Outcomes of Chronic Heart Failure

Daniel Benatar, MD; Mary Bondmass, RN; Jaime Ghitelman, MD; Boaz Avitall, MD, PhD

Background: Outcomes related to chronic heart failure (HF) remain relatively poor, despite advances in pharmacological therapy and medical and nursing care. Experts agree that outpatient care may be among the factors that affect HF outcomes. We hypothesized that the method by which outpatient care is delivered may affect outcomes in this patient population.

Methods: A prospective, randomized design was used to compare HF outcomes from 216 patients randomized to 1 of 2 home health care delivery methods for 3 months after discharge. Care was delivered by the home nurse visit (HNV) or the nurse telemanagement (NTM) method. In the latter, patients used transtelephonic home monitoring devices to measure their weight, blood pressure, heart rate, and oxygen saturation. These data were transmitted daily to a secure Internet site. An advanced-practice nurse worked collaboratively with a cardiologist and subsequently treated patients via the telephone. Both delivery methods used the same HF-specific clinical guidelines to direct care. Outcomes include HF readmissions and length of stay, anxiety, depression, self-efficacy, and quality of life. Data were primarily tested using a 2-group analysis of variance (ANOVA). We used a repeated-measures ANOVA to conduct preintervention-postintervention analyses.

Results: After 3 months, patients in the NTM group (n=108; mean±SD age, 62.9±13.2 years; 83% African American; 64% female) had fewer HF readmissions (13 vs 24; P<.001) with shorter lengths of stay (49.5 vs 105.0 days; P=.001) compared with the HNV group (n=108; mean±SD age, 63.2±12.6 years; 89% African American; 62% female). Hospitalization charges at 3 months were less in the NTM group compared with the HNV group ($65023 vs $177365; P=.02). At 6 and 12 months, cumulative readmission charges in the NTM group were also less ($223638 vs $300343 [P<.03] and $541378 vs $677710 [P=.16], respectively) compared with the HNV group. Quality of life was significantly improved for both groups when we compared postintervention and preintervention scores.

Conclusion: The adaptation of state-of-the-art computerized technology to closely monitor patients with HF with advanced-practice nurse care under the guidance of a cardiologist significantly improves HF management while reducing the cost of care.

Arch Intern Med. 2003;163:347-352

Heart failure (HF) is a clinical syndrome affecting nearly 5 million people in the United States. More than 400,000 new cases are diagnosed annually.1 Current mortality of HF is related to its severity, ranging from 5% to 10% in patients with mild symptoms to 30% to 40% in severe cases.2

Available data indicate that HF may cost the US health care system from $20 billion to $40 billion annually, including hospitalizations, medications costs, and medical follow-up.3 In patients older than 65 years, HF is the most frequent indication for hospitalization and the most frequent discharge diagnosis submitted for Medicare reimbursement.4,5 Moreover, as the US population ages, the incidence and prevalence of HF is expected to increase. As HF rates continue to grow, so does the impact of HF on patients, families, and health care systems, and increased significance is placed on research demonstrating positive outcomes related to this devastating health problem.

Past studies have shown that multidisciplinary treatments can improve compliance and reduce admission rates in patients with chronic HF. Some of these studies have included home monitoring with self-reported or electronically transmitted daily measurements of vital signs.6,7

Frequent occurrences of decompensated chronic HF, which can be related to multiple factors, are a major problem in the outpatient treatment of these pa-
patients. Once patients with HF undergo decompensation, HF requires movement of clinical management from the outpatient to the more costly inpatient hospital setting. However, we believe most HF decompensation episodes are preceded by changes in vital signs in the previous days that, if detected early, might have easily led to intervention while the patient was at home and avoided an inevitable hospital readmission. The method of delivering the HF home health care is the focus of this investigation.

The purpose of this study was to compare outcomes for patients whose home health care was provided by nurse telemangement (NTM) or home nurse visits (HNV). The outcomes of interest included HF readmissions and length of stay (LOS), HF hospitalization charges, and preintervention and postintervention quality-of-life (QOL) measurements. We used a prospective, randomized study design.

This study was approved by the University of Illinois at Chicago (UIC) institutional review board and the West Side Veterans Administration (WSVA) research and development committee, Chicago. All patients were required to sign informed consent forms before participation.

