フクダホームケアマネージメントシステム(FHM-02)を用いた在宅酸素療法患者の指導経験

鳥取大学医学部 保健学科 検査技術科学専攻
病態検査学講座 病因・治療管理学分野 教授 鰤岡 直人

1 背　景

在宅酸素療法は酸素療法の必要な患者が住み慣れた自宅で療養し,患者の生活の質(QOL)を改善できる重要な治療法である。本邦でも1985年に社会保険の適用が認められ,約14万人の患者が在宅酸素療法を受けている。在宅酸素療法は呼吸器疾患による慢性呼吸不全だけでなくチェーン・ストークス呼吸を合併した慢性心不全,肺高血圧症,チアノーゼ型先天性心疾患などにも適応がある。特に,慢性呼吸不全患者に在宅酸素療法を行うと生命予後が改善する[1,2]。また,12時間酸素吸入するより24時間酸素吸入した方が生命予後がよい[3]。しかし,患者が在宅酸素療法で使用する酸素濃縮器を医師の処方酸素流量通り適正に使用しているか,あるいは一度処方した流量が患者の様々な生活の場において適切かどうかは患者の自己申告によるところが大きく客観的な評価法がほとんどないのが現状である。

2 目　的

フクダホームケアマネージメントシステム(FHM-02)は酸素濃縮器の機器情報と生体情報を統合させた画期的システムで,療養生活において患者が使用する酸素濃縮器の動作状況と患者自身が測定したパルスオキシメータの測定データとの相関,統計情報を記録・表示できる。医師などが記録データを分析することで在宅酸素療法の客観的指導管理に活用できる装置群である。

FHM-02は大きく分けて2つのサブシステムからなる。一つは吸着型酸素濃縮器内部に酸素吸入量,酸素吸入時間など動作状況を自動で蓄積・保存する機器情報サブシステムと付属の専用パルスオキシメータ(エニィパル®)に患者が適時測定した酸素飽和度(SpO_2),脈拍のデータをすべて記録する生体情報記録サブシステムである。エニィパル®は高齢者に見やすい有機EL画面を用いたカラー表示で測定終了を音と振動で伝える。特徴はパルスオキシメータに患者が測定したSpO_2だけではなく酸素濃縮器の動作状況データを保存できる点である。すなわちエニィパル®をクレードルに接続すると酸素濃縮器に蓄積した動作状況データを自動転送し保存できる。これにより時刻が同期された機器情報と患者の生体情報が統合できる。通常,エニィパル®はクレードルに入れておくため酸素濃縮器の使用情報が自動転送され内蔵のリチウム電池も充電される。煩雑な電池交換の必要がなくなり高齢者が多い在宅酸素療法患者の利便性が増すと予想される。今回,FHM-02の有用性を調べるため,在宅酸素療法を受けている実際の患者に本システムを用いて指導し付属の専用解析ソフトで解析,検討した。

3 方　法

対象は在宅酸素療法を受けている患者である。自宅で適時専用パルスオキシメータ,エニィパル®でSpO_2を自己測定させた。システムの仕組み上,酸素濃縮器から酸素吸入せずにパルスオキシメータで酸素飽和度を測定すると機器情報との乖離が生じるため,酸素吸入していないときは酸素濃縮器の電源を切るように指導した。個々の患者によって問題点が異なると考え,FHM-02を用いて処方酸素流量の妥当性,使用時間などを確認し,問題があれば処方酸素流量を変更したり使用時間などを指導した。有用性は個別に検討し,アウトカムとして健康関連QOLのMedical Outcome Study 36-Item Short-Form Health Survey(SF-36)を指導前後で調査した。SF-36は36の質問事項から「身体機能,physical function (PF)」,「日常役割機能(身体),role physical (RP)」,「体の痛み,body pain (BP)」,「全体的健康感,general health perception (GH)」,「活力,vitality (VT) 」,「社会生活機能,social function (SF)」,「日常役割機能(精神),role emotion (RE)」,「心の健康,mental health (MH)」の8尺度を0点から100点に得点化する包括的健康関連QOL調査票である。得点が高いほど,その項目のQOLが良いことを意味している[4,5]。

