of blood pressure, SpO₂, pulse rate, and peak flow data significantly reduced the number of emergency department visits and hospitalizations and the duration of hospital stays.²⁸ In contrast, in a later study Ancochea et al. reported that telemonitoring of blood pressure, SpO₂, pulse rate, respiratory rate, and spirometry data did not reduce the number of COPD-related emergency department visits or hospitalizations of patients with severe COPD receiving HOT.²⁹

A study conducted in patients with severe COPD, some of whom were receiving HOT, found that telemonitoring of SpO₂, spirometry, and symptoms combined with video interviews decreased the number of outpatient consultations in the telemonitoring group, whereas the rate of hospitalizations and time to first hospitalization did not differ from the control group.³⁰ Similarly, a study on telemonitoring of SpO₂ and pulse rate data found a lower rehospitalization rate in the group of patients with severe COPD, some of whom were receiving HOT, than in the control group; in contrast, the study found no differences in the hospitalization rates or number of emergency department visits between the 2 groups.³¹

In conclusion, findings are inconsistent on whether or not telemonitoring of HOT is effective in preventing acute exacerbations and decreasing emergency department visits and hospitalizations. Determining when and how to intervene on the basis of telemonitoring data is important and requires further research. Studies are also needed to identify criteria for when telemonitoring is indicated because patients receiving HOT are generally severely ill.

NEW SYSTEM FOR TELEMONITORING OF HOME OXYGEN THERAPY

As mentioned above, oxygen concentrators are used as the primary sources of gaseous oxygen in HOT.

In Japan, new functions have been added to oxygen concentrators so that patients can use HOT comfortably.³² Interviews during outpatient hospital visits are not sufficient for confirming in adequate detail the usage conditions of oxygen concentrators at home, and research has shown the difficulties associated with determining whether oxygen is inhaled at an appropriate flow rate during HOT.³³ To solve these problems, we have developed an analytical system that allows health care providers to use their own computers to analyze the usage conditions of oxygen concentrators and integrated time-series data consisting of pulse rates and SpO₂ values measured by patients themselves with a dedicated pulse oximeter. Furthermore, in collaboration with a corporate partner we have used this system to develop an oxygen concentrator with an Internet-of-Things (IoT) function.

Various methods have been used for telemonitoring of HOT in patients with chronic respiratory failure. The telemonitoring system we have developed is a new medical technology. It does not monitor the patient's condition continuously but uses an internet-connected device to automatically save the time-series data on a dedicated server, which allows health care providers to use their own computers at any time to access and analyze the data (Fig. 1). These data include the device operating status and biological variables. Health care providers use the monitoring results to adapt the patients' HOT parameters as necessary.

The oxygen concentrator we developed for telemonitoring of HOT (FH-100/5L, Fukuda Denshi, Tokyo) is covered by the social insurance system in Japan. The information on the oxygen concentrator and the biological variables measured by the patient at home, ie, SpO₂ levels and pulse rates, are integrated by the part of the devices called the Fukuda Home Management System® (FHM-O2®, Fukuda Denshi) (Fig. 2). The HOT Careline® (Fukuda Denshi) comprises a cloud system, which automatically stores the data on a dedicated server via the internet, and the telemonitoring part (Fig. 1), which allows users to access the accumulated data on personal computers. After logging into a dedicated server online via the internet, our HOT telemonitoring allows for multifaceted actions, including: (i) checking the time periods and total time the oxygen concentrator was used; (ii) confirming the use of the prescribed flow rate for oxygen inhalation and the actual oxygen flow rates used; (iii) checking for hypoxemia (SpO₂ \leq 90%); and (iv) displaying self-measured SpO₂ levels and pulse rates for each flow rate of inhaled oxygen in the form of a scatter plot. Because the device itself connects to the internet via the mobile phone network, patients are not