TELEMEDICINE AND TELEMANAGEMENT

The term telemedicine encompasses a wide range of telecommunications and information technologies for various medical applications. We define telemanagement as a specific type of telemedicine that uses telecommunications to determine and implement management interventions in the absence of face-to-face contact.

In this study, patients with HF used transtelephonic home monitoring devices to measure their weight, blood pressure, heart rate, and oxygen saturation level. These data were transmitted daily to a secure Internet site.

The UIC telemangement model incorporates an advanced-practice nurse (APN) who works collaboratively with a cardiology fellow and a cardiology attending physician. Medical plans are developed by the physicians and implemented by the APN. Clinical goals for telemangement are set as desired physiologic ranges for blood pressure, heart rate, and laboratory values specified in each patient’s individual medical plan; the APN evaluates the objective data transmitted by the patient, conducts telephone assessments, titrates medication therapy, and conducts patient education as needed to achieve the goals of the medical plan.

MATERIALS

The home monitor is a small, lightweight device (64 × 152 × 89 mm; weight, 680 g) that automatically notifies patients to obtain their vital signs. The home monitor was programmed for this study to measure blood pressure, heart rate, arterial oxygen saturation, and weight. The telemangement hardware and software were developed by and purchased from AvidCare Corporation (Milwaukee, Wis). All devices used were extensively validated before this study and subsequently approved for use by the Food and Drug Administration in 1996.

Alarm parameters were established according to each patient’s baseline condition, as deemed appropriate by the medical director and the APN. Maximum and minimum deviations from baseline were programmed into the monitoring station software such that when a patient’s physiological data exceeded these limits, an alarm would be automatically transmitted to an alphanumeric pager carried by the APN.

DATA TRANSMISSION

The home monitor is attached in parallel to the patient’s telephone line and transmits the acquired physiological data to a central on-line server, which can be accessed by the caregivers using a secure Internet connection from anywhere an Internet link is available. In addition, the server automatically transmits physiological alarms along with the time, date of the alarm, and patient home telephone number to an alphanumeric pager. The pager and a cellular telephone allow for timely response relative to any aberrant data. Any patient data that exceed their specific physiologic parameters are sent as alarms to the receiving alphanumeric pager. Additional patient data and a complete electronic health file can also be accessed and reviewed from the same Internet site.

HOME NURSE VISITS

We used 3 home health care agencies to provide care for the HNV group. The agencies were chosen because they followed a specific HF program with clinical pathways based on the American Health Care and Policy Research clinical HF guidelines and used specialized cardiac nurses. Patients who were admitted at the WSVA Medical Center received the HF-specific home health care provided by their home-based health care service, and patients admitted at the UIC Medical Center received HF-specific home health care from the Ambulatory Health Care Services. Visit frequency was similar in all 3 groups, and was based on the following template: 3 visits during the first week, 2 visits during the second and third weeks, 1 visit during the fourth and fifth weeks, and further visits on an as-needed basis.

The first 4 visits included detailed discussions involving diet, symptom recognition, and compliance with medication regimens. The remaining visits included assessment of the patient’s symptoms and vital signs with physician notification if deemed necessary. From 9 to 12 home visits were made, depending on the need defined in each agency-specific clinical pathway.

SAMPLE SELECTION

Patients admitted to the UIC and WSVA medical centers between April 1997 and July 2000 with a diagnosis of HF and meeting inclusion/exclusion criteria were asked to participate.

Inclusion criteria included at least 1 of the following: (1) documented diagnosis of HF as determined by means of radiographic evidence of pulmonary congestion; (2) documented New York Heart Association functional classification III or IV; (3) conventional clinical HF symptoms of dyspnea and edema that responded to diuresis; and (4) echocardiographic evidence suggestive of HF. Heart failure was defined as an ejection fraction of 40% or less for systolic dysfunction, or impairment in 1 or more indices of ventricular filling with a corresponding clinical picture for diastolic dysfunction, in accordance with the American College of Cardiology/American Heart Association guidelines for chronic HF.