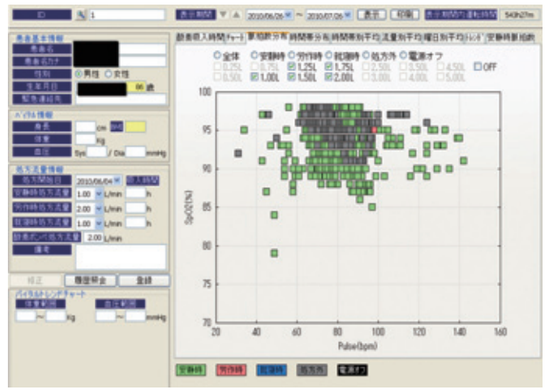
4 結　果

在宅酸素療法を受けている患者3名をFHM-02を用いて問題点を確認した。以下,症例ごとに提示する。

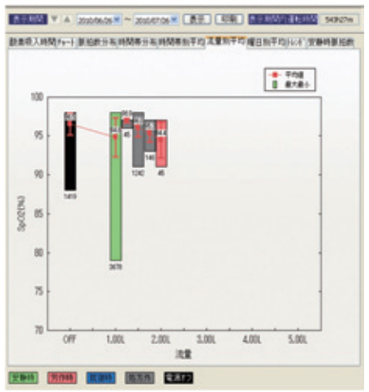
症例 1

80歳台,男性,動脈血ガス分析で pH 7.34, PaO_2 54 mmHg, $PaCO_2$ 48 mmHgとII型慢性呼吸不全を認めた.肺気腫による慢性呼吸不全治療のため,安静時 1L/分,労作時 2L/分,就寝時 1L/分の処方酸素流量で吸着式酸素濃縮器を使用し在宅酸素療法を受けていた。酸素濃縮器の流量を自己調節していると話したためFHM-02で解析した。2週間の解析の結果,図1のように処方外流量を認めた。図2はSpO_2と脈拍の関係である。安静時の処方酸素流量(黄緑色)でSpO_2が90%以下を多く認めた。図3は処方流量ごとのSpO_2グラフで,安静時(1L/分)の酸素吸入時でSpO_2が低下しているのがわかる。一方,自己増量した処方外流量ではSpO_2が90%以上になっている。患者本人に確認したところ,食事時および少し動く程度では労作時処方流量の2L/分に増量せず息苦しさを自覚していたと答えた。食事も想定以上の負荷があると考えられた。処方流量は入院した状態で決定しているため在宅での様々な負荷を考慮すべきと考え安静時 1.5 L/分に変更した。安静時,1.5 L/分に処方酸素流量を変更し約3ヶ月後,2週間の解析で処方外流量を認めず,SpO_2と脈拍の散布図でSpO_2が90%以下の割合が減少し自覚症状も改善していた(図4)。さらに詳細に検討するため保存データからCSV形式で脈拍,SpO_2,酸素濃縮器の稼働情報をエクセル(マイクロソフト,日本)に出力した。

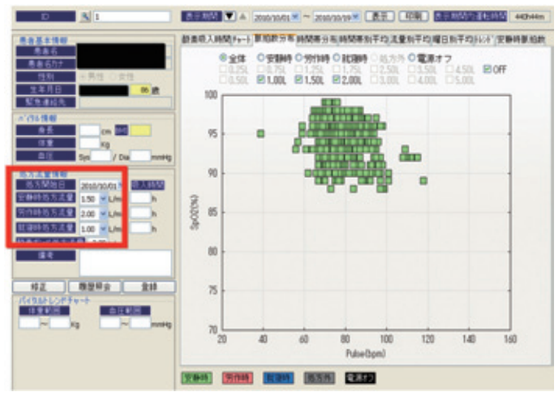
【図1】 タイムチャートの結果
処方外流量使用を約25%認めた。
処方外流量は灰色で示されている。



【図2】 酸素飽和度と脈拍散布図
処方外流量は灰色,安静時流量を使用した状態は黄緑色で示される。
安静時の処方酸素流量(黄緑色)では酸素飽和度90%以下を多く認めた。



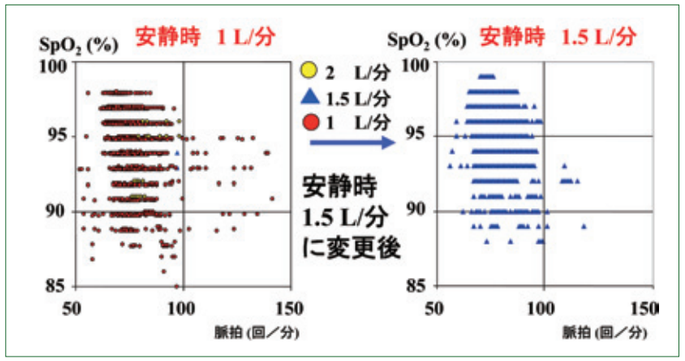
【図3】 処方流量ごとの酸素飽和度グラフ
安静時,1L/分の酸素吸入時(黄緑色)で酸素飽和度が低下しているのがわかる。
処方外流量(灰色)は1.25～1.75L/分とわかる。



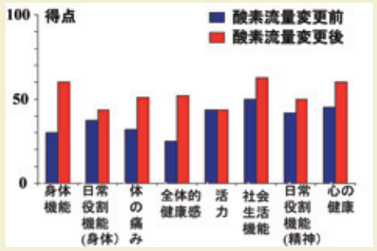
【図4】 処方流量変更後の酸素飽和度と脈拍の散布図
酸素飽和度90%以下の状態が減少していた。

図5は保存データから作図した結果で,酸素流量処方が安静時 1L／分,労作時 2L／分,就寝時 1L／分の期間,患者にエニィパル®で自己測定させた2週間の延べ3748拍分のうち,SpO_2 90%以下の割合は9.4%,脈拍100回／分以上の割合が1.4%と解析された。SpO_2 90%以下の割合が高く軽度労作時の酸素吸入量不足が確認された。安静時 1.5L／分に増量変更した3ヶ月後,安静時の酸素流量を増加させた状態で自己測定した2週間の延べ4796拍分のうち,SpO_2 90%以下の割合と脈拍100回／分以上の割合は各々,2.3%,0.4%と改善していた。

