Effective Technologies for Noninvasive Remote Monitoring in Heart Failure

Aaron Conway, PhD, BN (Hons),^{1,2}
Sally C. Inglis, PhD, BN, B HSc (Hons), FAHA,³
and Robyn A. Clark, RN, RM, ICUCert, Dip ApplSci, BN, Med, PhD,
ACCCN (Life Member), FAHA, FCNA⁴

¹School of Nursing and ²Institute of Health & Biomedical Innovation, Queensland University Technology, Kelvin Grove, Queensland, Australia.

³Faculty of Health, University of Technology, Sydney, New South Wales, Australia.

⁴School of Nursing & Midwifery, Flinders University, Adelaide, South Australia, Australia.

Abstract

Background: Trials of new technologies to remotely monitor for signs and symptoms of worsening heart failure are continually emerging. The extent to which technological differences impact the effectiveness of noninvasive remote monitoring for heart failure management is unknown. This study examined the effect of specific technology used for noninvasive remote monitoring of people with heart failure on all-cause mortality and heart failure-related hospitalizations. **Materials and Methods:** A subanalysis of a large systematic review and meta-analysis was conducted. Studies were stratified according to the specific type of technology used, and separate meta-analyses were performed. Four different types of noninvasive remote monitoring technologies were identified, including structured telephone calls, videophone, interactive voice response devices, and telemonitoring. **Results:** Only structured telephone calls and telemonitoring were effective in reducing the risk of all-cause mortality (relative risk [RR]=0.87; 95% confidence interval [CI], 0.75–1.01; $p=0.06$; and $RR=0.62$; 95% CI, 0.50–0.77; $p<0.0001$, respectively) and heart failure-related hospitalizations ($RR=0.77$; 95% CI, 0.68–0.87; $p<0.001$; and $RR=0.75$; 95% CI, 0.63–0.91; $p=0.003$, respectively). More research data are required for videophone and interactive voice response technologies. **Conclusions:** This subanalysis identified that only two of the four specific technologies used for noninvasive remote monitoring in heart failure improved outcomes. When results of studies that involved these disparate technologies were combined in previous meta-analyses, significant improvements in outcomes were identified. As such, this study has highlighted implications for future meta-analyses of randomized controlled trials focused on evaluating the effectiveness of remote monitoring in heart failure.

Key words: heart failure, remote monitoring, systematic review, meta-analysis

Introduction

In this era of rapidly advancing and wider community access to information technology, trials of new technologies to remotely monitor for signs and symptoms of worsening heart failure are continually emerging. Moreover, many health services around the world have already started to implement varying forms of these technologies into practice. This is most likely due to the fact that high-quality meta-analyses of randomized controlled trials have indicated that remotely monitoring people with heart failure reduces their relative risk of death and hospitalizations in comparison with usual care.^{1–4} However, debate regarding appropriate methods to compare remote monitoring studies in heart failure has emerged since the publication of results from two randomized controlled trials that directly contrasted with earlier meta-analyses.^{5,6}

In this regard, it is important to note that many specific technological differences exist. For example, technologies vary from a structured telephone call (normal telephone, conducted in person, supported by computer data gathering) to interactive voice response systems (a computer voice guides the patient to press phone keys in response to questions, similar to telephone banking). The extent to which these technological differences impact the effectiveness of postdischarge heart failure management has been unknown. The aim of this study was to examine the effect of specific technologies on outcomes in heart failure management.

Materials and Methods

We conducted a subanalysis of our previously published systematic review and meta-analysis using Cochrane methodology.^{3,7} First, the 25 randomized controlled trials included in our systematic review were further scrutinized in order to group the studies according to the specific type of noninvasive remote monitoring technology that was used. Then, separate meta-analyses of all-cause mortality and heart failure-related hospitalizations were performed for each group of studies. This subanalysis was not published in the Cochrane review.³

INFORMATION SOURCES AND SEARCH STRATEGY

The full report of the information sources and the search strategy is published elsewhere. In summary, as per the protocol,⁷ all known relevant search engines and electronic databases were utilized for the period to November 2008. In addition, bibliographies of relevant studies and systematic reviews were hand-searched. Abstracts from major cardiology conferences were also hand-searched for the years

2006, 2007, and 2008. Key words included “heart failure,” “cardiac failure,” “telehealth,” “telephone,” “telemonitoring,” and “disease management.” Language restrictions were not applied.

