Grand-Aides Markedly Reduce 6-Month and 30-Day Readmissions and Emergency Department Visits for Patients with Heart Failure: A Randomized Clinical Trial

Kathleen Reeves[1, 2], Nicolle Strand[2], Byron Udegbe[2], Bryson Hoover-Hankerson[2], Steuart Wright[2], Victor Jegede[2], Susan Freeman[3], Jeffrey Slocum[1], Arthur Garson[4, 5, *]

[1]Lenfest Center for Community Workforce Partnerships, Temple University Health System, Philadelphia, the United States

[2]Center for Urban Bioethics, Lewis Katz School of Medicine, Philadelphia, the United States

[3]ROffice of the Provost, Rush University, Chicago, the United States

[4]Department of Health Systems and Population Health Sciences, College of Medicine, University of Houston, Houston, the United States

[5]Office of the Chairman, Grand-Aides USA and International, Houston, the United states

Email address:

Garson.Tim@Gmail.com (A. Garson)

[*]Corresponding author

Abstract: While numerous approaches have been used to reducing hospital readmissions, few have been subjected to a randomized clinical trial (RCT). This RCT studied the effectiveness of a "Grand-Aides" home visitation program in the reduction of readmissions and emergency department (ED) visits for patients with heart failure. High-risk patients (N=97) were randomized to receive care either with Grand-Aides or an established program to reduce readmissions at one hospital over two years; 85% were covered by Medicare + Medicaid ("Dual Eligibles"). Grand-Aides patients had home visits, while the control patients received telephone follow-up from community health workers. Data on all-cause readmissions and all-cause ED visits were collected at 30 and 180 days. At 6 months: patients with Grand-Aides had a 60% reduction in all-cause 6-month readmissions (65% controls and 26% Grand-Aides), p<0.001, and a 67% reduction in all-cause emergency department visits (33% controls, 11% Grand-Aides), p<0.01. For readmissions in the first 30 days, patients with Grand-Aides had a 48% reduction in readmissions (42% controls, 21.7% Grand-Aides, p=0.03) and a 79% reduction in 30-day all-cause emergency. In the first randomized clinical trial on readmissions and ED, the Grand-Aides program showed significant reductions in patients with heart failure, as compared to the best available program at the time in our health system, suggesting the impact that regular tailored home visits can have on reducing hospital resource utilization and costs. Took out sections.

Keywords: Readmissions, Emergency Department, Heart Failure, Grand-Aides, Cost Reduction, Care Management, Randomized CLINICAL Trial

1. Introduction

Readmissions of patients to an acute care hospital within 30 days of discharge should rarely occur. These events interrupt recovery medically, socially and financially.

In 1994, Mary Naylor, Ph.D., RN, FAAN published the first randomized trial demonstrating in the elderly that a nurse practitioner program with intense discharge planning and two weeks of post-discharge contact significantly reduced readmissions at 2 weeks post-discharge, but did not change readmissions at 4 weeks or 3 months. [1] Since then, nurses and nurse practitioners have shown good results in reducing readmissions. [2, 3] Stauffer and colleagues [4] reported on nurse practitioner home visits showing a 48%

reduction in 30-day readmissions, but no effect on 60-day readmissions, and a net cost of $227 per patient. In an accompanying editorial, Mitchell Katz wrote, "Even if [this intervention] can reduce hospital readmissions, [it] can save money only if the savings from the decrease in readmission rate is greater than the cost of the program." [5] Our program called "Grand-Aides" has reported an 82% reduction in all-cause, 30-day readmissions in Medicare patients with heart failure. [6] At 6 months, all-cause readmissions were reduced 71% and Emergency Department visits decreased 77%. The overall net saving per Grand-Aide per year was >$560,000.

