Original Article

The Role of Ambulatory Heart Failure Clinics to Avoid Heart Failure Admissions

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ABSTRACT

Background: There is a complex relationship between heart failure (HF) clinic services and health outcomes. We hypothesized that ambulatory clinic activity may be associated with both hospital admission and also with avoidance of admission.

Methods: A retrospective comparative cohort study was conducted examining activity in an ambulatory HF Clinic. Consecutive clinic visits in 2013 were recorded (n = 1728) and periods of high-intensity utilization (HIU) were identified (n = 128). A HIU period was defined by ≥2 consecutive clinic visits within 30 days, ending after 30 days passed without an additional clinic visit. For each HIU period identified, patient characteristics (n = 107) and all clinic visits (n = 324) were examined. HIU periods were then classified by association with hospital admission (±30 days).

Results: In 2013, 18.8% of all clinic visits occurred during HIU periods, involving 13.7% of the clinic population. Thirty-eight percent of HIU periods were associated with 62 total hospital admissions (±30 days),

RÉSUMÉ

Contexte : Il existe un lien complexe entre les services cliniques relatifs à l'insuffisance cardiaque (IC) et les résultats liés à la santé. Nous avons posé l'hypothèse que l'activité dans les unités de soins ambulatoires pourrait avoir une influence à la fois sur les hospitalisations et sur l'évitement des hospitalisations.

Méthodologie : Une étude de cohorte comparative rétrospective a été menée afin d'examiner l'activité dans une unité de soins ambulatoires auprès de patients atteints d'IC. Les visites consécutives effectuées à l'unité de soins en 2013 ont été compilées (n = 1728) et les périodes d'utilisation intensive des services (UIS) ont été relevées (n = 128). Une période d'UIS était définie par au moins 2 visites consécutives à l'unité de soins ambulatoires en l'espace de 30 jours; la période était considérée comme terminée après 30 jours sans nouvelle visite. Pour chaque période d'UIS relevée, les caractéristiques des patients (n = 107) et toutes les visites à l'unité de soins (n = 324) ont été examinées. Les périodes d'UIS

Heart failure (HF) is a chronic condition with a variable course, requiring longitudinal ambulatory care, interrupted by episodes of acute worsening, requiring hospitalization for management.[1] There is a complex relationship among the intensity of HF ambulatory clinic services, the need for hospitalization, and health outcomes. HF clinics improve survival of high-risk patients with HF but may also increase rates of hospitalization.[2] On the one hand, higher levels of surveillance in the ambulatory clinic setting may increase hospitalization by recognition of decompensation.

On the other hand, HF clinics can provide unscheduled visits, rapid intervention, and follow-up, which may allow outpatient treatment of congestion and avoidance of hospitalization or readmission. Our objective was to understand, with relative granularity, the activities devoted to frequent or urgent clinic visits to an ambulatory HF clinic. The characteristics of the population of patients requiring these periods of high-intensity outpatient care and the relationship of their ambulatory visits to hospital admissions either before or after clinic activity and other health outcomes were also described. We hypothesized that it was possible to identify periods of clinic activity that may result in successful treatment of congestion and avoidance of hospital admission.

Methods

Study design and setting

A retrospective comparative cohort chart review study was conducted examining clinical activity in an ambulatory HF

of which 58% (n = 36) were for a primary diagnosis of HF. In addi-
tion,17 HIU periods met criteria for admission avoided, and 7 HIU
periods occurring after hospital discharge also met criteria for
admission avoided.

Conclusions: We identified periods of intensive ambulatory clinic ac-
tivity dedicated to patients with high burdens of comorbidities and
both HF and non-HF—related admissions. These periods were also
associated with episodes of successful decongestion with oral di-
uretics, resulting in avoidance of admission. Identifying HF patients
who can be treated successfully or who are likely to require admission
may be helpful for allocating clinic resources.

ont ensuite été classées en fonction de leur association avec une
hospitalisation (± 30 jours).

Résultats : En 2013, 18,8 % de toutes les visites à l'unité de soins
ambulatoires étaient rattachées à une période d'UIS et concernaient
13,7 % des patients de l'unité. Au total, 38 % des périodes d'UIS ont
été associées à 62 hospitalisations (± 30 jours), dont 58 % (n = 36)
étaient liées à un diagnostic primaire d'IC. En outre, 17 périodes d'UIS
répondaient aux critères définissant une hospitalisation évitée, et 7
périodes d'UIS survenues après que le patient soit sorti de l'hôpital
répondaient aussi aux critères définissant une hospitalisation évitée.