酸素流量変更で健康関連QOL,SF-36の得点は全体的に増加しQOLの改善を認めた(図6)。本システムを利用した結果,処方酸素流量を客観的に変更でき客観的な酸素飽和度の改善と主観的な健康関連QOL改善効果を確認できた。



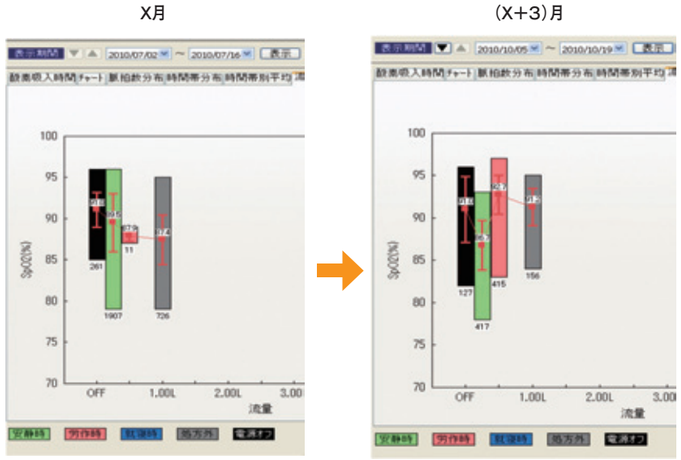
【図5】 酸素流量変更前後の酸素飽和度と脈拍の散布図(各2週間)
保存データをCSV形式で出力し解析した。
変更前,酸素飽和度90%以下の割合は9.4%であったが,変更し約3ヶ月後,2.3%まで改善した。



【図6】
酸素流量変更による健康関連QOL
SF-36の得点変化 全体的に改善していた。

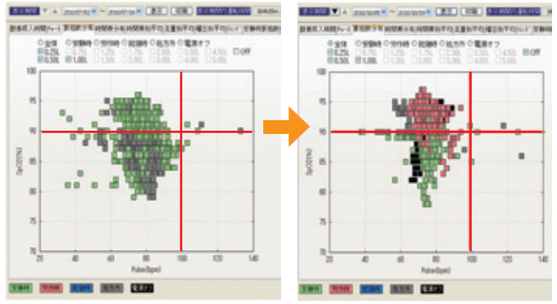
症例 2

80歳台,男性,肺結核後遺症があり動脈血ガス分析でpH 7.31, PaO_2 52mmHg, $PaCO_2$ 68mmHg(酸素0.25L/分吸入時)とⅡ型慢性呼吸不全を認めた。慢性呼吸不全治療のため,安静時 0.25L/分,労作時 0.5L/分,就寝時,非侵襲的人工呼吸(NPPV)を使用と共に1L/分の処方酸素流量で吸着式酸素濃縮器を使用していた。自覚症状は労作時呼吸困難,起床時の頭痛,呼吸困難などがあり,動脈血二酸化炭素分圧が高く酸素吸入量調整が難しかった。2週間,FHM-02で解析の結果,労作時の酸素吸入が処方通りされていなかったため労作時0.5L/分の酸素吸入を遵守するように指導した(図7)。また,NPPVが適切に行われていなかったため再指導した。約3ヶ月後,2週間,FHM-02で解析の結果,SpO_2が改善し(図8),動脈血ガス分析もpH 7.35, Pa O_2 64mmHg, $PaCO_2$ 63mmHg(酸素0.25 L/分吸入時)と改善した。労作時0.5L/分の酸素吸入を遵守するように指導およびNPPVの再指導により健康関連QOLが改善した。特に,活力,社会生活機能,心の健康の尺度が改善した(図9)。

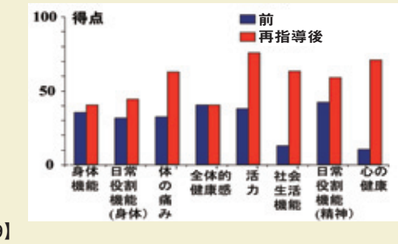


【図7】 酸素流量別の酸素飽和度
1L/分の酸素流量が処方外になっているが非侵襲的人工呼吸に併用し就寝時以外も使用することもあるため就寝時の青色にしていない。
労作時の酸素吸入として0.5L/分の酸素流量を遵守することとNPPVの使用を再指導した結果,酸素飽和度は改善した。

引用文献
1. Miyamoto K, Aida A, Nishimura M, et al. Gender effect on prognosis of patients receiving long-term home oxygen therapy. Am J Respir Criti Care Med 152: 972-976,1995.
2. Long term oxygen and advanced chronic bronchitis. Lancet 317(8222):701-2, 1981.
3. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Nocturnal Oxygen Therapy Trial Group. Ann Intern Med 93(3):391-8, 1980.
4. Fukuhara S, Bito S, Green J, et al., Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. J Clin Epidemiol 51: 1037-1044, 1998.
5. Fukuhara S, Ware J E, Kosinski M, et al., Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. J Clin Epidemiol 51: 1045-1053, 1998.



