Clinical Trial

Cost of Medical Services in Older Patients With Heart Failure: Those Receiving Enhanced Monitoring Using a Computer-Based Telephonic Monitoring System Compared With Those in Usual Care: The Heart Failure Home Care Trial

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ABSTRACT

Background: Prior studies suggest that disease management programs may be effective in improving clinical and economic outcomes in patients with heart failure. Whether these types of programs can lower health care cost and be adapted to the primary care setting is unknown. This study was designed to assess the impact of a home-based disease management program, the Alere DayLink HF Monitoring System (HFMS), on the clinical and economic outcomes of Medicare beneficiaries recently hospitalized for heart failure who received the care from a community-based primary care practitioner.

Methods and Results: The Heart Failure Home Care trial was a multicenter, randomized, controlled trial of sophisticated, monitoring of heart failure patients with an interactive program versus standard heart failure care with enhanced patient education and follow-up (SC) in Medicare-eligible patients. The study endpoints included cardiovascular death or rehospitalization for heart failure, length of hospital stay, total patient cost, and cost to Medicare at 6 months of enrollment. A total of 315 patients age ≥65 years old were randomized: 160 to the HFMS and 155 to SC. There were no significant statistical differences between the groups in regards to 6-month cardiac mortality, rehospitalizations for heart failure, or length of hospital stay. Of those, 304 patients had their Medicare data available. The information from the Medicare claims data was used to determine the cost. Information from the trial was used to determine costs of out-patient drugs and the interventions. The 6-month mean Medicare costs were estimated to be $17,837 and $13,886 for the HFMS and the SC groups, respectively. We found that overall medical costs of medicare patients were significantly higher for patients who were randomized to the HFMS arm than they were for the patients randomized to the SC arm.

Conclusions: Our study results suggest that enhanced patient education and follow-up is as successful as a sophisticated home monitoring device with an interactive program and less costly in patients who are elderly and receive the care from a community-based primary care practitioner. (*J Cardiac Fail 2010;16:859–866*)

Key Words: Heart failure, disease management programs, cost.

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Heart failure is a syndrome of epidemic proportions in the United States, affecting more than 5 million patients.[1] The disease disproportionately affects the aged. Indeed, between 5% and 10% of patients older than age 75 years have heart failure, resulting in frequent hospitalizations and enormous cost to the health care system.[2] The cost burden of heart failure is best demonstrated by the fact that it is the most common diagnosis-related group for hospitalized patients older than age 65 years.[2]

Although medical therapy improves outcomes and decreases hospitalizations in patients with heart failure, the uneven use of evidence-based therapies has led to the development of disease management programs. These programs provide measurable benefit, especially for patients cared for by cardiologists at academic or community-based tertiary care facilities.[3–8] Whether these types of programs can be adapted to a primary care setting and would lead to lower health care costs and improve outcomes, however, is unknown. Furthermore, information is even more limited regarding the cost and success of home care disease management programs among elderly, women and non-Caucasian men, compared with Caucasian men.[9] This randomized, controlled study was designed to assess the impact of a home-based disease management program on the clinical and economic outcomes of Medicare beneficiaries representing the elderly, women, and non-Caucasian males who received the care from a community-based primary care practitioner.

The clinical outcomes have been published elsewhere, and showed no differences between the 2 groups with respect to cardiovascular deaths, rehospitalizations for heart failure, and length of stay for heart failure.[10] In this article, the economic outcomes are reported; we examined whether the overall medical costs of Medicare patients randomized to the heart failure monitoring system were lower than the costs for those randomized to standard care.

Methods

The heart failure home care (HFHC) Trial was a multicenter, randomized controlled clinical trial with blinded endpoint evaluation, designed to compare a control group receiving standard heart failure care with enhanced patient education and follow-up (SC) with a test group managed with computer-based telephonic heart failure monitoring system (HFMS: Alere Day Link Heart Failure Monitoring System, Alere Medical, Reno, NV).

Eligible patients were randomized between April 2002 and September 2005. Data were collected, compiled, and analyzed at the University of Pittsburgh. The trial used an independent adjudication event committee to classify deaths, hospitalizations, and adverse events and was monitored by an independent Data Safety Monitoring Board. The trial was approved by the Institutional Review Board of the University of Pittsburgh, Case Western University, and Mount Sinai Medical Center. Informed consent was obtained from all patients before study enrollment.

Study Population

The study population was elderly (≥65 years old); women and non-Caucasian males, primarily African Americans and Hispanics who carried the diagnosis of heart failure secondary to systolic dysfunction, and had symptoms despite optimal treatment with pharmacologic therapy. To ensure that baseline therapies were identical in the 2 treatment arms of the study and that patients were receiving adequate and appropriate medical therapy we focused this study on patients with systolic heart failure. All patients were Medicare beneficiaries and had to have been hospitalized for heart failure within 6 months of randomization.

The trial was conducted at 3 sites with affiliations to a major academic medical center: Pittsburgh, PA (University of Pittsburgh); Cleveland, OH (Case Western Reserve University); and Miami, FL (Mount Sinai Medical Center). However, a unique aspect of this trial was that patients were recruited through the development of cooperative networks that had been established with primary care groups in each of these cities. Thus, this trial assessed the utility of the HFMS in a ''real-world setting'' rather than within the confines of the academic medical center. The study design and clinical outcomes were reported in detail elsewhere.[10]

Procedures

After eligibility was assessed patients were randomized in a 1:1 ratio to either SC, which included patient 1-on-1 education, education to clinicians, an effort to use evidenced-based optimal medical treatment, and a commercially available digital home scale with management by primary physician ; or the intervention group (SC plus HFMS). HFMS consists of a home-based disease management program to monitor and to detect early signs and symptoms of heart failure using telecommunication equipment; such early detection could allow practitioners to focus their clinical resources on patients needing interventions. Each primary care physician who participated in the trial and at least one nurse from each primary care office have undergone a didactic training program lead by either University of Pittsburgh Medical Center in Pittsburgh, Case Western Reserve Hospital, or Mount Sinai Medical Center. The training program was either the ''Advanced Heart Failure Scene'' program or a similar program. In addition, each participating physician was provided with copies of the Guidelines for the care of patients with heart failure published by the Heart Failure Society of America. In addition they were provided with the updated American College of Cardiology/American Heart Association Heart Failure Guidelines. Each site's project coordinator visited the primary care physicians to familiarize the participating sites with the schedule of evaluation. Patients assigned to HFMS were contacted to arrange the delivery and setup of the device. The system includes an electronic scale and an individualized symptom response system (DayLink monitor) linked via a standard phone line to a computerized database staffed by trained nurses. Patients were instructed to weigh themselves and respond to heart failure symptom questions daily. Each patient's primary care physician was responsible for selecting the monitoring parameters according to their patients' disease status.

The patients were asked questions such as: did you wake up with shortness of breath during the night; did you use an extra pillow last night, are your feet more swollen than usual; are you more tired than usual; and are you coughing more than usual? The HFMS nurses reviewed the transmitted data daily (7 days/week, 365 days/year) and contacted the patient to verify any changes observed in heart failure symptoms or weight. Changes in weight beyond a prespecified amount or changes in symptoms were reported to the attending primary care physician. There was a standardized alert in which physicians individually choose the