STUDY SELECTION

Randomized controlled trials of noninvasive remote monitoring for heart failure compared with usual care were eligible to be included in this subanalysis if they were published in full in a peer-reviewed journal.⁷ Studies that were published as abstracts were excluded because in the main review, it was identified that addition of the studies published as abstracts had no substantial impact on results of the meta-analyses.¹

DATA EXTRACTION

Two reviewers independently reviewed the results of each search according to the inclusion and exclusion criteria with a standardized data extraction tool and also applied standard scales to judge study quality and risk of bias. A third reviewer adjudicated.

DATA ANALYSIS

Meta-analyses on the primary outcomes of all-cause mortality, congestive heart failure-related, and all-cause hospitalizations were performed according to Mantel-Haenszel methods, using a fixed effects model, risk ratios (RRs), intention-to-treat, and assessment of statistical heterogeneity using the I^2 statistic.⁷ All analyses were performed using Review Manager (RevMan) version 5.0 software (The Nordic Cochrane Centre [Copenhagen, Denmark], Cochrane Collaboration [London, United Kingdom], 2008).⁷ In technology applications where there was only a small number of studies, results were not subjected to meta-analysis, and instead individual results have been presented and discussed narratively.

Results

TECHNOLOGIES IDENTIFIED

Four different modes of noninvasive remote monitoring technologies were identified among the 25 randomized controlled trials included in our systematic review (Table 1). A summary of the studies included in our review is reported in detail elsewhere.¹ The specific technologies identified include (1) structured telephone calls, (2) videophone, (3) interactive voice response, which involved the manual input of data using a telephone keypad in response to questions from a computerized interactive voice response system, and (4) telemonitoring, which involved transmission of physiological data, such as weight, heart rate and rhythm, oxygen saturations, and blood pressure, from the measuring device to a central server via telephonic, satellite, or broadband capabilities for interpretation by the healthcare team. Table 2 presents a summary of the results of meta-analyses, or results of single randomized controlled trials where meta-analysis could not be conducted, according to the type of technology used.

Structured telephone call. Meta-analysis of 15 studies that compared structured telephone calls for postdischarge heart failure

management with usual care identified reductions in all-cause mortality (RR=0.87; 95% confidence interval [CI], 0.75–1.01; $p=0.06$) (Fig. 1). Similarly, the relative risk of heart failure-related hospitalizations was reduced in meta-analysis of 13 studies that involved structured telephone calls (RR=0.77; 95% CI, 0.68–0.87; $p<0.0001$) (Fig. 2).

Videophone. Only one study ($n=148$ participants) examined the effectiveness of videophone follow-up on heart failure outcomes.²³ No differences were found for all-cause mortality in this study (RR=1.28; 95% CI, 0.66–2.52). Hospitalizations were not reported.

Interactive voice response. The effectiveness of interactive voice response devices was examined in two studies included in our review.^{16,24} No significant reductions in the RR of all-cause mortality, all-cause hospitalizations, or heart failure-related hospitalizations were observed in either of these studies (Table 2).

Telemonitoring. Significant reduction in the RR of all-cause mortality (RR=0.62; 95% CI, 0.5–0.77; $p<0.0001$) was identified in meta-analyses of nine studies (Fig. 3). Fewer studies reported on heart failure-related hospitalizations. However, the RR of heart failure-related hospitalizations (RR=0.75; 95% CI, 0.63–0.91; $p=0.003$) was also reduced compared with usual care in meta-analysis of three studies (Fig. 4).