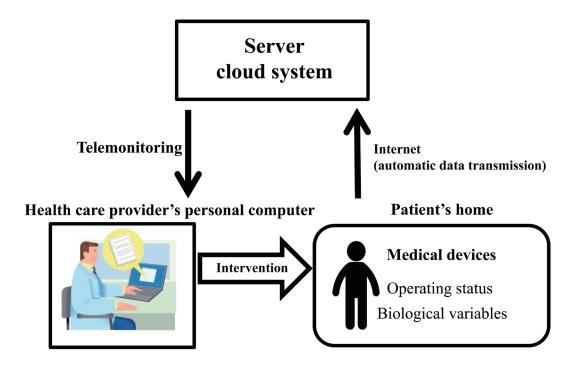


Fig. 1. Telemonitoring of home oxygen therapy. A conceptual diagram of telemonitoring. A communication card inserted into the medical device at home automatically uploads the operating status and measurement results to a dedicated server on a periodically basis by connecting to the internet (the so-called cloud system). The analysis software installed on the server is used to create charts to allow objective analysis of the stored time-series data. Health care providers can check the results and use them to support medical treatment of patients.

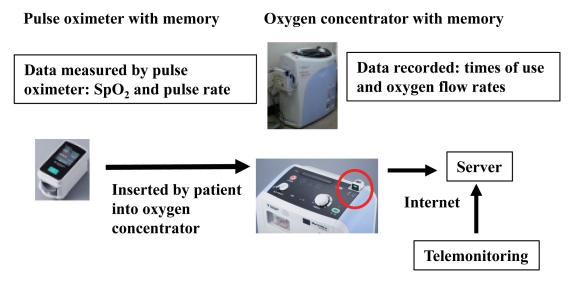


Fig. 2. An overview of the system used to integrate biological variables and usage information of an oxygen concentrator. The patient measures SpO₂ levels and pulse rates with a dedicated pulse oximeter and inserts the pulse oximeter into the oxygen concentrator, which stores and integrates the usage data of the oxygen concentrator and biological variables from the pulse oximeter. The oxygen concentrator connects to the internet via a mobile phone network that periodically and automatically uploads the integrated information to the server of the cloud system.

required to do anything more complicated than using a dedicated pulse oximeter (Anypal®, Fukuda Denshi).

As an example, Fig. 3 shows a telemonitoring

screen of HOT displaying the device usage information for a 28-day period in a 78-year-old man receiving HOT for chronic respiratory failure due to COPD. After

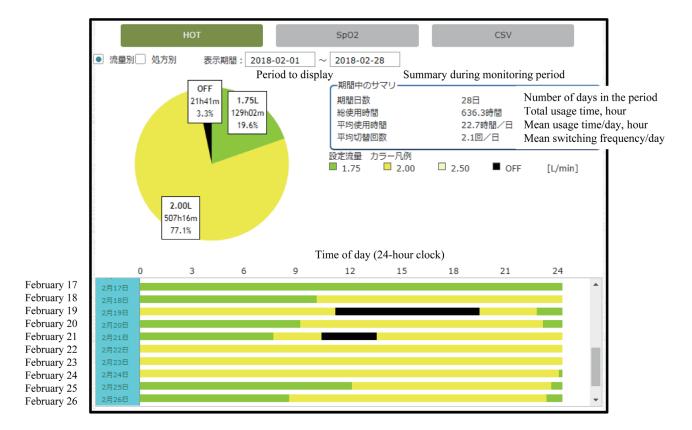


Fig. 3. Example usage conditions of an oxygen concentrator. The figure shows a health care provider's view of an example analysis screen. The pie chart allows health care providers to check oxygen flow rates over 1 month and the percentage of time during which the oxygen concentrator was not used. The 78-year-old patient in this example used the oxygen concentrator adequately but did not use the 3 L/min oxygen flow rate prescribed for use during exertion. CSV, comma-separated values; SpO₂, percutaneous arterial blood oxygen saturation.