Conclusions : Nous avons relevé des périodes d'activité intensive de
l'unité de soins ambulatoires consacrées à des patients présentant un
lourd fardeau de comorbidité, ainsi que les hospitalisations liées à l'IC
et non liées à l'IC. Ces périodes étaient aussi associées à des épisodes
de congestion soulagée grâce à des diurétiques oraux, ce qui a permis
d'éviter des hospitalisations. Le repérage des patients atteints d'IC qui
peuvent être traités efficacement en consultation externe et de ceux
qui risquent de devoir être hospitalisés pourrait permettre d'optimiser
l'affectation des ressources des unités de soins.

Clinic. We examined consecutive in-person ambulatory visits
occurring over 1 year at the Anna Prosserman Heart Function
Clinic, a high-intensity subspecialty ambulatory HF clinic
located in an academic institution. The clinic does not offer
transplantation or circulatory support, and the population is a
mix of patients with HF with reduced, preserved, mid-range, and
recovered ejection fraction. Permission for retrospective chart
review was obtained from our institutional research ethics board.

HF cohort identification

Identification of high-intensity users HF cohort. A
complete listing of all consecutive patient visits to the Anna
Prosserman Heart Function Clinic is maintained in a database
by clinic administration. Consecutive patient clinic visits
starting January 1, 2013, and over the following calendar year
were collected and cross referenced with the electronic patient
record (EPR, Cerner Powerchart). Every patient contact with
the hospital is assigned a unique visit number in the EPR. For
each unique patient, the first clinic visit after January 1, 2013
was considered the index visit. The EPR was then scanned to
document all episodes of hospital registration within 30 days
of each index visit. A high-intensity utilization (HIU) period
was defined by 2 or more consecutive visits to the clinic
within 30 days of the index visit. The HIU period was
considered active if less than 30 days passed before a subse-
quent registered clinic visit. Visits were counted until a period
of ≥ 30 days was recorded without a visit. The HIU period
was measured in days, beginning with the index visit and
ending 30 days after the last visit. It was possible for patients
to have more than 1 period of HIU over the period of data
collection. All patients having at least 1 HIU period over the
time of data collection were included in the HIU cohort.

Identification of the control HF cohort. The control
group comprised 50 randomly selected, age- (±5 years) and
sex-matched HF clinic patients from the same clinic lists used
to identify the HIU cohort. Each control was selected from
the clinic date corresponding to the HIU patient's index visit.

Data extraction. Demographic and clinical data were extrac-
ted from the chart and from the EPR using standardized case
case-report forms. Information on age, sex, New York Heart
Association (NYHA) class, and current medications at the time
of the index visit were captured. Historical information
including etiology of HF, cardiovascular risk factors, and
comorbid medical conditions, and history of cardiac interven-
tional and surgical procedures were also recorded. Admissions
to hospital from January 1, to December 31, 2013, were
reviewed for patients in both cohorts. Data collected for each of
these admissions included primary reason for admission, length
of stay (LOS), and status at discharge. We also recorded last-
known vital status for all patients in both groups and record
admissions to hospital during the follow-up period.

HIU period classification. For each HIU period identified,
all clinic visits within the period were examined. At every
clinic visit, the patients weight, heart rate, and blood pressure
were recorded. All medications and medication changes were
also recorded.

HIU periods were then classified based on an association
with hospital admission. An HIU period was defined as
"associated with hospital admission" if admission occurred
either within 30 days before the first visit of the HIU period
or within 30 days after the last visit of the HIU period.

If no admission to hospital was identified within 30 days
before the first HIU visit or 30 days after the last HIU visit,
the HIU period was defined as "not associated with hospital
admission." An HIU period was defined as an "admission
avoided" if a weight loss of ≥2 kg[3] was documented within
the HIU period, with clinical improvement and no admissions
to hospital were recorded between the first visit of the HIU
period up to 30 days after the last HIU period.

Statistical analysis. Normally distributed data are presented
as mean (standard deviation [SD]); non-normally distributed
data are presented as median (interquartile rage [IQR]).
Continuous variables were compared using Student's *t*-tests, if
normally distributed, whereas the Kruskal-Wallis test was used

