Home Surveillance in Chronic Disease – Evidence for Use and Evidence Gaps

Remote patient monitoring has the ability to improve patient care and clinical outcome in a wide range of disease states, from in-hospital acute care to long-term care and home care settings. The scope of what is possible and feasible in terms of remote patient monitoring is constantly evolving. While there is considerable heterogeneity among studies to date, there is evidence supporting the use of remote patient monitoring in patients with chronic disease. Despite this promise, however, continued research is needed, particularly in terms of well-controlled studies designed to evaluate the clinical benefit of adding state-of-the-art remote patient monitoring technology to current standard of care.

The field of remote patient monitoring is rapidly changing, with the continued advancement of new technologies that can effectively monitor a wide range of physiological parameters, including, but not limited to, heart rate, single-lead ECG, pulse rate, oxygen saturation, respiration rate, blood pressure, temperature, and accelerometer-based patient movement, activity, and posture. These new technologies can be seamlessly integrated into patient care strategies either in-hospital or in long-term care or home care settings. Across settings, such monitors can be programmed to deliver patient updates and preprogrammed alarms to caregivers via WiFi, pager, and/or smartphone alerts. With this editorial, our goal is to provide a brief introduction into the ever-changing world of remote patient monitoring, with particular focus on the use of home monitoring of patients with chronic disease.

Chronic diseases are the leading cause of mortality worldwide, representing more than 60 % of all deaths.[1,2] In 2008, the chronic conditions responsible for the most deaths included cardiovascular diseases (17 million deaths), cancers (7.6 million deaths), respiratory diseases, including asthma and chronic obstructive pulmonary disease (COPD)(4.2 million deaths), and diabetes (1.3 million deaths).[2] Predictably, chronic disease represents an enormous healthcare burden, accounting for 78 % of all medical costs in the United States and 46 % of all costs worldwide.[3] With an aging population, the socioeconomic impact of chronic disease and its burden on the healthcare system continues to rise. In recent years, advances in wireless remote monitoring technologies have facilitated the increased use of home surveillance in patients with chronic disease. Thus far, the chronic diseases that appear most amenable to such monitoring strategies include congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), diabetes, hypertension, and chronic kidney disease (CKD).

In CHF patients, worsening cardiac function results in peripheral edema that can be monitored by tracking changes in body weight. Given the relative ease of remote body weight monitoring, it is not surprising that body weight has been the most commonly evaluated parameter in this patient population to date. Other commonly monitored parameters include symptoms, heart rate, and blood pressure. Less commonly monitored parameters include ECG (for both arrhythmia and heart rate variability), oxygen saturation (SpO^2), intrathoracic impedance (to assess fluid status), activity, and falls. In the case of COPD, sudden worsening of clinical conditions (i.e. acute exacerbation) is the primary cause of hospitalisation and death. Studies to date have monitored a variety of parameters in COPD patients, including body weight, blood pressure, lung function, heart rate or pulse rate, and oxygen saturation. Another important parameter for COPD patients is activity level, as physical activity has been found to be a strong predictor of both mortality and risk of readmission. Other chronic conditions frequently associated with home surveillance and their associated monitored parameters include: asthma (spirometry), diabetes (glucose), hypertension (blood pressure), and chronic kidney disease (blood pressure). In addition to these chronic diseases, there are a number of acute conditions that are amenable to home surveillance, including rehabilitation after acute myocardial infarction (activity, ECG), rehabilitation after stroke (activity), and rehabilitation after surgery (activity).

In patients with chronic disease, home surveillance may provide early warning of patient deterioration and help with the identification of acute clinical worsening. The rapid identification of clinical decline in these patients has the potential to reduce the incidence and severity of subsequent hospitalisations and thus reduce the cost of this care. In a recent review by Pare *et al.*, the authors concluded that "home telemonitoring of chronic diseases seems to be a promising patient management approach that produces accurate and reliable data, empowers patients, influences their attitudes and behaviors, and potentially improves their medical conditions."[3] Despite this promise, however, studies to date have yielded inconsistent results. While the reasons for this are unclear, it is apparent that these studies have encompassed a wide range of monitoring technologies, study designs, and enrolled patient characteristics.[4] Below is a summary of selected key studies to date, including both those that support and those that fail to support the use of telemonitoring in chronic disease patients.