【図8】 酸素飽和度と脈拍の散布図
労作時の酸素吸入として0.5L/分の酸素流量を遵守することとNPPVの使用を再指導した結果,酸素飽和度は全体的に改善した。

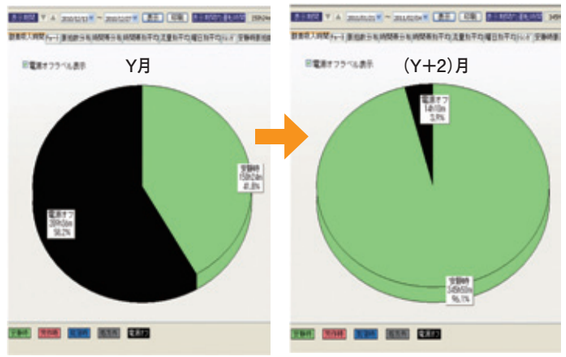


【図9】
労作時,処方流量遵守およびNPPV再指導による健康関連QOL SF-36の変化
FHM-02で解析の結果,労作時の酸素吸入が処方通りされていなかったため,労作時 0.5L/分の酸素吸入を遵守するように指導およびNPPVの再指導により健康関連QOLが改善した。特に,活力,社会生活機能,心の健康の尺度が改善した。

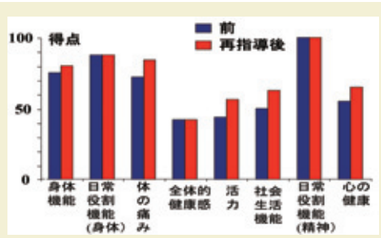
症例 3

70歳台,女性,気管支拡張症,肝硬変を基礎疾患とし動脈血ガス分析で pH 7.41, PaO_2 58 mmHg, $PaCO_2$ 32 mmHg と慢性呼吸不全を認めた。慢性呼吸不全治療のため,安静時 1L/分,労作時 2L/分,就寝時 1L/分の処方酸素流量で吸着式酸素濃縮器を使用し在宅酸素療法を受けていた。

FHM-02で2週間分を解析した結果,在宅酸素療法を導入したが十分に使用していないことが明らかになり24時間使用を指導した。約2ヶ月後,使用を確認できた(図10)。健康関連QOLも,わずかであるが改善した(図11)。



【図10】 酸素吸入時間チャート
在宅酸素療法を導入したが十分に使用していないことが明らかになり24時間使用を指導した。約2ヶ月後,使用を確認できた。



【図11】 再指導による健康関連QOL, SF-36の変化
酸素吸入を24時間するように再指導し,
SF-36の尺度はわずかではあるが改善を認めた。

FHM-02の使用経験から在宅酸素患者の指導に,主に以下の確認が有用と思われた。

(1) 酸素濃縮器使用状態のタイムチャートで処方外酸素流量が生じているかの確認。その後,患者に理由聴取。

(2) 酸素吸入時間図で電源オフの時間の確認。

(3) SpO_2と脈拍の散布図からSpO_2 90%以下の割合と脈拍100回／分以上の割合の確認。

(4) SpO_2の流量別平均値および最大最小値の図での処方酸素流量の妥当性確認。

(5) 必要があれば保存データからエクセルなどの市販ソフトにデータを出力し詳細に検討。

その他,FHM-02の解析ソフトに長期間の平均脈拍図もあるため平均脈拍から大きく増加した場合,急性増悪の把握にも役立つ可能性がある。また,SpO_2の時間帯別平均,曜日別平均などもあり,測定時刻を一定にしたり安静時,労作時のパルスオキシメータ測定を厳密にすれば,より明確な状態把握ができると思われる。

5 おわりに

FHM-02は専用パルスオキシメータ(エニィパル®)にSpO_2,脈拍だけでなく酸素濃縮器使用情報を保存しUSB利用で手持ちコンピュータを用いて簡単にレポート作成･解析でき,従来の在宅酸素療法に残された臨床的問題を解決可能な装置群である。今回,患者には専用パルスオキシメータの測定時刻を指定せず自己測定してもらったが,同一患者で概ね同様の時刻で測定していた。しかし,測定時刻を指定して検討も必要と考えられた。FHM-02を利用し在宅酸素療法患者を解析した結果,在宅酸素療法の臨床的問題点が明確になった。FHM-02を用いて酸素流量を検討し再指導を行い健康関連QOLが改善した。本システムは今後の在宅酸素療法の新たな進化を促進する複数の重要な技術を実現したと評価される。

Yonago Acta Medica 2020;63(4):239–245 doi: 10.33160/yam.2020.11.001

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

Naoto Burioka*

**Department of Pathobiological Science and Technology, Graduate School of Medical Sciences, School of Health Science, Faculty of Medicine, Tottori University, Yonago 683-8503, Japan*

ABSTRACT

Home oxygen therapy allows patients requiring long-term 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 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 cost-effectiveness 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 (SpO_2) levels[9] (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

Corresponding author: Naoto Burioka, MD, PhD
burioka@tottori-u.ac.jp
Received 2020 August 25
Accepted 2020 August 26
Online published 2020 September 19
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; SpO_2, percutaneous arterial blood oxygen saturation

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	None
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; SpO_2, 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 SpO_2 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 SpO_2 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 SpO_2 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, SpO_2 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, SpO_2, 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, SpO_2, 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, SpO_2, 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 SpO_2, 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 SpO_2 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 SpO_2 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, SpO_2 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 ($SpO_2 \leq 90\%$); and (iv) displaying self-measured SpO_2 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