Interactive voice response and telemonitoring. One arm of the study reported by Mortara et al.¹⁶ included a group of patients who used both interactive voice response and telemonitoring technologies. No significant differences were identified for all-cause mortality, all-cause hospitalizations, or heart failure-related hospitalizations between the intervention and control groups in this study.¹⁶

RISK OF BIAS

The heterogeneity within the structured telephone call and telemonitoring studies that were subjected to meta-analysis was low for all-cause mortality ($I^2=0\%$). Meta-analyses of all-cause and heart failure-related hospitalizations for structured telephone call studies was low ($I^2=13\%$ and 7% , respectively). In contrast, for telemonitoring studies, heterogeneity for all-cause hospitalizations was substantial ($I^2=81\%$), and for heart failure-related hospitalizations, heterogeneity was moderate ($I^2=42\%$) (for the I^2 statistic, low=0–40%, moderate=30–60%, substantial=50–90%, and considerable=75–100%).³³

Discussion

This subanalysis of our Cochrane Collaboration systematic review¹ has identified that only two of the four specific technologies used for noninvasive remote monitoring in heart failure showed statistically significant improvements on the primary outcomes. These results are in contrast to our previous systematic review and those published by other groups, where these disparate technologies have been

Table 1. Study Characteristics Categorized by Type of Technology

STUDY, REFERENCE (YEAR)	INTERVENTION	FOLLOW-UP
Structured telephone call versus usual care		
Barth ⁸ (2001)	Education and monitoring	3 months
Cleland et al. ⁹ (2005) (TEN-HMS Study)	Education and monitoring	240 days; 15 months
DeBusk et al. ¹⁰ (2004)	CHF lifestyle education and medication management	12 months
DeWalt et al. ¹¹ (2006)	Education and monitoring	12 months
Galbreath et al. ¹² (2004)	Education and monitoring	18 months
Gattis et al. ¹³ (1999) (PHARM Study)	Pharmacist-led medication review and education	6 months
GESICA Investigators ¹⁴ (2005) (DIAL Trial)	Education and monitoring	16 months (mean)
Laramie et al. ¹⁵ (2003)	Education and monitoring	3 months
Mortara et al. ¹⁶ (2009) (HHH Study)	Education and monitoring	11.6 months (mean)
Rainville ¹⁷ (1999)	Pharmacist-led medication review, education, and medication management	12 months
Ramachandran et al. ¹⁸ (2007)	Education and drug dose modification	6 months
Riegel et al. ¹⁹ (2002)	Education and counseling	6 months
Riegel et al. ²⁰ (2006)	Education, monitoring, and guidance	6 months
Sisk et al. ²¹ (2006)	Patient assessment and education	12 months
Tsuyuki et al. ²² (2004)	Education and monitoring	6 months
Wakefield et al. ²³ (2008)	Education and monitoring	12 months
Videophone versus usual care		
Wakefield et al. ²³ (2008)	Education and monitoring	12 months
Interactive voice response versus usual care		
Capomolla et al. ²⁴ (2004)	Weight, systolic BP, and HR	12 months
Mortara et al. ¹⁶ (2009) (HHH Study)	Weight, HR, BP, and symptoms (telemonitoring data were collected but not used)	11.6 months (mean)
Interactive voice response plus telemonitoring versus usual care		
Mortara et al. ¹⁶ (2009) (HHH Study)	Weight, HR, BP, and symptoms plus ECG, respiration rate, and physical activity	11.6 months (mean)
Telemonitoring versus usual care		
Antonicelli et al. ²⁵ (2008)	BP, HR, weight, 24-h urine output, and ECG	12 months
Balk et al. ²⁶ (2008)	MOTIVA system	288 days (mean)
Cleland et al. ⁹ (2005) (TEN-HMS Study)	Weight, BP, and ECG	240 days; 15 months
de Lusignan et al. ²⁷ (2001)	Pulse, BP, and weight	12 months
Giordano et al. ²⁸ (2009)	One-lead ECG	12 months
Goldberg et al. ²⁹ (2003) (WHARF Trial)	Weight	6 months (mean)
Kielblock et al. ³⁰ (2007)	Weight	12 months
Mortara et al. ¹⁶ (2009) (HHH Study)	Weight, BP, and symptoms	11.6 months (mean)
Soran et al. ³¹ (2008)	Weight	6 months
Woodend et al. ³² (2003)	Weight, ECG, and BP	3 and 12 months

BP, blood pressure; CHF, congestive heart failure; ECG, electrocardiogram; HR, heart rate.

