CLINICAL RESEARCH STUDY

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The Diuresis Clinic: A New Paradigm for the Treatment of Mild Decompensated Heart Failure

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ABSTRACT

BACKGROUND: Heart failure results in approximately 1 million hospital admissions annually in the United States and is the leading cause of 30-day readmissions.

METHODS: This study explores the impact of a diuresis clinic on heart failure outcomes and cost. Data were collected prospectively on all consecutive patients who received intravenous diuretics and multidisciplinary care in the clinic from its establishment from October 2011 to December 2012, as well as a comparison cohort of patients with heart failure who were admitted to the hospital for <48 hours. The percentage of hospitalized days was calculated for both cohorts 180 days before and 180 days after each patient's index visit.

RESULTS: In the diuresis clinic group, 106 patients (mean age, 68.2 ± 13 years; 48% were women) were treated over 328 visits (1-22 visits per person), with a mean intravenous furosemide dose of 100 mg, average urine output of 1460 ± 730 mL, and weight loss of 2.3 ± 1.8 kg. Days hospitalized decreased from 38.3 to 31.2 per 1000 patient-days after the index diuresis clinic visit ($P < .01$). In the comparison group, 143 patients (mean age, 69 ± 16 years; 54% were women) were admitted for <48 hours. Days hospitalized increased from 14.4 to 21.0 per 1000 patient-days after index admission ($P < .01$). On multivariate analysis, the diuresis clinic was associated with 3 fewer days in the hospital per 180 days per patient, with an estimated annual savings of $12,113 per patient.

CONCLUSIONS: Compared with a brief hospital stay, treatment of mild decompensated heart failure in a diuresis clinic resulted in a substantial and cost-effective decline in the rate of subsequent hospitalization.
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KEYWORDS: Care delivery; Health innovation; Heart failure; Quality improvement

Heart failure affects more than 5 million Americans, accounts for more than 1 million hospital admissions annually,[1] and is the leading cause of readmissions with rates approaching 50% at 6 months.[2] Adequate treatment of clinical and subclinical intravascular congestion with intravenous (IV) loop diuretics[3] and a comprehensive approach to address comorbidities, precipitating factors, patient education, and social support is essential to reduce hospitalization rates.[4] Ambulatory multidisciplinary teams improve heart failure outcomes,[5] and studies of outpatient IV diuretic therapy, although limited, demonstrate a reduction in readmissions.[6-8]

In this study, we examine the impact of a novel clinic that provides IV diuretics and multidisciplinary care for patients with mild decompensated heart failure. We hypothesized that this innovative strategy can cost-effectively reduce the number of days a patient with heart failure spends in the hospital and reduce readmission rates when compared with standard inpatient treatment.

MATERIALS AND METHODS

The Johns Hopkins Bayview Diuresis Clinic was established in October 2011 with the goals of: (1) providing outpatient IV diuretics to treat congestion in mild decompensated heart failure; (2) delivering patient and caregiver

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education; (3) providing outpatient care coordination; (4) addressing social needs; and (5) connecting patients with resources such as transportation or inexpensive medications. Protocols and inclusion and exclusion criteria for the service were approved by relevant medical center committees. Exclusion criteria included pregnancy; creatinine >2.5 mg/dL; potassium <3.0 mEq/L or >5.5 mEq/L; sodium <128 mEq/L; temperature >101°F; systolic blood pressure <90 mm Hg or >180 mm Hg; diastolic blood pressure <50 mm Hg or >100 mm Hg; heart rate <50 beats/min or >120 beats/min; electrocardiogram (EKG) with new ST changes, new left bundle branch block, new-onset atrial fibrillation/flutter, or rapid ventricular response; active chest pain; pro-brain natriuretic peptide <200 pg/mL; presence of rales more than halfway up lung fields; presence of urinary obstruction; and oxygen saturation <90% on room air (or home oxygen). The study was approved by the institutional review board.

CLINICAL SIGNIFICANCE

- Treatment of mild decompensated heart failure with intravenous diuretics and multidisciplinary care management in an outpatient clinic was associated with a significant reduction in the days hospitalized on follow-up.
- The first comprehensive study of its kind, this work builds on the handful of studies on outpatient intravenous diuretics and, scaled nationally, has the potential to reduce hospitalizations, improve quality of life, and save more than $1 billion.