A Grand-Aide is a certified nurse aide who makes frequent home visits to patients after hospital discharge, with every visit supervised by a nurse close to the end of the visit so the nurse can interact with the patient and their family. The nurse supervision is mostly done by video, but at a minimum by telephone. Grand-Aides make no decisions. The supervising nurse interacts with the patient's physician who makes care-management decisions. The number of visits decrease over time depending upon the needs of the patient over the first month, with continued contact by telemedicine or in-person, as deemed necessary by the care team. [3, 6, 7]

The Grand-Aides program differs from home health agencies in the following: Grand-Aides: 1. Have every nurse aide visit supervised real-time by a nurse, with the nurse observing the patient and answering questions; 2. Are not limited by being skilled in a service such as physical therapy but can address all patient needs; 3. Can care for all patients whether meeting requirements for home health or not; only 20% of Grand-Aides patients also have home health and the two interact well; 4. Spend as much time as necessary with the patient on each visit; and can see patients at home for as long as needed (e.g. >60 days); 5. Address factors associated with readmission on every visit such as medication adherence, and knowledge of subtle risk factors. The Grand-Aide becomes like a member of the family, regardless of how old the Grand-Aide is.

Previous data on Grand-Aides used concurrent controls. The current study adds to the body of science on Grand-Aides as it is the first randomized clinical trial and extends to 6 months as longer-term management is important.

2. Methods

Subjects were recruited from Temple University Hospital inpatient units with a diagnosis of heart failure (HF). The randomized study was approved by the Temple University Health System Institutional Review Board. Patients were not paid. Each patient was followed for 180 days.

The ClinicalTrials.gov identifier is NCT04966442. The site was Temple University.

Inclusion criteria: Discharge to private home, resides in a zip code within a 10-mile radius of Temple University Hospital, followed by a cardiologist in the Temple Advanced Heart Failure Clinic. *Exclusion criteria*: Transplant patients, dialysis, not fluent in English, discharge to skilled nursing facility or non-Temple rehabilitation, psychosis, inability to consent, active unremitting.

Patients with Grand-Aides were compared with patients in an existing program, the Temple Advantage Community Health Worker program, where community health workers would support the patient through telephone calls and with a varying number of home visits. This was standard of care at Temple.

This was a randomized clinical trial with random assignment to the Grand-Aide or comparison group. The random assignment was electronically generated with appropriate blocking to assure temporal balance of treatment assignments while maintaining adequate randomness. Treatment assignments were secured within sealed envelopes. Following consent of each study subject, he or she was informed of which arm of the study they would follow. Addressing allocation concealment [8], the investigator opened the next sequential envelope to inform the subject of his or her randomization assignment.

Patients with Grand-Aides were compared to those with community health workers using analysis of variance, paired t-tests and chi-square. It was determined that proximity matching was not necessary. Two statisticians consulted on the design and analysis of the study.

Grand-Aides procedure have been detailed elsewhere. These have been detailed elsewhere. [6, 7] In brief, the patients had home visits by a Grand-Aide decreasing in frequency from the first to the fourth week post-discharge. For the last 10-15 minutes of each visit, a nurse supervisor was either on video or audio telephone.

Funding was provided by Temple University Health System. There was no grant funding.

# 3. Results

3.1. Patient Number, Follow-up and Demographics

Medicaid + Medicare covered 85% of these patients ("Dual Eligibles"). Each patient was followed for 180 days. There were initially 97 patients (51 patients in the control group and 46 in the Grand-Aides group). Two patients died in the control group, one at 29 days and one at 46 days. Otherwise, there were no dropouts. The analysis for the control group therefore had 50 patients for 30-day data and 49 for the 31-180 day data. There were no statistical differences in the demographics of the two groups. The average age of the patients with Grand-Aides was 58.1 years with a range of 34-80; 86% of the patients were African-American with no difference between groups.