logging into the dedicated server from a computer, the man's health care provider can analyze any period and prescribe an oxygen inhalation flow rate. In general, at least 3 different flow rates are prescribed, ie, one at rest, one during exertion, and one during sleep. In the presented case, the prescribed oxygen flow rates are 2 L/min at rest, 3 L/min during exertion, and 1.75 L/ min during sleep. The pie chart depicts the percentage of time that oxygen flowed at 2 different rates (rest and sleep) over the 28-day period and the percentage of time during which the oxygen concentrator was not used. The mean usage time during the period was 22.7 h/day, indicating that the patient was using the system enough. Figure 4 shows a scatter plot of SpO₂ levels on the vertical axis and pulse rates on the horizontal axis; the clustering of data in the upper left area is considered to indicate a favorable state. The colors of the squares show the oxygen flow rates at the time of measurement. The normal ranges for SpO₂ and pulse rate are greater than 90% and below 100 beats/min, respectively. The patient's health care provider confirmed with the patient that the SpO₂ values less than or equal to 90%

were measured after exertion; accordingly, health care provider reminded the patient to inhale oxygen at a flow rate of 3 L/min during exertion. The system allows health care providers to show analysis results directly to patients when giving them specific instructions and explaining them.

CONCLUSIONS

No consensus has been reached regarding the evaluation of telemonitoring of HOT because patients receiving this therapy are critically ill and have many comorbidities, and various methods are used for telemonitoring. Frequent monitoring is required to prevent acute exacerbations, emergency department visits, and hospitalizations, but providing frequent instruction and intervention on the basis of monitoring results is difficult. The above-mentioned good results found in some studies may be attributable to adequate instruction and intervention based on monitoring.

In general, the use of telemonitoring in HOT makes it easier to determine the usage of oxygen concentrators and oxygen flow rates.³³ HOT is less useful if a

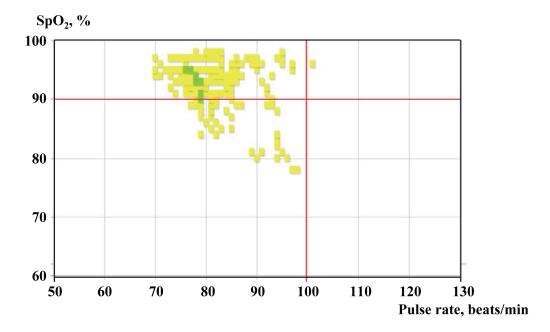


Fig. 4. An example scatter plot of oxygen saturation (SpO₂) levels and pulse rates. Oxygen flow rates are color coded for easy interpretation. The upper left area of the scatter plot, in which SpO₂ is above 90% and pulse rate is below 100 beats/min, is considered to represent a good condition. In this example, because some SpO₂ values were equal to or below 90% and the 3 L/min oxygen flow rate was not used on exertion, the health care provider reminded the patient to inhale oxygen at a flow rate of 3 L/min during exertion. Green square: oxygen flow rate, 1.75 L/min. Yellow square: oxygen flow rate, 2 L/min.

patient does not inhale oxygen at home for long enough. Therefore, an important benefit of using telemonitoring is the ability to easily examine usage of the oxygen concentrator. Moreover, telemonitoring allows for an objective analysis of the appropriateness of the prescribed oxygen flow rates by using SpO₂ and pulse rate data measured by patients themselves with dedicated pulse oximeters. Prolonged intervals between face-to-face outpatient consultations made it difficult for care providers to understand patients' conditions in a timely manner. Telemonitoring allows for closer monitoring and makes it possible to be longer intervals between hospital visits.

It should be noted that the telemonitoring of HOT approved in Japan does not provide continuous monitoring. Therefore, it is not currently suitable for detecting acute exacerbations, and patients should be informed of this point. Nevertheless, telemonitoring of HOT can be expected to improve the HRQOL and prognosis of patients receiving HOT for home medical care in the future.

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