Patients who were referred to the clinic by primary care providers, hospitalists, geriatricians, and cardiologists were evaluated by a board-certified cardiologist to determine suitability for IV diuretic therapy. This included a baseline comprehensive history and physical examination including documentation of demographics, comorbidities, medication use, height, weight, body mass index, and New York Heart Association class of heart failure. On each visit to the clinic, orthostatic vital signs were checked, IV access was established, laboratory tests (basic metabolic panel, magnesium, pro-brain natriuretic peptide) were performed, and an EKG was obtained. IV diuretics were not administered if preestablished exclusion criteria were present. If no contraindications existed, IV furosemide ± metolazone was administered at a patient-specific dose along with magnesium and potassium supplementation as per previously established protocol. All patients were monitored for adverse events for at least 3 hours, but not more than 5 hours post-IV diuretic dose. Pre-diuresis and post-diuresis weights, along with urine output per hour, were recorded on the same day. During the course of monitoring, patients or caregivers received education from a heart failure nurse and comprehensive care coordination and medication reconciliation. Clinically unstable patients were stabilized and referred to the emergency department. Before discharge, patients were reassessed and arrangements were made for subsequent diuresis sessions or follow-up by their regular provider(s) at the discretion of the treating clinician. All patients were referred back to their regular provider for post-clinic treatment if no further diuresis sessions were warranted. Patients were not followed in the Johns Hopkins Bayview Diuresis Clinic long term. Once referred back to their regular providers, no further additional data on patients were collected except for hospitalization rates for 180 days after the initial diuresis clinic visit.

All patients receiving at least 1 treatment in the diuresis clinic from October 1, 2011, to December 31, 2012, were included in the study. By using medical records, the number of days spent in the hospital was recorded for each patient 180 days before and after the initial diuresis clinic visit. Patients who were referred to hospice or died during follow-up were no longer eligible for hospitalization; therefore, these patient days were excluded from the denominator as per a predetermined approach.

To serve as a comparison group, data were collected from all consecutive patients who were admitted to the Johns Hopkins Bayview Medical Center with a primary diagnosis of decompensated heart failure with a length of stay less than 48 hours from October 1, 2011, to December 31, 2012. Patients who were admitted to the intensive care unit, patients on dialysis, and patients who had been already seen in the Johns Hopkins Bayview Diuresis Clinic were excluded from this group. Clinical history, urine output, height, weight, laboratory results, and medications administered were collected from the medical record. As done in prior studies of diuretics, 20 mg of torsemide, 1 mg of bumetanide, and 40 mg of furosemide were considered to be equivalent.[9] Of note, all patients in this cohort received standard care coordination, patient education, and support services as per the standard of care. The number of days spent in the hospital for each patient 180 days before and after the index hospitalization were recorded in the same fashion as that of the diuresis clinic cohort. Costs of a diuresis clinic session and inpatient hospitalization were calculated using data from facility billing databases.

Statistical Analysis

Baseline characteristics of patients who were seen in the diuresis clinic and those admitted to the hospital were compared using the *t* test for normally distributed continuous variables, Wilcoxon rank-sum test for skewed continuous variables, and Pearson's chi-square test for categoric variables. Changes in rates of hospitalization were compared using a paired *t* test. For the multivariate analysis, a stepwise linear regression model was created with the difference in hospitalization before and after the index visit as the independent variable. Covariates were added in a stepwise forward regression with a *P* value of .2 required to enter the

model. Results did not change substantially when the analysis was repeated with outliers excluded (difference in days hospitalized >20 or <−20, n = 9). All analyses were performed using Stata version 13.1 (StataCorp LP, College Station, Tex).

RESULTS

From October 1, 2011, to December 31, 2012, 106 patients received at least 1 treatment in the diuresis clinic, whereas 143 patients met criteria for inclusion in the hospitalized cohort. The number of visits per person to the diuresis clinic ranged from 1 to 22 (median, 2 visits) for a total of 328 distinct clinic visits. Baseline characteristics, including demographics, vital signs, comorbidities, medication use, and initial laboratory results, of all patients are summarized in Table 1.

Diuresis Sessions

There were a total of 328 sessions lasting an average of 220 minutes. At the beginning of the session, the average blood pressure was 125/69 mm Hg (±21/13) and heart rate was 75 beats/min (±16). The average furosemide equivalent outpatient dose of oral diuretic was 120 mg/d. Eight patients were in New York Heart Association class I, 139 patients were in class II, 133 patients were in class III, and 33 patients were in class IV. A total of 23 patients did not have their New York Heart Association class recorded. The mean IV furosemide dose was 100 mg, and metolazone was administered in 99 sessions. The average urine output was 1460 ± 730 mL, and weight loss was 2.3 ± 1.8 kg. There were 12 patients with orthostasis by heart rate or blood pressure after the diuresis session, only 1 of which was symptomatic. One patient had asymptomatic bigeminy after the diuresis session. There were no other adverse events. Of note, some patients experienced substantial cumulative weight loss of more than 50 pounds over the course of their sessions.

