

Executive Summary

Clinical Effectiveness of Telehealth Monitoring Intervention for Asthma and Chronic Obstructive Pulmonary Disease: A Systematic Review

Dong Ah Park¹, Ah Ram Sul¹, Youjin Jung¹, Jimin Kim¹, Da Hyun Lyu¹

¹ National Evidence-based Healthcare Collaborating Agency

□ Background

As a result of analysing cause of death announced by Statistics Korea in 2015, it was found that chronic diseases and cardiovascular diseases requiring continuous care account for the largest part of it. The prevalence of chronic disease is growing due to bad eating habits of modern people and decline of physical activities, etc. as well as aging of modern society, but, despite the development of medical technology, the treatment rate of chronic disease such as asthma and COPD (Chronic Obstructive Pulmonary Disease) is remarkably low (Choi et al., 2009).

Patients with chronic disease such as asthma and COPD should make accurate diagnosis and treatment conducted by observing and recording daily symptoms and treatment effects, and complication occurrence status and reporting them to medical team, and the active attitude for taking medicine or life style correction is required of them.

Nowadays, owing to an increase in accessibility, ICT (Information and Communication Technology) development and low cost, the patient care utilizing a home telemonitoring intervention is drawing massive interest (Bolton, 2010). Telehealth or telemedicine may be defined as the use of information and communication technologies to deliver healthcare at a distance and to support patient self-management through remote monitoring and personalised feedback. Telemonitoring for asthma or COPD involves

patients regularly recording and transmitting their symptoms and physiological measurements to supervising clinicians. These symptoms are scored and if the total score breaches an agreed level or if a physiological measure is out-with preset parameters, then clinicians are alerted and can respond promptly to changes which may be interpreted as significant worsening of the patients' clinical condition. In this way it is hoped that exacerbations can be identified at an early stage and treatment instituted to prevent serious deterioration and hospital admission (McKinstry, 2013). Therefore, in this study, we tried to analyse clinical effects of the telemonitoring intervention in chronic diseases such as asthma and COPD which are most applied to this intervention after diabetes, hypertension, heart failure and depressive disorder already assessed in 2015.

□ Objective

This study aims to provide objective basis which is of help in making a decision for the telemedicine policy figuring out detailed characteristics of telemonitoring intervention for managing asthma and COPD and contemplating systematically documentary basis on clinical effects of it.

□ Methods

1. Rapid review

We conducted the overview of systematic reviews about telemonitoring intervention for asthma and COPD management. Relevant systematic reviews of telemonitoring interventions were identified through searches in Ovid-MEDLINE, Ovid-EMBASE, Cochrane Library using SIGN (Scottish Intercollegiate Guidelines Network) systematic review filter. We included the systematic reviews that were published in English and Korean from 2010. The reviews were finally selected by an agreement of opinions following an individual examination of 2 investigators. Appropriate literatures were selected examining original texts in accordance with selection/exclusion criteria. For all literatures finally selected, these materials were agreed after

one investigator extracted them and then other investigator examined independently the extracted results. Research country, targeted disease, intervention characteristics, literature search period and number of selected literatures, and outcome indicator, etc. were included as a general characteristic, and the results of clinical effects were presented in order of major outcome indicators defined in this study.

2. Systemic review

We searched Ovid-MEDLINE, Ovid-EMBASE, CENTRAL (the Cochrane Central Register of Controlled Trials), CINAHL (Cumulative Index to Nursing and Allied Health Literature) and 5 domestic databases (KoreaMed, KMBase, KISS, RISS, KISTI) up to March 2016. We included randomized controlled trials (RCT). Two review authors independently extracted data and assessed the risk of bias. Data was synthesized quantitatively or qualitatively depending on type of extracted data.

□ Results

1. Results of rapid review

1) Asthma

We included 8 systematic reviews to examine the effect of telemonitoring intervention in patients with asthma. There was no literature presenting the improvement of consistent results in asthma symptom control which is a clinical outcome indicator, quality of life, use of medical service, pulmonary function, side effect and compliance. Owing to an insufficiency of number of included literatures, these were mainly qualitatively synthesized, and even in case the quantitative synthesis was conducted, it was not statistically significant.

The literatures presenting outcome indicators of the intervention application side reported for accessibility and the expense and number of medical treatment, utilization of medical sources and drug use, and applicability of telemonitoring intervention. In terms of accessibility, the

accessibility of telemonitoring intervention was better than that of usual care, and, for the number and expense of medical treatment, even if the number was more in telemonitoring intervention, and the expense was less. As a result of comparing the internet intervention group with the normal treatment group for application of medical sources and drug use, there was no difference between the two groups. In case of the number of treatment not reserved, the internet intervention group was shown to be higher.