Exclusion criteria included (1) unstable angina, (2) renal failure, (3) severe dementia or another debilitating psychiatric disorder, (4) end-stage heart failure requiring regular inotropic infusions, (5) anticipated survival of less than 6 months, (6) planned discharge to a long-term care facility, (7) current use of illicit drugs, (8) participation in another HF research protocol within the past 6 months, (9) scheduled HF-specific home...
health nursing, and/or (10) lack of an operational home telephone line.

Two hundred seventy-two hospitalized patients were identified during our time frame with a diagnosis of HF. Fifty-six patients were excluded from participation for the following reasons: participation in other HF-related research within the past 6 months (n=15), requirement of dialysis (n=8), consideration for dialysis (n=4), previously scheduled home nursing services on discharge (n=10), recent myocardial infarctions resulting in unstable angina (n=2), discharge to a long-term care facility (n=5), death before discharge (n=4), lack of an operational telephone line (n=6), and suspicion of current abuse of drugs other than alcohol (n=2). No eligible patient refused participation. Patients entered the study 1 to 3 weeks after discharge from the hospital. The study continued until 108 patients were randomized to each group to allow for attrition. All randomized patients completed at least 3 months of study. Although short, this period allowed for a rapid turnover of NTM and HNV methods in an attempt to decrease overall costs while still accomplishing the HF teaching goals. Outcomes were measured and compared at the end of the intervention period. Additional outcomes were measured at 6 and 12 months after the intervention.

Quality-of-life measurements were obtained before and after the intervention. Four QOL measures were used. The 21-item Minnesota Living with Heart Failure Questionnaire provides an overall total score and physical and emotional subscale scores that relate how patients perceive the effect that HF has had on their lives. Total scores can range from 0 to 105, with higher scores indicative of a less favorable experience of living with HF.

The 2-part, 70-item Quality of Life Index—Cardiac Version contains health/functioning, psychological/spiritual, socioeconomic, and family subscales. Scoring for this scale is weighted such that higher scores result when persons are more satisfied with items that are of more importance to them.

Psychological distress, as manifested by anxiety and depression, was measured with the Hospital Anxiety and Depression Scale. This scale was developed for measuring the existence and severity of emotional distress in physically ill persons who received outpatient health care services. The 4-point, 14-item Hospital Anxiety and Depression Scale does not include the somatic items usually found in other instruments. Total score suggested cut-point scores that can range from 13 for moderate psychological distress to 19 for significant psychological distress.

Self-efficacy was measured in this study with the Heart Failure Self-Efficacy Scale. This questionnaire contains 5 subscales designed to measure self-efficacy with medications, diet, symptom control, activity, and HF readmissions. Higher scores are indicative of higher self-efficacy.

Hospitalization charges were calculated for each admission according to discharge summary data and totaled for each group. Intervention costs in the NTM group were calculated according to methods described in a previous publication. At that time (1993-1997), a single monitoring unit at the telemetry unit of UIC Medical Center required an experienced telemetry technician 24 h/d. Since then, we use an Internet software program connected with a pager system that allows the APN to receive and correct the alarms directly, eliminating the need of a telemetry technician.

DATA ANALYSIS

Data for all variables were tested for normal distribution using the Shapiro-Wilk test. We used a 2-group repeated-measures analysis of variance for within-group preintervention-postintervention comparisons for normally distributed continuous variables, $\chi^2$ for discrete variables, and the Mann-Whitney and Wilcoxon rank sum tests for nonnormally distributed variables. We used SPSS Version 10.0+ for Windows statistical software for these analyses (SPSS Inc, Chicago, Ill). Unless otherwise indicated, data are given as mean±SD.

### RESULTS

Two hundred sixteen patients who met the inclusion criteria constituted the final sample and were randomized to receive NTM or HNV for 3 months after discharge. Mean age of the participants was 63.06±12.09 years; 136 (63.0%) were female; and 186 (86.1%) were African American. Mean New York Heart Association functional class was 3.13±0.26. Sex and race of the sample are relatively representative of the ethnic and sex composition of the general population of patients who receive health care services at the UIC and WSVA medical centers. No significant individual baseline differences were found (Table 1 and Table 2). The composite group of patients who were receiving angiotensin-converting enzyme inhibitors (ACEIs) and/or $\beta$-blockers (Table 2) was higher in the NTM group; however, this difference was not statistically significant ($P$=.057). The outcomes of interest included HF readmissions and length of stay (LOS), HF hospitalization charges, and QOL measurements.