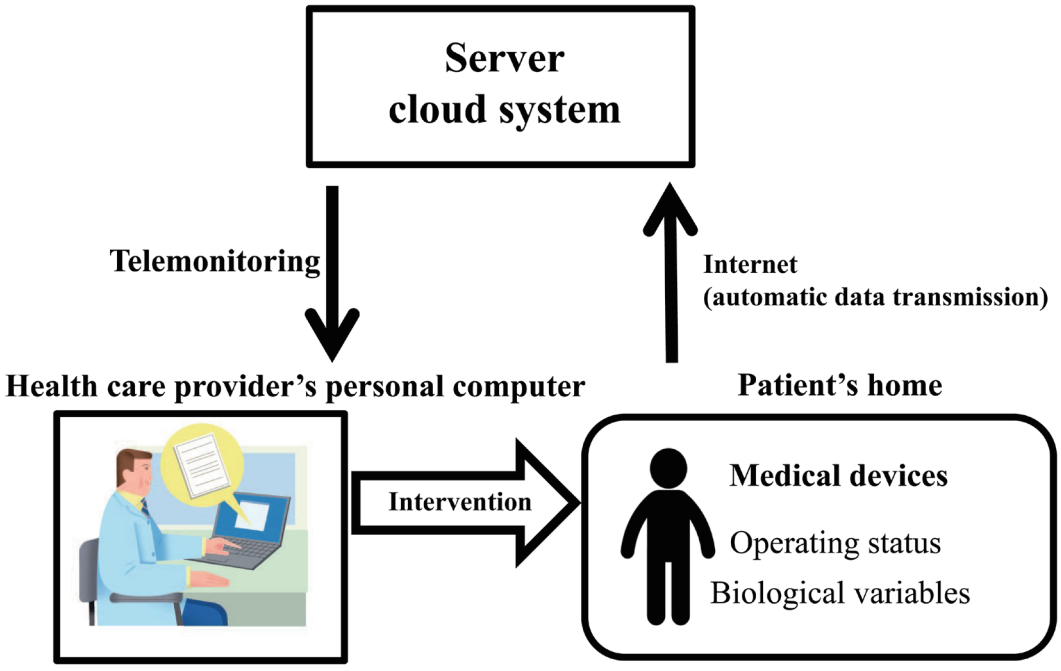


Fig. 1. Telemonitoring of home oxygen therapy. A conceptual diagram of telemonitoring. A communication card inserted into the medical device at home automatically uploads the operating status and measurement results to a dedicated server on a periodically basis by connecting to the internet (the so-called 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.

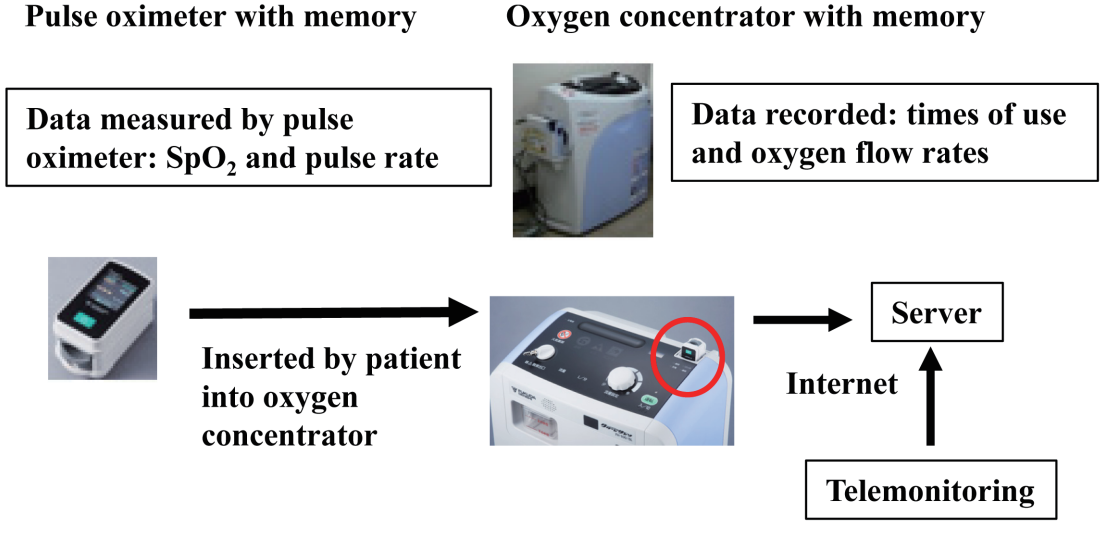


Fig. 2. An overview of the system used to integrate biological variables and usage information of an oxygen concentrator. The patient measures SpO_2 levels and pulse rates with a dedicated pulse oximeter and inserts the pulse oximeter into the oxygen concentrator, which stores and integrates the usage 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