3.2. Readmissions and Emergency Department Visits

The patients with Grand-Aides had a 60% reduction in all-cause 6-month readmissions (65% controls and 26% Grand-Aides), p<0.001, and a 67% reduction in all-cause emergency department visits (33% controls, 11% Grand-Aides), p<0.01. For readmissions in the first 30 days, patients with Grand-Aides had a 48% reduction in readmissions (42% controls, 21.7% Grand-Aides, p=0.03) and a 79% reduction in 30-day all-cause emergency department visits from 8.9% to 1.9%, p=0.12 with small numbers. See Figure 1.
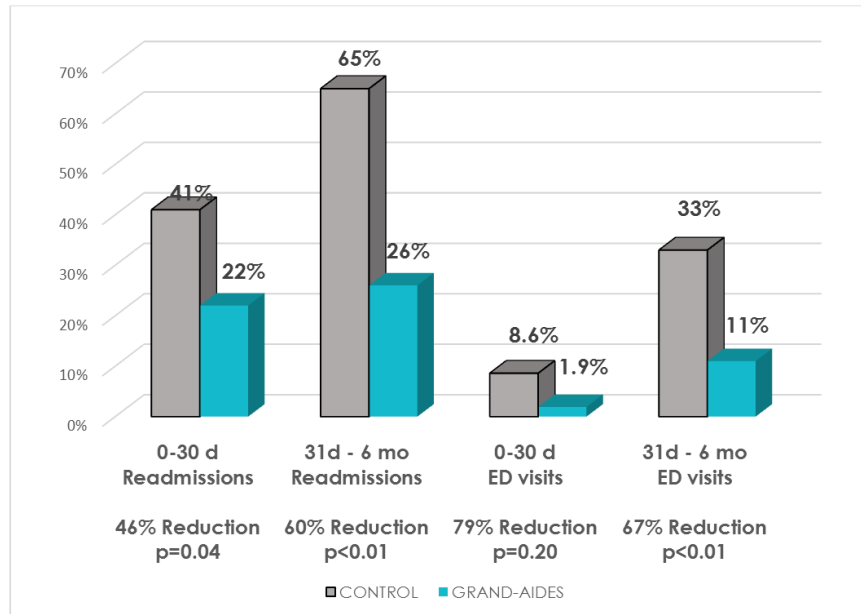
Figure 1. *All-cause readmissions and ED visits (0-30 day and 31 day-6 months) show reduction in all parameters between controls and those with Grand-Aides. Abbreviations: d=Day; ED-Emergency Department; mo-Month.*
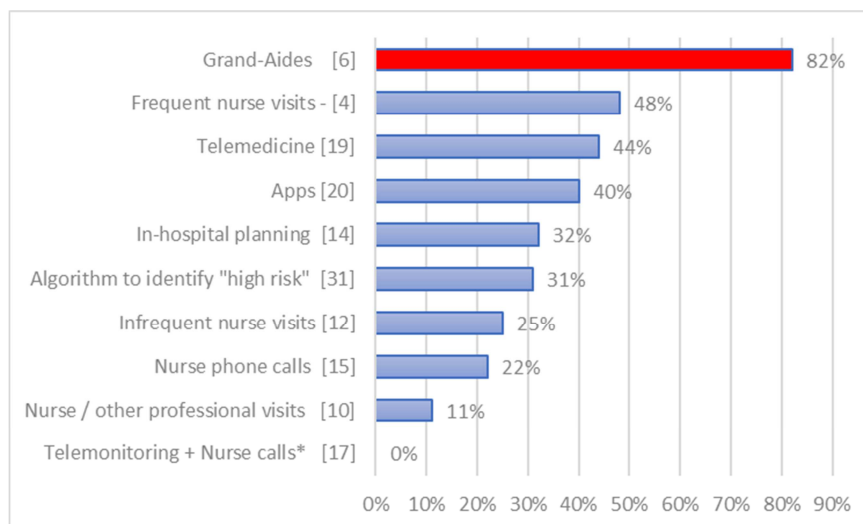
* This study did not report 30-day readmissions but 6-month readmissions only

Figure 2. *Reports on reduction in 30-day readmissions in post-acute patients The numbers [in brackets] are reference numbers in the text. Median 31%.*

3.3. Heart Failure Data

The Brain Natriuretic Peptide levels on admission to the study did not differ significantly between those with Grand-Aides (1555 pg per ml ± 1250) (Standard deviation) and the controls (1432 ± 1331). The ejection fraction on admission of patients with Grand-Aides (24.8% ± 15.0%) was significantly lower than the controls (32.0 ± 19.6%, p<0.05).

4. Discussion

[Eliminated descriptive beginning] While numerous approaches have been taken to reduce readmissions in post-acute patients the results of this study show a marked improvement (46-60% reduction) over previous approaches that had a median reduction in readmissions of 31%.