The literatures described for outcome indicators in the economic views reported for medical expense per case, expense-effectiveness of the telemonitoring, etc. Upon examination of medical expense per case, the medical expense of telemonitoring group was lower, and annual medical expense appeared also to be less. As a result of the expense-effectiveness of telemonitoring, in case of adults, it was shown that the medical expense of telemonitoring group was \$695.54 high and the effectiveness was 0.03QALY high, and thus the ratio of the gradual expense-effectiveness was 42,520\$/QALY. In case of children, it is found that the medical expense was \$829.56 high and the effectiveness was 0.01QALY high.

2) COPD (Chronic Obstructive Pulmonary Disease)

13 documents were finally selected to conduct the systemic review in literatures investigating the effect of telemonitoring intervention in patients with COPD.

As a result of the clinical outcome indicators such as deteriorated symptoms, healthcare usage, mortality, degree of physical activity, and physical performance, there was no literature presenting consistent improvement of outcomes. With regard to quality of life outcomes, it was found that quality of life improvement was statistically consistent.

The literatures stated for outcome indicators in terms of economics reported for healthcare-related expense and its reduction, and average expense per each person. As a result of the expense relevant to medical

treatment, the decreasing tendency appeared in the telemonitoring group compared to the control group, indicating that the reduction of the number of hospitalization, etc. was main cause. As a result of analysing average expense per each person, the average expense of the telemonitoring group was found to be lower.

2. Results of systemic review

1) Asthma

We included 17 Randomised controlled trials (21 articles) in this review. The effects of intervention were evaluated in accordance with asthma symptoms (asthma control score, asthma exacerbation, asthma symptom, and symptom-free days), use of medical service (hospitalization, emergency room visits, and unscheduled visit of outpatient clinic), quality of life and limited activity, pulmonary function (FEV₁, FVC, PEFr), outcomes related to drug use (drug adherence, use of daily inhaled corticosteroid, use of bronchodilators, use of leukotriene modifier, and use of whole drugs), and intervention compliance and satisfaction. Also, according to the control group type, we compared them discriminating between usual care and other intervention.

Firstly, studies comparing telemonitoring intervention to usual care were found in 21 trials (17 articles) in total, and they were conducted targeting 3,025 participants: 9 in children and 8 in adults. Studies generally recruited people with mild to severe asthma and followed them for between two and 12 months. People in the telemonitoring intervention group transmitted patient information such as asthma control score, result of pulmonary function test, drug administration status using a variety of technologies (web systems, mobile phones), and such information was monitored by the medical professionals and various types of feedbacks were provided.

Upon a comparison of telemonitoring intervention and usual care, there were no indicators showing statistically significant results. In case of examining it by each major outcome variable, as a result of meta-analysis for asthma control score (7 studies, 8 arms), a difference between the

telemonitoring intervention group and the control group was not statistically significant (SMD 0.15, 95% CI -0.07 ~ 0.38). Also, as the heterogeneity between literatures was shown to be high ($I^2=74%$), subgroup analysis was performed, but we couldn't find out any factor describing it. As a result of integrated analysis of the studies reporting the frequency of asthma exacerbations (6 studies, 7 arms), a difference between the telemonitoring intervention group and the control group was not statistically significant (RR 0.75, 95% CI 0.51 ~ 1.10). As a result of meta-analysis of symptom-free days (4 studies), a difference between the two groups was not statistically significant (WMD 3.92, 95% CI -4.96 ~ 12.80). As a result of meta-analysis related to use of medical service, a difference between the two groups was not found in hospitalization rate (5 studies, RR 2.34, 95% CI 0.82 ~ 6.62), emergency room visit rate (6 studies, RR 0.77, 95% CI 0.43 ~ 1.39), and unscheduled outpatient clinic visit rate (2 studies, RR 0.90, 95% CI 0.34 ~ 2.35). Also, the result of meta-analysis of quality of life (6 studies, 7 arms), there is no difference between the two groups (SMD 0.10, 95% CI -0.10 ~ 0.31). The studies reporting the pulmonary function (FEV_1) was 10 trials, and the quantitative synthesis was possible in 4 studies. As a result of meta-analysis, there was no difference between the two groups in FEV_1 (SMD 0.07, 95% CI -0.22 ~ 0.36).

Secondly, the studies comparing telemonitoring intervention and other intervention was 2 trials (3 arms), there was a lack of basis to evaluate the effect of telemonitoring. However, as a result of meta-analysis integrated in the manner of exploration by using 1 RCT (2 arms), there was a statistically significant difference in asthma exacerbation rate (RR 0.13, 95% CI 0.07 ~ 0.25) and quality of life (WMD 0.55, 95% CI 0.18 ~ 1.02).