Heart Failure

In two larger studies (TELE-HF and TIM-HF), telemonitoring in CHF patients failed to demonstrate clinical benefit.[5,6] In the TELE-HF study, 1653 HF patients were randomly assigned to either usual care (n=827) or telemonitoring (n=826).[5] Telemonitored patients were instructed to make daily, toll-free calls to the monitoring system. During these calls, the patients responded to a series of questions about general health and heart-failure symptoms using the telephone keypad. Information from the telemonitoring system was downloaded daily to a secure website and was reviewed every weekday by site coordinators. All questions had

predetermined thresholds of concern that alerted clinicians and prompted direct patient follow-up. In this study, the primary endpoint was composite re-admission for any reason or death from any cause within 180 days after enrollment. Secondary endpoints included hospitalization for any reason or death from any cause, hospitalization for heart failure, number of days in the hospital, number of hospitalizations for any cause, and times to the primary endpoint and its components. It is notable, that for this study, despite the relative simplicity of the telemonitoring requirements, patient compliance was somewhat poor, especially in the later weeks of the study. Over the course of the study, 14 % of patients failed to make at least one call to the telemonitoring system. Compliance was highest (90 %) during the first week of the study but dropped to 55 % by week 26. With respect to the primary endpoint, there was no significant difference between groups (Hazard Ratio: 1.04; 95 % CI, 0.91 to 1.19).

In the TIM-HF study, 710 HF patients were randomly assigned to usual care (n=356) or telemonitoring (n=354); telemonitored patients were equipped with a 3-lead ECG, a blood pressure device, and a weighing scale.[6] Patients performed daily self-assessments with these devices, and the data were transferred to the responsible telemedical centres. The primary study endpoint was all-cause mortality, with a number of secondary endpoints, including: composite cardiovascular mortality and hospitalisation for HF, duration of hospitalisation for HF, rate of hospitalisation for a cardiovascular reason, and rate of hospitalisation for HF at 6, 12, and 24 months, respectively. Overall, the median follow-up for the study was 26 months. Of the 354 patients randomly assigned to receive telemonitoring, 287 (81 %) were at least 70 % compliant with the daily transfer of data. For this study, no significant differences were observed between usual care and telemonitoring for any of the evaluated endpoints.

In contrast to these two studies, in a meta-analysis encompassing over 8600 patients, Klersy *et al*. concluded that remote patient monitoring in the context of heart failure conferred a significant protective clinical effect as compared to usual care.[7] Similarly, a systematic review and meta-analysis of existing CHF telemonitoring studies by Polisena *et al*. concluded that home surveillance in this patient population could improve mortality, reduce the number of hospitalisations, and reduce the overall healthcare burden.[8] More specifically, these authors identified three randomised controlled trials (RCTs) and one observational study that compared the number of hospitalisations for home surveillance vs. usual care. The meta-analysis of these studies indicated that surveillance reduced the number of hospitalisations (RR=0.77). Similarly, meta-analysis of five RCTs and one observational study suggested that patients with home surveillance had a lower risk of death than usual care patients (RR=0.64). Finally, among eleven studies (six RCTs and five observational studies) that examined all-cause hospitalisations, six of the studies reported fewer hospitalisations per patient in the home surveillance group as compared to the usual care group.[8] In their review, Polisena *et al*. also noted that home telemonitoring in CHF patients tended to reduce the number of emergency department visits and the number of bed days of care, while improving quality of life and overall satisfaction of care.[8] Similarly, Purcell et al. recently provided a systematic review of reviews of telemonitoring in chronic cardiovascular disease (CVD) and concluded that "telemonitoring has the potential to enhance primary care management of CVD by improving patient outcomes and reducing health costs."[9]