Table 2. Outcomes According to Type of Technology Used

TECHNOLOGY	ALL-CAUSE MORTALITY	HEART FAILURE-RELATED HOSPITALIZATIONS
Structured telephone call versus usual care	Meta-analysis of 15 studies: RR=0.87 (95% CI, 0.75–1.01)	Meta-analysis of 13 studies: RR=0.77 (95% CI, 0.68–0.87)
Videophone versus usual care	Wakefield et al. ²³ : RR=1.28 (95% CI, 0.66–2.52)	Not reported
Interactive voice response versus usual care	Capomolla et al. ³³ : RR=0.7 (95% CI, 0.24–2.11) Mortara et al. ¹⁶ : RR=1.32 (95% CI, 0.51–3.44)	Mortara et al. ¹⁶ : RR=1.03 (95% CI, 0.60–1.78)
Telemonitoring and interactive voice response versus usual care	Mortara et al. ¹⁶ : RR=1.41 (95% CI, 0.56–3.53)	Mortara et al. ¹⁶ : RR=1.02 (95% CI, 0.60–1.74)
Telemonitoring versus usual care	Meta-analysis of 9 studies: RR=0.62 (95% CI, 0.50–0.77)	Meta-analysis of 3 studies: RR=0.75 (95% CI, 0.63–0.91)

CI, confidence interval; RR, relative risk.

combined to show significant improvements in outcomes.^{2,3} As such, the results from this subanalysis have considerable implications for future research and provide methodological insights to consider in the conduct of future meta-analyses of randomized controlled trials focused on evaluating the effectiveness of remote monitoring in heart failure.

It is interesting that one of the technologies that significantly improved outcomes in this subanalysis was the telephone call between a patient and health professional following a structured format. The other effective technology was telemonitoring. The most notable difference between these two effective technologies is that, in the studies that involved a structured telephone call, education, self-care, and symptom monitoring were an essential part of the process conducted. In contrast, the studies that involved telemonitoring only involved transmission of physiological data and maintained dependence on the providers. The unique contribution of incorporating the

provision of education for self-care and self-monitoring empowerment and autonomy has not specifically been determined. However, results from our subanalysis suggest the additional benefit may be limited, as both strategies produced significant reductions in mortality and hospitalizations in our meta-analyses. As such, further investigation is required, as there are cost and health service implications associated with the allocation of a case manager to conduct follow-up calls to patients with heart failure. For example, it has been reported that it is typical for a case manager to provide follow-up calls for 50 patients in comparison with the 200–300 patient capacity of a telemonitoring strategy.³⁴

On the other hand, more complex information technology infrastructure is required to facilitate telemonitoring as opposed to a simple telephone call, which might limit the extent to which telemonitoring can be made available for heart failure patients to access. However, only 50% of the trials that involved structured telephone

Fig. 1. Effect of structured telephone calls on all-cause mortality. CI, confidence interval; M-H, Mantel-Haenszel.

Fig. 2. Effect of structured telephone calls on heart failure-related hospitalizations. CI, confidence interval; M-H, Mantel-Haenszel.

calls were conducted after 2005 in comparison with 80% that involved telemonitoring. This temporal trend, which indicates a recent preference for evaluating the potentially more cost-effective technology of telemonitoring for remote monitoring in heart failure, may indicate that information technology infrastructure issues are not a significant barrier to implementation.

We have also considered the results of our subanalysis in regard to the mechanisms by which providing follow-up for heart failure patients with either a structured telephone call or with telemonitoring might produce their protective effects. In this regard, recent evidence suggests that remote monitoring, in which change in weight is the only variable recorded, is not sensitive enough to detect worsening heart failure. Zhang et al.³⁵ found only 20% of episodes of worsening heart failure were preceded by an increase in weight. It has been proposed that fluid redistribution as opposed to fluid accumulation is an important contributory mechanism in exacerbation of heart failure.^{36,37} Three studies of telemonitoring included in our subanalysis monitored weight in isolation, whereas others included

blood pressure, electrocardiography, and oxygen saturations measurement. As such, consideration should be given to measuring more than weight in telemonitoring interventions. Moreover, although the provision of education during remote follow-up would theoretically lead to improved self-care in patients with heart failure, a recent review that focused specifically on this issue noted that results from trials are equivocal.³⁸ For these reasons, we suggest that future trials should directly compare structured telephone call and telemonitoring strategies to provide further insight into which particular technology is the most effective in terms of clinical effectiveness and cost-effectiveness.