2) COPD (Chronic Obstructive Pulmonary Disease)

The literatures finally selected to analyse clinical effects of telemonitoring intervention in patients with COPD were 24 randomized controlled trials, and total subjects were 2,014 people. In the studies, all COPD patients with

disease severity from mild to very serious condition were included.

For the intervention period, 5 studies were long-term (≥ 12 months), 13 studies were mid-term (> 3 months, < 12 months), and 5 studies were short-term (≤ 3 months). In one study, intervention period was not reported.

For the follow-up period, 9 studies were long-term (≥ 12 months), 12 studies were mid-term (> 3 months, < 12 months), and 3 studies were short-term (≤ 3 months).

Upon a comparison of telemonitoring intervention and control group, there were no indicators showing statistically significant results. As a result of meta-analysis related to exacerbation rate (6 studies), a difference between the two groups was not found (RR 0.67, 95% CI 0.31 ~ 1.42). Also, as the moderate degree of the heterogeneity between literatures was shown to be high ($I^2=67\%$), subgroup analysis was performed, and we found that intervention period could be the factor describing it. As a result of meta-analysis of the exacerbation period (6 studies), a difference between the two groups was not statistically significant (MD 0.12, 95% CI -1.18 ~ 1.43, $I^2=7\%$). As a result of meta-analysis of the number of exacerbations (6 studies), a difference between the two groups was not statistically significant (MD -0.12, 95% CI -0.32 ~ 0.07, $I^2=0\%$).

When meta-analysing all the studies which were reported quality of life of health status (10 studies), a difference between the two groups was not statistically significant (SMD -0.17, 95% CI -0.41 ~ 0.07, $I^2=51\%$). As a result of meta-analysis of all-cause mortality (5 studies), a difference between the two groups was not statistically significant (RR 0.80, 95% CI 0.48 ~ 1.35, $I^2=0\%$).

Outcomes on healthcare usage were also not statistically significant between tele-monitoring group and control group. When meta-analysing total length of hospital stay (5 studies), a difference between the two groups was not statistically significant (MD 0.54, 95% CI -1.49 ~ 2.58, $I^2=9\%$). As a result of meta-analysis of total number of hospitalization (5 studies), a difference between the two groups was not statistically significant (MD -0.13, 95% CI -

0.58 ~ 0.32, $I^2=58\%$). As a result of meta-analysis of total number of emergency room visiting (2 studies), a difference between the two groups was not statistically significant (MD -0.16, 95% CI -0.38 ~ 0.05, $I^2=0\%$). As a result of meta-analysis of total number of outpatient visiting (2 studies), a difference between the two groups was not statistically significant (MD -0.16, 95% CI -2.05 ~ 1.74, $I^2=62\%$).

As a result of meta-analysis of CRQ dyspnea score (3 studies), a difference between the two groups was not statistically significant (MD 0.60, 95% CI -2.75 ~ 3.96, $I^2=60\%$). Performing meta-analysis of degree of physical activity and physical performance (6-minute walk distance, FEV₁%), a difference between the two groups was not statistically significant. As a result of meta-analysis of 6-minute walk distance (5 studies), a difference between the two groups was not statistically significant (MD 38.32, 95% CI -2.04 ~ 78.68, $I^2=44\%$). As a result of meta-analysis of FEV₁% (2 studies), a difference between the two groups was not statistically significant (MD -3.25, 95% CI -10.08 ~ 3.57, $I^2=0\%$).

Plain Language

As a result of this study, current evidence does not support that the telemonitoring intervention in patients with asthma is effective in control of asthma symptom, reduction of asthma exacerbation, and improvement of quality of life compared to the usual care. As detailed contents of the telemonitoring intervention included in this study were heterogeneous, there is limitation in concluding what character of interventions is more effective, and thus it is considered that further studies are required in the future to examine the telemonitoring intervention effect of asthma patients.

As a result of this study, there were no obvious reasons that the telemonitoring intervention in patients with COPD is effective in reduction of COPD exacerbation, improvement of quality of life or health status, and reduction of death compared to the usual care. Only, when the intervention period was over 6 months, exacerbation rate was significantly

reduced and synthesized studies were not heterogeneous. However, as there is limitation that the subject characteristics (disease severity), detailed contents of telemonitoring intervention, and measurement of outcome indicator are different according to each study, and therefore continued investigations should be conducted in terms of the telemonitoring intervention effect in COPD and the effective intervention type through additional studies in the future.

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Key words

telemonitoring, u-health, telehealth, homecare, asthma, chronic obstructive pulmonary disease