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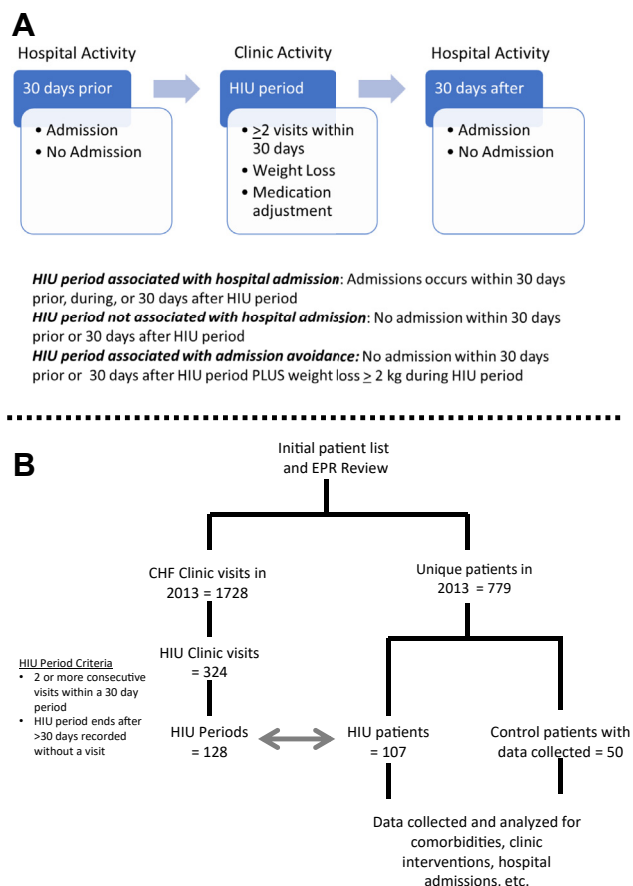
Figure 1. (**A**) Data gathered relative to high-intensity utilization period and (**B**) breakdown of clinic activity.

for nonparametric distributions. *Post hoc* analysis was conducted with the Mann-Whitney U test with *P* values adjusted by the Bonferroni method. Categorical data were compared using the χ^2 test.

Results

HF clinic activity and patient population

Figure 1 shows the definitions used to identify HIU periods (Panel A) and the initial description of clinic visits and unique patients assessed during the study duration (Panel B). Within the period of analysis, we identified 779 unique patients, responsible for 1728 discrete ambulatory clinic visits. We identified 128 HIU periods, involving 107 unique patients (13.7%) who were responsible for 324 discrete ambulatory HF clinic visits (18.8% of all visits).

Table 1 shows the characteristics of the 107 patients experiencing at least 1 HIU period. Eighteen patients in the HIU cohort experienced 2 or more HIU periods within the duration of the study. As planned, 50 patients were selected for the control group from the same clinics as HIU patients, similar in age and proportion of men and women. Compared with controls, patients requiring HIU periods of care demonstrated higher burden of comorbidities including diabetes, hypertension, dyslipidemia, and chronic kidney disease

(CKD). Among the HIU cohort, 69 patients (64%) had at least 1 hospital admission during the year of data collection, and 45 patients (42%) had at least 1 admission for HF. Patients in the HIU cohort were responsible for a total of 77 hospital admissions for HF, with a median LOS of 6 days (IQR: 3 to 15) within the entire analysis period. There were 6 deaths within the analysis period, all occurring among the HIU cohort.

HIU periods and association with hospital admissions

We identified 128 HIU periods totalling 324 visits. The median duration of the HIU periods was 28 days (IQR: 21 to 29). Patients required a median of 2 visits (IQR: 2 to 3) with 21 (IQR: 15 to 28) days between visits. The maximum number of visits in a single HIU period was 9. In total, 3883 patient days were spent in an HIU period.

To demonstrate interactions between HIU clinic activity and hospitalization, Figure 2A shows the breakdown of HIU periods. Figure 2B shows the disposition of unique HIU patients, as some patients experienced more than 1 HIU period.

HIU periods associated with hospital admissions. Forty-nine of the 128 (38%) HIU periods, involving 43 unique patients, were associated with 62 hospital admissions. Of these 49 HIU periods, 19 were associated with admissions that occurred within 30 days before, 24 were associated with admissions that occurred during or within 30 days after the HIU period, and 6 were associated with more than 1 admission before and during or after the HIU period. Admission occurred directly from the clinic during 11 HIU periods. Of the 62 admissions, 36 were primarily due to HF, whereas 26 were due to other cardiac or noncardiac reasons. The mean age of the patients in this group was 68 ± 14 years, and 68% were men.

HIU periods associated with avoided admissions. Seventy-nine of the 128 HIU periods (62%) were not associated with a hospital admission. Of these, 17 HIU periods involving 15 unique patients fulfilled the definition of an admission avoided. The mean age of patients in this group was 68 ± 15 years, and 77% were men. Compared with HIU patients with hospital admissions, there were no significant differences in comorbid illness, only a trend to fewer patients with CKD.