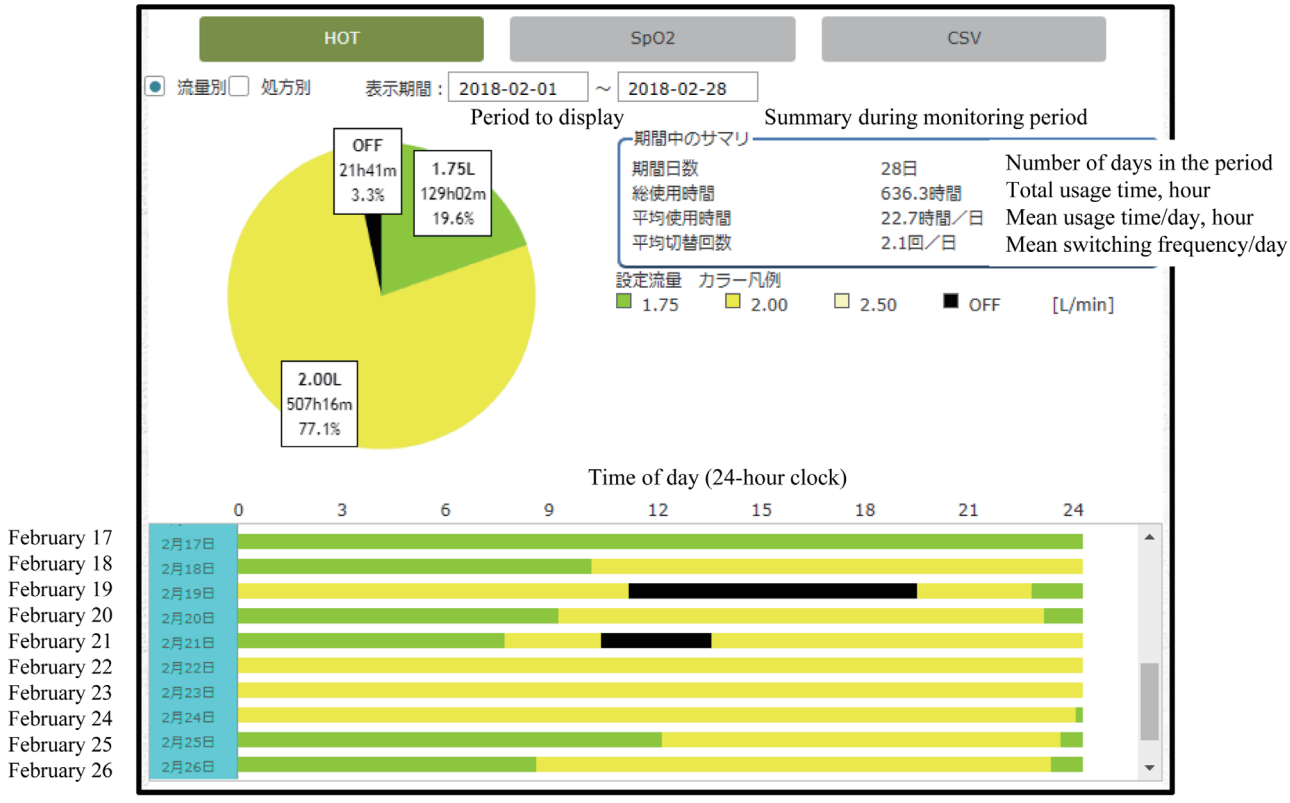


Fig. 3. Example usage conditions of an oxygen concentrator. The figure shows a health care provider's view of an example analysis screen. The pie chart allows health care providers to check oxygen flow rates over 1 month and the percentage of time during which the oxygen concentrator was not used. The 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; SpO_2, 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 SpO_2 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 SpO_2 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 SpO_2 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

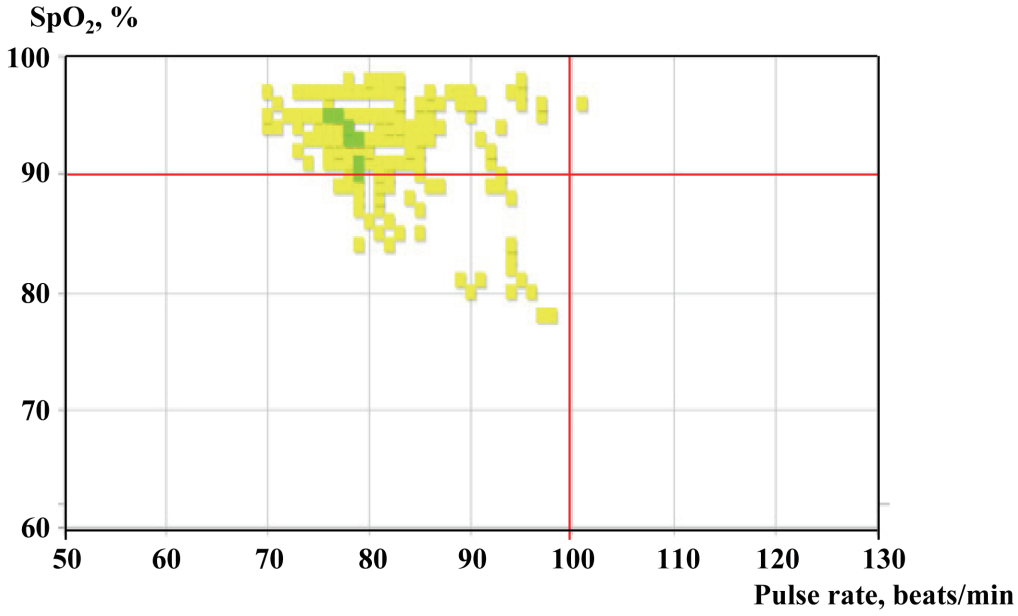


Fig. 4. An example scatter plot of oxygen saturation (SpO_2) levels and pulse rates. Oxygen flow rates are color coded for easy interpretation. The upper left area of the scatter plot, in which SpO_2 is above 90% and pulse rate is below 100 beats/min, is considered to represent a good condition. In this example, because some SpO_2 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 SpO_2 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.