In a recent study by Riley *et al*., the authors evaluated the implementation of a remote monitoring programme in a cohort of 50 rural HF patients.[4] In this analysis, monitored patients were equipped with a preconfigured kit containing wireless peripheral devices for measuring weight, blood pressure, heart rate, and pulse oximetry. A unique aspect of this study was that the authors included two control groups for comparison with the telemonitored patients. The first control group consisted of patients who declined to participate in the monitoring programme; the second control group included a matched group of patients who did not participate in the remote monitoring project but were hospitalised for HF during the study period. This group of patients was matched on gender, racial/ethnic group, age decile, severity of illness rating for the reference hospitalisation, and date of hospitalisation (within seven days of the enrolled patient).

The results of this study revealed a number of interesting findings. For the main comparisons of the enrolled group vs. the declined group, telemonitoring significantly improved health care utilisation. For example, for the six months prior to versus following enrolment, the average number of hospitalisations decreased 43 % in the enrolled group and 20 % in the declined group. Similarly, the average number of days hospitalised decreased 63 % in the enrolled group and 13 % in the declined group and average hospital charges decreased 67 % in the enrolled group and 3 % in the declined group.[4] Interestingly, the matched control group demonstrated similar reductions in health care utilisation as the enrolled group, indicating that study design and control group selection are of critical importance in these types of studies. These findings and apparent discrepancies further highlight the need for additional, rigorous, well-designed studies in this area.

Chronic Obstructive Pulmonary Disease

COPD is one of the most common chronic diseases, with

an estimated 210 million affected patients worldwide.[10] According to the World Health Organization, COPD is the third most common cause of death worldwide, accounting for 3.1 million deaths in 2012.[11] In 2005 dollars, the economic health care burden of COPD in the United States was approximately $39 billion, with estimated costs of $2700 to $5900 per patient per year.[12] In the case of COPD, sudden worsening of clinical conditions (i.e. acute exacerbation) is the primary cause of hospitalisation and death.[10]

There is a relatively large and diverse literature base investigating the clinical benefits of home surveillance in COPD patients. As with CHF, the literature is somewhat heterogeneous with respect to the observed benefits of home surveillance in this patient population.[10,13,14] In a recent review and meta-analysis of nine original studies encompassing 858 COPD patients, Polisena *et al.* determined that home surveillance was associated with reduced rates of hospitalisation and emergency department visits.[10] Overall, the authors concluded that in COPD patients, "home telehealth is generally clinically effective."[10] Similarly, Cruz *et al*. conducted a systematic literature review with meta-analysis and found a significant reduction in hospitalisation rates with telemonitoring along with a trend towards reduced cost of care.14 These authors concluded that home telemonitoring for COPD patients "appears to have a positive effect in reducing respiratory exacerbations and hospitalisations and improving quality of life."[14] In a prospective study of 57 COPD patients, Jensen *et al*. implemented a four-month telemonitoring programme and observed a significant reduction in prescriptions for antibiotics and steroids, clinical consultations, and blood pressure.[15] In elderly patients, Pedone *et al*. demonstrated a reduced rate of exacerbations and COPD-related hospitalisations in patients randomised to telemonitoring as compared to patients randomised to usual care.[16]

Conclusions

The available evidence to date suggests that home surveillance of chronic disease patients has the potential to provide early detection of clinical deterioration, reduce readmission rates, and reduce the cost of care. However, questions still remain regarding the magnitude of clinical benefit provided by telemonitoring, and additional studies are needed to rigorously evaluate the value of existing (and future) technology. Perhaps the greatest promise of next generation remote monitoring technology lies in the ability to seamlessly monitor multiple body systems at once, thus allowing for the programming of composite 'smart-alerts' designed to better detect clinically significant changes in multiple metrics such as heart rate and respiration rate, while effectively reducing false alarms. The continued integration of these home surveillance technologies into the standard of care for patients with chronic disease and patients with certain acute conditions has the potential to improve patient outcomes and reduce the cost of care.

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