Hospitalization Analysis

The diuresis clinic cohort had 38.3 days of hospitalization per 1000 patient days of follow-up (or 728 of 19,080 patient days) in the 180 days before the index visit versus 31.2 days (or 572 of 18,318 eligible patient days) in the 180 days after the index visit ($P < .01$) (Figure). Of note, 7 patients died

Table 1 Baseline Characteristics of Patients in Diuresis Clinic Compared with Patients with a Heart Failure Admission of Less than 48 Hours (Hospitalized Cohort)

	Diuresis Clinic (n = 106)	Hospitalized Cohort (n = 141)	*P* Value
Age, y (mean, SD)	68.2 ± 14.2	69.4 ± 16.2	.57
Female (n, %)	50 (47%)	77 (54%)	.25
White (n, %)	66 (62%)	97 (69%)	.28
BMI (median, IQR)	34.3 (26.8-40.2)	30.6 (25.7-38.4)	.13
Diabetes mellitus (n, %)	66 (62%)	64 (45%)	.01
Chronic kidney disease (n, %)	61 (58%)	49 (35%)	<.01
Atrial fibrillation (n, %)	51 (48%)	57 (40%)	.23
COPD (n, %)	41 (39%)	47 (33%)	.39
Coronary artery disease (n, %)	68 (64%)	78 (55%)	.16
Hypertension (n, %)	96 (91%)	128 (91%)	.95
Hyperlipidemia (n, %)	72 (68%)	92 (65%)	.66
Stroke (n, %)	18 (17%)	17 (12%)	.27
Ejection fraction (mean, SD)	39 ± 18	41 ± 15	.33
Heart failure with preserved ejection fraction (n, %)	38 (36%)	57 (41%)	.45
ACE or ARB (n, %)	76 (72%)	81 (57%)	.02
Beta-blocker (n, %)	86 (81%)	114 (81%)	.96
Hydralazine (n, %)	12 (11%)	14 (10%)	.72
Nitrates (n, %)	13 (12%)	22 (16%)	.46
Digoxin (n, %)	11 (10%)	9 (6%)	.26
Spironolactone (n, %)	22 (21%)	9 (6%)	<.01
Aspirin (n, %)	71 (67%)	86 (61%)	.33
Statin (n, %)	67 (63%)	81 (57%)	.36
Sodium mEq/L (median, IQR)	140 (138-143)	140 (138-142)	.38
Potassium mEq/L (median, IQR)	4.0 (3.7-4.4)	4.0 (3.7-4.4)	.84
BUN mg/dL (median, IQR)	24 (16-35)	14 (19-31)	.01
Creatinine mg/dL (median, IQR)	1.3 (1.0-1.8)	1.2 (0.9-1.7)	.12
Magnesium mg/dL (median, IQR)	2.0 (1.7-2.2)	1.7 (1.9-2.1)	.17
ProBNP (median, IQR)	3204 (511-6744)	3372 (1494-9169)	.048

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; BMI = body mass index; BUN = blood urea nitrogen; COPD = chronic obstructive pulmonary disease; IQR = interquartile range; ProBNP = pro-brain natriuretic peptide; SD = standard deviation.

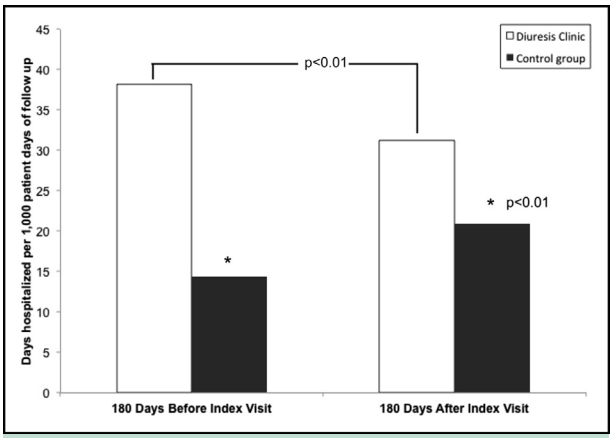

Figure Number of days hospitalized per 1000 patient days of follow-up in the 180 days before and after the index diuresis clinic visit (diuresis clinic) or index hospital admission for <48 hours (control group).

and 3 patients were referred for hospice within 180 days after their first diuresis clinic visit; therefore, 762 patient days were excluded from the denominator. The comparison cohort of patients hospitalized for less than 48 hours received an average furosemide dose of 136 mg, but only 1 patient received metolazone. The cohort had 14.4 days of hospitalization per 1000 patient days of follow up (or 371 of 25,740 patient days) in the 180 days before hospitalization compared with 21.0 days (or 525 of 25,048 eligible patient days) in the 180 days after hospitalization ($P < .01$) (Figure). Of note, 6 patients died within 180 days after their initial hospitalization; therefore, 692 patient days were excluded from the denominator. To account for differences in the 2 groups, a multivariate regression model was created (Table 2), and the diuresis clinic was associated with a reduction of 3.0 patient days of hospitalization in the 180 days of follow-up even after adjusting for demographics and comorbidities ($P = .02$).