Acknowledgments: This work was supported by JSPS KAKENHI, Grant Number JP17K12454.

Conflict of interest: Naoto Burioka received research funding from Fukuda Denshi.

REFERENCES

1 Miyamoto K, Aida A, Nishimura M, Aiba M, Kira S, Kawakami Y; The Respiratory Failure Research Group in Japan. Gender effect on prognosis of patients receiving long-term home oxygen therapy. Am J Respir Crit Care Med. 1995;152:972-6. DOI: 10.1164/ajrccm.152.3.7663812, PMID: 7663812

2 Hjalmarsen A, Melbye H, Wilsgaard T, Holmboe JH, Opdahl R, Viitanen M. Prognosis for chronic obstructive pulmonary disease patients who receive long-term oxygen therapy. Int J Tuberc Lung Dis. 1999;3:1120-6. PMID: 10599017

3. Long term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Report of the Medical Research Council Working Party. Lancet. 1981;1:681-6. PMID: 6110912

4 Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Ann Intern Med. 1980;93:391-8. DOI: 10.7326/0003-4819-93-3-391, PMID: 6776858

5 Oba Y. Cost-effectiveness of long-term oxygen therapy for chronic obstructive disease. Am J Manag Care. 2009;15:97-104. PMID: 19284806

6 Hindricks G, Taborsky M, Glikson M, Heinrich U, Schumacher B, Katz A, et al.; IN-TIME study group*. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. Lancet. 2014;384:583-90. DOI: 10.1016/S0140-6736(14)61176-4, PMID: 25131977

7 Mabo P, Victor F, Bazin P, Ahres S, Babuty D, Da Costa A, et al.; COMPAS Trial Investigators. A randomized trial of long-term remote monitoring of pacemaker recipients (The COMPAS trial). Eur Heart J. 2012;33:1105-11. DOI: 10.1093/eurheartj/ehr419, PMID: 22127418

8 Guédon-Moreau L, Lacroix D, Sadoul N, Clémenty J, Kouakam C, Hermida JS, et al.; ECOST trial Investigators. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial. Eur Heart J. 2013;34:605-14. DOI: 10.1093/eurheartj/ehs425, PMID: 23242192

9 Yamamoto A, Burioka N, Eto A, Amisaki T, Shimizu E. Usefulness of pulse oximeter that can measure SpO_2 to one digit after decimal point. Yonago Acta Med. 2017;60:133-4. DOI: 10.33160/yam.2017.06.010, PMID: 28701897

10 Gregersen TL, Green A, Frausing E, Ringbæk T, Brøndum E, Suppli Ulrik C. Do telemedical interventions improve quality of life in patients with COPD? A systematic review. Int J Chron Obstruct Pulmon Dis. 2016;11:809-22. DOI: 10.2147/COPD.S96079, PMID: 27143872

11 Global Initiative for Chronic Obstructive Lung Disease [Internet]. Fontana: Global Initiative for Chronic Obstructive Lung Disease, Inc [cited 2020 Aug 24]. Global strategy for prevention, diagnosis and management of COPD: 2020 report. Available from: https://goldcopd.org/gold-reports/.

12 Burioka N, Nakamoto S, Amisaki T, Horie T, Shimizu E. A modified method for examining the walking pattern and pace of COPD patients in a 6-min walk test before and after the inhalation of procaterol. Intern Med. 2017;56:1949-55. DOI: 10.2169/internalmedicine.56.7961, PMID: 28768962

13 Hong Y, Lee SH. Effectiveness of tele-monitoring by patient severity and intervention type in chronic obstructive pulmonary disease patients: A systematic review and meta-analysis. Int J Nurs Stud. 2019;92:1-15. DOI: 10.1016/j.ijnurstu.2018.12.006, PMID: 30690162

14 Meguro M, Barley EA, Spencer S, Jones PW. Development and validation of an improved, COPD-specific version of the St. George Respiratory Questionnaire. Chest. 2007;132:456-63. DOI: 10.1378/chest.06-0702, PMID: 17646240

15 Brooks R. EuroQol: the current state of play. Health Policy. 1996;37:53-72. DOI: 10.1016/0168-8510(96)00822-6, PMID: 10158943

16 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand. 1983;67:361-70. DOI: 10.1111/j.1600-0447.1983.tb09716.x, PMID: 6880820

17 McDowell JE, McClean S, FitzGibbon F, Tate S. A randomised clinical trial of the effectiveness of home-based health care with telemonitoring in patients with COPD. J Telemed Telecare. 2015;21:80-7. DOI: 10.1177/1357633X14566575, PMID: 25586812