An extensive literature review was performed and the best results in each method are included in Figure 2) A summary of those comparative data follows. Hansen and colleagues did a rigorous analysis of 43 studies and [9] found, "No single intervention implemented alone was regularly associated with reduced risk for 30-day rehospitalization." Kripalani [10] noted that, "three larger investigations implemented multicomponent intervention bundles, which resulted in absolute reductions in 30-day readmission of 3.6 to 28 percentage points." These were the Naylor [1], the Coleman "Care Transition Intervention" [11] which involved both intense discharge planning and home visits, and "Project RED" which had a number of in-hospital

approaches. [12] Most recently, the Naylor "Transitional Care Model" reported a 25% reduction [13], the Coleman Care Transition Intervention's Centers for Medicare and Medicaid report showed an 11% reduction [14], and Project RED showed a 32% reduction [15]. Nurse follow-up phone calls are extremely common, but are not comparatively effective in reducing readmissions - with 22% reported in 2018. [16] Recently, determining which patients are "high risk" with proprietary mathematical algorithms has become popular with Ascension Health, reporting a 31% decrease in readmissions using such a process. [17]

Telemedicine and telemonitoring have become increasingly popular. However, Ong reported in a randomized trial that, "Among patients hospitalized for HF, combined health coaching telephone calls and telemonitoring did not reduce 180-day readmissions." [18] A review of all telemonitoring in heart failure found similarly poor results at 90 and 180 days for hospitalizations and was associated with an increase in ED visits. [19] Partner's Health care in Boston reduced heart failure readmissions by 44% with telemedicine. [20] The use of apps has also increased. The Mayo Clinic app reduced readmissions by 40%. [21] One problem with apps is that people rarely remain engaged for periods longer than 3 months. [22] The Mayo Clinic concluded that using people to help reduce readmissions was more effective than newer technology. [23]

The major limitation of this study is the size of the patient population. An important reason for this is the number of patients who agreed to participate. This is not surprising as we have published experience in other low-income groups with similar acceptance rates. [24] We have hypothesized that some of the families may have people in the household who are "undocumented" and may consider permitting an outsider into the house to be a risk. The relatively low numbers are reflected in the data on 0-30 day ED visits, where the 79% reduction is not statistically significant (1/51 vs 4/45).

What is "unique" about the Grand-Aides approach?
1. Grand-Aides have a personal relationship with the patient and family. This relationship elicits more openness in reporting to the Grand-Aide than, for example, a nurse in the home.
2. The choice of Grand-Aides and nurses is critical to provide empathy and "tough love."
3. Grand-Aides are inexpensive compared with physicians and nurses in the home.
4. The approach to medication reconciliation with patient and Grand-Aide going room-to-room searching for all drugs is unique.
5. Every visit, a questionnaire tailored to the individual patient is administered; each visit is supervised by an RN.
6. Training is standardized but modified for each program.
7. Standard outcomes and process data are collected and compared to local controls. Added data specified by the client (e.g. a specific depression questionnaire) can be added.
8. The duration of home visits can be adjusted to the patient.

In response to, "Everybody does this," the above description shows that "everyone does not do it this way," and the data from this study as well as previous studies show a favorable comparison.

5. Conclusions

These data, collected and analyzed as a randomized trial, showed reductions in readmissions and ED visits out to 6 months in patients with heart failure. The "control" group in this study consisted of patients already in a program designed to reduce readmissions and ED visits, therefore the reduction is compared to the best available program at the time and yet, still showed important improvements.

We have not found better results in the literature for reduction of readmissions. In that study, concurrent controls were used with proximity matching. This study adds the importance of a randomized trial showing major reductions in readmissions and ED visits, especially when considering that the comparison group in this study had patients cared for by the best available program using community health workers to reduce readmissions and ED visits.

Additionally, given that the patients in the present study were almost entirely low-income, and the published readmission results [25] in those with low-income show less favorable outcomes, the results in a general population with Grand-Aides are more likely to be better than those reported here, and more similar to those published from the University of Virginia [6], with an 82% reduction in 30-day readmissions.

Initiating and maintaining behavior change using people in the home, at least initially, and the technology of video supervision by a nurse provides better results than "apps." It surely is possible that a "software Grand-Aide" using Artificial Intelligence is coming, but the experts in the field say that at least in the current timeframe, people need people.

Declaration of Interest

1. Dr. Garson is the unpaid chair of Grand-Aides, USA. His role was "Writing review and editing." He had no involvement in carrying out the study.
2. The remainder of the authors: Declaration of interest: None.

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