After 3 months of outpatient care, patients in the NTM group had fewer HF readmissions (13 vs 24; $P$=.001) and shorter LOS (49.5 vs 105.0 days; $P$=.001), compared with the HNV group. Readmission rate at 6 and 12 months was also lower in the NTM compared with the HNV group (38 vs 63 readmissions [$P$=.05] and 75 vs 103 readmissions [$P$=.12], respectively) (Figure 1). As given in Table 3, we performed a subgroup analysis comparing patients who did not receive ACEIs or $\beta$-blockers vs patients receiving a combination of ACEIs and/or $\beta$-blockers. After 3 months, patients not receiving ACEIs or $\beta$-blockers had a similar rate of readmission in both groups (2/8 [25%] in the NTM group vs 5/27 [19%] in the HNV group [$P$=.26]). In patients receiving a combination of ACEIs and/or $\beta$-blockers, the rate of

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**Table 1. Sociodemographic Characteristics of the Sample**

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>NTM (n=108)</th>
<th>HNV (n=108)</th>
<th>$P$ Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y</td>
<td>62.9 ± 13.2</td>
<td>63.2 ± 12.6</td>
<td>NS</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>69 (63.9)</td>
<td>67 (62.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Male</td>
<td>39 (36.1)</td>
<td>41 (38.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>90 (83.3)</td>
<td>96 (88.9)</td>
<td>NS</td>
</tr>
<tr>
<td>White</td>
<td>9 (8.3)</td>
<td>6 (5.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6 (5.6)</td>
<td>6 (5.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (2.8)</td>
<td>0</td>
<td>NS</td>
</tr>
</tbody>
</table>

Abbreviations: HNV, home nurse visits; NS, not significant; NTM, nurse telemonitoring.

†Calculated using the $\chi^2$ test and 2-group analysis of variance.
readmission was lower in the NTM vs the HNV group (11/100 [11%] vs 19/81 [23%] [P=.003]). At 6 and 12 months, cumulative readmission charges in the NTM were also less ($65023 vs $177365 [P=.02]) compared with the HNV group (Figure 2). A breakdown of the outpatient intervention cost in the NTM group is shown in Figure 3.

Overall, QOL measurements improved in both groups after the intervention, compared with baseline. However, we found a trend toward better improvement in the NTM group compared with the HNV group, as given in Table 4. The mean Minnesota Living with Heart Failure Questionnaire score decreased from 77.92 to 51.64 in the NTM group (P=.01) compared with a decrease from 77.17 to 57.72 in the HNV group (P=.01). The mean Quality of Life Index–Cardiac Version score increased from 16.65 to 20.93 in the NTM group (P=.01) compared with an increase from 15.06 to 18.34 in the HNV group (P=.01). The mean Heart Failure Self-Efficacy Scale 30 score increased from 31.98 to 35.90 in the NTM group (P=.01) compared with an increase from 31.02 to 32.74 in the HNV group (P=.01). The mean Hospital Anxiety and Depression Scale score decreased from 18.89 to 12.53 in the NTM group (P=.11) compared with a decrease from 17.69 to 13.52 in the HNV group (P=.046).

Table 2. Illness-Related Characteristics of the Sample

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>NTM (n = 108)</th>
<th>HNV (n = 108)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA class, mean ± SD</td>
<td>3.13 ± 0.27</td>
<td>3.12 ± 0.25</td>
<td>NS</td>
</tr>
<tr>
<td>LVEF, mean ± SD, %</td>
<td>38.05 ± 13.70</td>
<td>38.83 ± 13.97</td>
<td>NS</td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>108 (100.0)</td>
<td>96 (88.9)</td>
<td>NS</td>
</tr>
<tr>
<td>CAD</td>
<td>63 (58.3)</td>
<td>68 (63.0)</td>
<td>NS</td>
</tr>
<tr>
<td>DM</td>
<td>39 (36.1)</td>
<td>11 (10.2)</td>
<td>.001</td>
</tr>
<tr>
<td>HF medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACEI</td>
<td>93 (86.1)</td>
<td>71 (65.7)</td>
<td>NS</td>
</tr>
<tr>
<td>β-Blocker</td>
<td>69 (63.9)</td>
<td>46 (42.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Diuretics</td>
<td>105 (97.2)</td>
<td>103 (95.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Digoxin</td>
<td>74 (68.5)</td>
<td>80 (74.1)</td>
<td>NS</td>
</tr>
<tr>
<td>ACEI and β-blocker</td>
<td>100 (92.6)</td>
<td>81 (75.0)</td>
<td>&lt;.057</td>
</tr>
</tbody>
</table>