In contrast to structured telephone calls and telemonitoring, we have identified in this subanalysis that more research data would be required to provide a robust evaluation of the effectiveness of two other specific technologies: videophone and interactive voice response systems. That being said, the need to conduct further investigations of videophone technology is not abundantly clear from the evidence at hand because the use of structured telephone calls seems

Fig. 3. Effect of telemonitoring on all-cause mortality. CI, confidence interval; M-H, Mantel-Haenszel.

Fig. 4. Effect of telemonitoring on heart failure-related hospitalizations. CI, confidence interval; M-H, Mantel-Haenszel.

to be a highly effective remote monitoring strategy. Videophone technology is associated with more costs than telephone follow-up, because of the cost of equipment.²³ As such, if investigations of videophone technology are conducted in the future, it is suggested that the research design should incorporate a group of patients receiving structured telephone call follow-up for comparison.

Interactive voice response technology was investigated in only two studies included in our review.^{16,24} The trials enrolled 594 patients in total, and there were no significant reductions in mortality or hospitalizations identified in either of the studies. These findings are consistent with a more recent and larger randomized controlled trial of interactive voice response technology, which was published after our systematic review. The Tele-HF trial, which randomized 1,653 patients, found that there were no significant differences between the primary outcome of hospitalization or death within 6 months.⁵ Of note, however, is that when we grouped the two interactive voice response studies under the broader “telemonitoring” group in our Cochrane review, reductions in mortality and hospitalizations remained statistically significant. Therefore, based on the disparate results of our subanalysis, it does not seem that grouping interactive voice response systems with telemonitoring technologies is an appropriate strategy for comparison of clinical studies of remote monitoring for heart failure. For this reason, in the update of our Cochrane review, capturing the latest randomized controlled trial evidence, subgroup analysis of specific technologies will provide further insight into the effectiveness of interactive voice response technology in improving postdischarge heart failure follow-up care. Once these findings of the updated review are published, if it is confirmed that remote monitoring using an interactive voice response device is not associated with reductions in mortality or hospitalizations, serious consideration should be given as to the appropriateness of further investigations of this particular technology.

It should also be noted that, to provide more standardized comparisons between trials of remote monitoring for heart failure, Anker et al.³⁴ recently proposed a classification scheme in their review of contemporary issues related to remote telemedical management of heart failure. Their proposed scheme comprised four generations. The main discriminating factors between generations are the methods by which the information that is collected is used by the healthcare practitioner and whether or not data from invasive devices have been

incorporated into clinical decision-making. Although we share the view of Anker et al.³⁴ that it is important to establish robust methods of comparing the results of similar studies in order to determine which specific approach is the most effective, as we have identified in this subanalysis, there are substantial differences in outcomes between just the noninvasive technologies; therefore it does not seem appropriate to apply this specific classification scheme as the sole basis to make comparisons.³⁴

LIMITATIONS

It is important to note that the degree of heterogeneity in this subanalysis was similar to that reported in our overall Cochrane review.¹ This is likely due to the facts that only one study that involved videophone technology was separated out from the broader structured telephone support category and that only two studies that involved interactive voice response technology were separated out from the broader telemonitoring category. An important limitation of this analysis is the exclusion of more recent randomized controlled trials of noninvasive remote monitoring in heart failure. In order to avoid introducing bias into our methodology, we have limited this analysis to the studies currently included in our Cochrane review.¹ The latest randomized controlled trial evidence will be included in the update of our Cochrane review.

Conclusions

This subanalysis has identified that although four unique technologies for the noninvasive remote monitoring of heart failure have been evaluated in randomized controlled trials, only structured telephone calls and telemonitoring, in which physiological data are automatically transmitted, reduced the relative risk of all-cause mortality and hospitalizations when results were combined in the meta-analyses. More research data are required to evaluate the effectiveness of videophone and interactive voice response technologies.

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Disclosure Statement

No competing financial interests exist.

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Address correspondence to:

Robyn A. Clark, RN, RM, ICUCert, Dip AppliSci, BN, Med, PhD,
ACCCN (Life Member), FAHA, FCNA
School of Nursing & Midwifery
Flinders University
Sturt Road
Bedford Park, South Australia 5042
GPO Box 2100
Adelaide 5001
Australia

E-mail: robyn.clark@flinders.edu.au

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