18 Sintonen H. The 15D instrument of health-related quality of life: properties and applications. Ann Med. 2001;33:328-36. DOI: 10.3109/07853890109002086, PMID: 11491191

19 Tupper OD, Gregersen T, Ringbaek T, Brøndum E, Frausing E, Green A, et al. Effect of tele–health care on quality of life in patients with severe COPD: a randomized clinical trial. Int J Chron Obstruct Pulmon Dis. 2018;13:2657-62. DOI: 10.2147/COPD.S164121, PMID: 30214183

20 Blumenthal JA, Emery CF, Smith PJ, Keefe FJ, Welty-Wolf K, Mabe S, et al. The effects of a telehealth coping skills intervention on outcomes in chronic obstructive pulmonary disease: primary results from the INSPIRE-II study. Psychosom Med. 2014;76:581-92. DOI: 10.1097/PSY.0000000000000101, PMID: 25251888

21 Koff PB, Jones RH, Cashman JM, Voelkel NF, Vandivier RW. Proactive integrated care improves quality of life in patients with COPD. Eur Respir J. 2009;33:1031-8. DOI: 10.1183/09031936.00063108, PMID: 19129289

22 Burioka N, Yamamoto A, Morimoto M, Yamasaki A, Hirayama Y, Takata M. Health-related quality of life in patients on home oxygen therapy with telemonitoring. Yonago Acta Med. 2020;63:132-4. DOI: 10.33160/yam.2020.05.004, PMID: 32494220

23 Chatwin M, Hawkins G, Panicchia L, Woods A, Hanak A, Lucas R, et al. Randomised crossover trial of telemonitoring in chronic respiratory patients (TeleCRAFT trial). Thorax. 2016;71:305-11. DOI: 10.1136/thoraxjnl-2015-207045, PMID: 26962013

24 Walker PP, Pompilio PP, Zanaboni P, Bergmo TS, Prikk K, Malinovschi A, et al. Telemonitoring in Chronic Obstructive Pulmonary Disease (CHROMED). A Randomized Clinical Trial. Am J Respir Crit Care Med. 2018;198:620-8. DOI: 10.1164/rccm.201712-2404OC, PMID: 29557669

25 Kamei T, Yamamoto Y, Kajii F, Nakayama Y, Kawakami C. Systematic review and meta-analysis of studies involving telehome monitoring-based telenursing for patients with chronic obstructive pulmonary disease. Jpn J Nurs Sci. 2013;10:180-92. DOI: 10.1111/j.1742-7924.2012.00228.x, PMID: 24373441

26 Li X, Xie Y, Zhao H, Zhang H, Yu X, Li J. Telemonitoring interventions in COPD patients: overview of systematic reviews. BioMed Res Int. 2020;2020:1-9. DOI: 10.1155/2020/5040521, PMID: 32016115

27 Kamei T, Yamamoto Y, Kajii F, Nakayama Y, Kamei N. Preventing acute respiratory exacerbation and readmission of chronic obstructive pulmonary disease (COPD) patients with home oxygen therapy: evaluation of home monitoring-based telenursing practice by a randomized controlled trial. Journal of Japan Academy of Nursing Science. 2011;31:24-33. DOI: 10.5630/jans.31.2_24 Japanese with English abstract.

28 Segrelles Calvo G, Gómez-Suárez C, Soriano JB, Zamora E, Gónzalez-Gamarra A, González-Béjar M, et al. A home telehealth program for patients with severe COPD: the PROMETE study. Respir Med. 2014;108:453-62. DOI: 10.1016/j.rmed.2013.12.003, PMID: 24433744

29 Ancochea J, García-Río F, Vázquez-Espinosa E, Hernando-Sanz A, López-Yepes L, Galera-Martínez R, et al. Efficacy and costs of telehealth for the management of COPD: the PROMETE II trial. Eur Respir J. 2018;51:1800354. DOI: 10.1183/13993003.00354-2018, PMID: 29599185

30 Ringbæk T, Green A, Laursen LC, Frausing E, Brøndum E, Ulrik CS. Effect of tele health care on exacerbations and hospital admissions in patients with chronic obstructive pulmonary disease: a randomized clinical trial. Int J Chron Obstruct Pulmon Dis. 2015;10:1801-8. DOI: 10.2147/COPD.S85596, PMID: 26366072

31 Vianello A, Fusello M, Gubian L, Rinaldo C, Dario C, Concas A, et al. Home telemonitoring for patients with acute exacerbation of chronic obstructive pulmonary disease: a randomized controlled trial. BMC Pulm Med. 2016;16:157. DOI: 10.1186/s12890-016-0321-2, PMID: 27876029

32 Burioka N, Takano K, Chikumi H, Suyama H, Sako T, Sasaki T. Clinical and in vitro evaluation of membrane humidifier that does not require addition of water. Respir Med. 2000;94:71-5. DOI: 10.1053/rmed.1999.0673, PMID: 10714482

33 Faria I, Gaspar C, Zamith M, Matias I, César das Neves R, Rodrigues F, et al. TELEMOLD project: oximetry and exercise telemonitoring to improve long-term oxygen therapy. Telemed J E Health. 2014;20:626-32. DOI: 10.1089/tmj.2013.0248, PMID: 24796364