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; CAD, coronary artery disease; DM, diabetes mellitus; HF, heart failure; HTN, hypertension; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association. Other abbreviations are explained in the first footnote to Table 1.

*Unless otherwise indicated, data are expressed as the number (percentage) of patients.
†Calculated using the χ² test and 2-group analysis of variance.

Table 3. Subgroup Analysis of Admissions at 3 Months According to Medications at Baseline

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>NTM</th>
<th>HNV</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients receiving no ACEIs or β-blockers at baseline</td>
<td>8</td>
<td>27</td>
<td>.001</td>
</tr>
<tr>
<td>No. (%) of readmissions at 3 mo</td>
<td>2 (25)</td>
<td>5 (19)</td>
<td>NS</td>
</tr>
<tr>
<td>No. of patients receiving ACEIs and/or β-blockers at baseline</td>
<td>100</td>
<td>81</td>
<td>NS</td>
</tr>
<tr>
<td>No. (%) of admissions at 3 mo</td>
<td>11 (11)</td>
<td>19 (23)</td>
<td>&lt;.003</td>
</tr>
</tbody>
</table>

Abbreviations are explained in the first footnotes to Tables 1 and 2.
*Calculated using the χ² test.
The sequelae of chronic HF are well known, with frequent decompensation of the chronic state resulting in recurrent hospitalizations. However, most HF experts agree that many of these costly incidences of decompensation can be avoided or at least lessened in severity and can require less inpatient time when hospitalization is unavoidable. Therefore, the importance of maintaining an optimally compensated state in patients with HF is critical. Reports suggest that inadequate physician follow-up, insufficient titration of medication dosages, patient noncompliance, and failure to promptly seek medical attention when symptoms reoccur are among the contributing, preventable factors leading to readmissions for chronic HF decompensation.

Clinical management strategies and patient compliance aimed at maintaining an optimally compensated state may decrease the need for HF readmissions, shorten hospital stays, reduce hospital charges, and perhaps improve humanistic and QOL outcomes.

Several HF programs and clinics have addressed these contributing factors and been successful at preventing hospital admissions by following a multidisciplinary but traditional clinical model. Moreover, these programs have not required sophisticated technology and have still demonstrated cost-effectiveness.

In this randomized, control trial, a telemonitoring service was more efficacious than HNV in decreasing readmission rates for patients with HF. The 3-month readmission rate was 11% for the NTM group compared with 23% for the HNV group; subsequent readmission LOS and charges decreased in a similar fashion.

The QOL measurements were significantly improved in both groups, reinforcing the importance of outpatient support in chronic illnesses such as HF. Although the intervention period was limited to 3 months, the benefits of HTM seem to have persisted for 6 and possibly 12 months, an effect that may be related to the teaching factor. Reinforcements by periodic telephone calls might have been key in this lingering effect. The 12-month difference in benefits, however, was not statistically significant, possibly reflecting regression to the mean, as fewer patients were free of hospitalizations.

Our study differs in several ways from previous studies that have used multidisciplinary and/or telemedicine approaches for patients with HF. Previous telemedicine studies have shown clear benefits in patients with HF. Cordisco et al19 used a daily telemonitoring system similar to ours and showed a 28% reduction in hospitalizations. However, their study was not randomized, and the control group consisted of a combination of patients who had refused the telemonitoring system or who were waiting for cardiac transplantation, thereby adding a possible bias in the study.

A similar study conducted by Heidenreich et al6 used a system that included daily recording of vital signs. They compared 68 patients with HF with a control group that consisted of 86 patients matched to the intervention group on medical claims during the preceding year.