Table 2 Multivariate Analysis of the Change in Days Spent in the Hospital Before and After Index Visit to Diuresis Clinic or Index Admission to Hospital

	Coefficient	95% CI	*P* Value
Age	0.1	−0.01 to 0.2	.09
White patients	2.3	−0.3 to 5.0	.09
ACE or ARB	2.5	−0.03 to 5.1	.053
Hydralazine	−4.2	−8.1 to −0.3	.04
Statin	−4.1	−6.6 to −1.5	<.01
Stroke	−3.8	−7.2 to −0.4	.03
Cardiac device	2.3	−0.9 to 5.4	.16
Diabetes mellitus	1.8	−0.7 to 4.3	.17
Diuresis clinic	−3.0	−5.5 to −0.5	.02

The coefficient symbolizes the number of additional days spent in the hospital per 180 days. For example, white patients spent an average of 2.3 more days in the hospital after the index visit, and patients in the diuresis clinic spent 3 days less.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CI = confidence interval.

Estimation of Costs

The average total cost of each IV diuresis clinic visit was $642 (average professional fee, $91; average cost for room, laboratory tests, pharmacy, and EKG, $551). There were 328 visits for the diuresis clinic cohort with an average of 3.09 visits or $1987 per patient. In contrast, the average daily inpatient cost at Johns Hopkins Bayview Medical Center of a hospitalization for decompensated heart failure in 2012 was $2652. The multivariate analysis estimates a reduction in 3 hospital days per 180 days of follow-up in the diuresis clinic cohort or $7956 avoided costs. The estimated net saving is $5969 per patient per 180 days of follow-up or $12,113 annually.

DISCUSSION

The major finding of this study is that treatment of mild decompensated heart failure in the Johns Hopkins Bayview Diuresis Clinic was associated with a substantial reduction in the number of days spent in the hospital on follow-up. In contrast, brief (<48 hour) hospital admission was associated with an increase in days spent in the hospital on follow-up. These differences remained statistically significant after multivariate adjustment and were associated with dramatic cost reductions.

These findings represent the first comprehensive study of the impact of an outpatient clinic that provides both IV diuretics and multidisciplinary care management. This work expands on prior studies of IV diuretics by collecting detailed information on a large number of patients, analyzing outcomes in a before and after fashion and comparing them with a hospitalized cohort. These results are especially remarkable given that the patients in the diuresis clinic were more medically complex than the patients with heart failure in a nationwide sample[10] and patients in the comparison cohort, as evidenced by a greater prevalence of comorbidities and higher baseline hospitalization rates.

The improved outcomes likely reflect the impact of a combination of patient education, caregiver empowerment, care coordination, and outpatient IV diuretics. In addition, the team in the diuresis clinic was from cardiology, whereas a variety of providers were responsible for the management of inpatients with heart failure. The cardiology input likely contributed to a different diuretic profile as reflected by the fact that patients in the hospitalized cohort received a higher dose of furosemide, whereas patients in the diuresis clinic were more likely to receive metolazone. Each of these components has been associated with improved outcomes, and the present study is the first to demonstrate that their effects are additive in an outpatient setting.

This study has important implications if the diuresis clinic can be scaled. In a national sample of 802,796 hospital admissions, 25% had a length of stay of less than

2 days.[11] If half of these 200,699 patients were treated in a diuresis clinic, the cost reduction over the course of 1 year would be more than $1.2 billion nationally. In addition, there would likely be an associated increase in the quality of life of patients associated with fewer days hospitalized and a reduction in iatrogenic harms and nosocomial infections.

Study Limitations

Although the analysis included both a before and after component and a control group, this study is nonrandomized. We did not have vital signs for the comparison cohort on arrival to the hospital, which limits the comparison. The study is of modest size and limited to a single urban center, and patients had greater comorbidities than a national sample with outcomes assessed through hospital databases. Despite these limitations, the results are exciting and should be explored in other settings, ideally in a randomized fashion.

CONCLUSIONS

The evolution of a therapy from an inpatient to outpatient setting is not a novel concept in medicine. Nesiritide began as an inpatient treatment for heart failure and was used in the outpatient setting until studies showed limited efficacy.[12] Outpatient clinics such as oncology and rheumatology centers routinely provide IV infusions of chemotherapeutics and immune modulators, respectively. Likewise, the ability for an institution to provide outpatient IV diuretics in a monitored setting combined with multidisciplinary care coordination can provide a valuable resource to outpatient cardiology or internal medicine practices giving patients with mild decompensated heart failure an attractive alternative to the emergency department. The present study suggests that the outpatient diuresis clinic represents a novel strategy that could improve outcomes in heart failure cost-effectively.

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