Another strength of our study is the expanded role given to the APN, who checked alarms and adjusted medication therapy with further notification to the supervising physician. Previous studies6,20 have shown the effectiveness of such an approach. This system is easily adaptable to many different types of clinical practices.

Generalization of these results, however, is not possible at this time, and the results presented herein can be applied only to the sample studied. This study examined the feasibility and effectiveness of a management method that included transtelephonic monitoring and telemetry. Therefore, we suggest that for this study sample, the efficiently achieved positive outcomes resulted from a combination of the initial availability of objective data with rapid and vigilant attention to aberrancy (a physiological monitoring period immediately after hospital discharge). Furthermore, the results achieved could be attributed to the clinical management directed by evidence-based guidelines and continued periodic disease-specific patient education provided throughout the study. This study was not powered as a mortality study, making it impossible to draw any mortality conclusions as such.21

When analyzing baseline differences, the NTM group had more patients receiving a composite treatment of ACEIs and β-blockers. Subgroup analysis according to intake of ACEIs and/or β-blockers at baseline still shows a consistent reduction in readmission rate in the NTM vs HNV interventions.

The setting for this study may actually be considered a limitation, because it was an urban academic medical center with a sample composition not representative of the ratio of white to African American persons in the

Table 4. Comparison of Quality-of-Life Questionnaires

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>NTM</th>
<th>HNV</th>
<th>Between-Group P Values†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minnesota Living with Heart Failure Questionnaire</td>
<td>77.92 ± 10.30/51.64 ± 17.36‡</td>
<td>77.17 ± 8.52/57.72 ± 16.24‡</td>
<td>.98/.47</td>
</tr>
<tr>
<td>Index–Cardiac Version IV</td>
<td>16.65 ± 2.76/20.93 ± 3.35‡</td>
<td>15.06 ± 3.25/18.34 ± 3.73‡</td>
<td>.18/.63</td>
</tr>
<tr>
<td>Heart Failure Self-Efficacy</td>
<td>31.98 ± 3.08/35.90 ± 2.73‡</td>
<td>31.02 ± 4.49/32.74 ± 3.53‡</td>
<td>.78/.43</td>
</tr>
<tr>
<td>Hospital Anxiety and Depression Score</td>
<td>18.89 ± 6.04/12.53 ± 5.08§</td>
<td>17.69 ± 5.27/15.52 ± 5.97§</td>
<td>.20/.03</td>
</tr>
</tbody>
</table>

*Scores represent total scale scores.
†Calculated using the y2 test and 2-group analysis of variance.
‡P<.01, preintervention vs postintervention scores.
§P<.11, preintervention vs postintervention score.
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general population. However, in many US urban academic medical centers, the patient population is similar to the study population presented herein. Another limitation consisted in the variance introduced by the 3 agencies used in the control group compared with a single telemonitoring APN.

In summary, the results of this randomized study demonstrate significant improvements in outcomes and quality of care for patients with severe HF using aggressive remote telemonitoring vs traditional HNV. The data provide further evidence that the introduction of current state-of-the-art computerized technologies allows rapid and accurate monitoring of patients with severe HF. The combination of these technologies and HF management by an APN under the guidance of a cardiologist is cost-effective and leads to improve outcomes and care.

Accepted for publication June 13, 2002.

This study was supported by grants 1 R41 HL 55083-01 and 1 R41 HL 55.83-01A1 from the National Institutes of Health, Bethesda, Md.

This study was presented in part at the 73rd Scientific Session of the American Heart Association, October 30, 2000, New Orleans, La, and the 50th Scientific Session of the American College of Cardiology, March 20, 2001, Orlando, Fla.

We thank Nadine Boldger, MD, and Gerard Castro, MPH, for their initial study contribution; the Department of Medicine of the University of Illinois at Chicago; and, in particular, the practitioners of the internal and general medicine and cardiology sections for their continued support and patient referrals.

Corresponding author and reprints: Boaz Avittal, MD, PhD, Department of Medicine, University of Illinois at Chicago (MC 787), 840 S Wood St, Suite 930, Chicago, IL 60612-7323 (e-mail: bavittal@uic.edu).

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