HIU periods not associated with admission or admission avoided. By definition, 62 remaining HIU periods were not associated with either hospital admission or admission avoidance. The mean age of patients in this group was 68 ± 14 years, and 66% were men. Compared with the other 2 groups, there were no significant differences in comorbid illness.

Clinic activity during HIU periods

The changes in weight, number of visits, and clinical interventions (medication adjustments) during the HIU periods classified by association with hospital admission are shown in Table 2. Overall, HIU activity included medication changes in 84% HIU periods, with adjustment of a median of 2 medications.

Table 1. Comparison between HIU patients and control patients

	HIU patients (N = 107)	Control patients (N = 50)	P value
Demographics			
Age (average)	68 ± 14	70 ± 14	0.52
Male, n (%)	73 (68%)	29 (58%)	0.21
New diagnosis of HF	5%	8%	0.40
Comorbidities			
Hypertension (proportion of cohort)	67%	48%	0.02
Diabetes mellitus	39%	20%	0.02
Hyperlipidemia	25%	10%	0.03
Smoking	25%	26%	0.92
Atrial fibrillation	27%	32%	0.53
Chronic kidney disease	21%	6%	0.02
Previous TIA/stroke	12%	10%	0.69
Ischemic heart disease	38%	28%	0.16
Previous MI	28%	22%	0.42
Previous PCI or CABG	34%	18%	0.04
Medical therapy			
Loop diuretics (proportion of cohort)	82%	48%	< 0.01
Loop diuretic dose, mg (mean ± SD)	92 ± 79	67 ± 45	0.14
ACE inhibitors (proportion of cohort)	49%	56%	0.38
ARB	26%	32%	0.45
β blockers	80%	82%	0.81
Aldosterone antagonists	39%	30%	0.30
Digoxin	28%	22%	0.42
Anticoagulants	36%	34%	0.77
Hospital admissions during the 1-year study period			
Patients with all-cause admissions, n (% cohort)	69 (65%)	11 (20%)	< 0.01
Patients with HF admissions, n (% cohort)	45 (42%)	1 (2%)	< 0.01
Total number all-cause admissions	147	20	
Total number HF admissions	77	3	
Total days all-cause admission	1676	184	
Total days HF admission	829	53	

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CABG, coronary artery bypass graft; HF, heart failure; MI, myocardial infarction; PCI, percutaneous coronary intervention; SD, standard deviation; TIA, transient ischemic attack.

HIU periods associated with admissions avoided. By definition, HIU periods defined as an admission avoided were associated with significant weight loss, with a mean decrease of 4.5 ± 3.6 kg from the start to end of the HIU period. Virtually all of these HIU periods included adjustments to medical therapy, particularly with respect to loop diuretics. Responses to oral loop diuretic changes occurred quickly, with 88% of these HIU periods achieving ≥2 kg of weight loss between the index visit and the first follow-up, with a median interval of 14 (IQR: 7 to 28) days (mean 14.8 ± 9.5) between the 2 visits.

HIU periods associated with hospital admissions. Although these HIU periods were associated with hospital admission, a weight loss of ≥2 kg was still observed in 49%. Overall, the mean weight decrease was smaller than weight changes occurring in HIU periods associated with admission avoidance. HIU periods associated with hospital admission were similar in duration and frequency of visits to periods

defined as admission avoided. These majority of these periods (84%) also included adjustments to medical therapy, although loop diuretics were adjusted less frequently compared with HIU periods associated with admission avoidance.

HIU periods not associated with admission or admission avoided. These HIU periods were not associated with significant changes in body weight. These periods were associated with a high proportion of medication adjustments (80%), but diuretics were adjusted less frequently than for the other HIU periods.

HIU periods occurring before or after associated hospital admissions

Table 3 shows the clinic activity and length of hospital stay related to admissions associated with HIU periods. Figure 3 illustrates the frequency distribution of all cause and HF admissions in semimonthly intervals starting 30 days before the index HIU visit. All together, there were 62 hospital admissions associated in some way with HIU periods. Forty percent of admissions preceded the HIU period, and 60% occurred either during or after the HIU period. The median LOS was similar regardless of timing of admission or reason for admission.

Among all admissions, 36 were attributed to HF as the primary reason for admission. In this subgroup, 50% of admissions occurred during or after the HIU period, and 50% occurred before the HIU period. There were 18 HF admissions that occurred during or after the HIU period, 50% of which occurred within 15 days of the index HIU visit.

We examined the 18 HIU periods that occurred after hospital admission. The majority of HIU periods (14 of 18) occurred within 15 to 30 days after hospital discharge. In this group, 7 met the weight loss target of 2 kg, fulfilling the definition for admission avoided. These HIU periods were in addition to the HIU periods that were classified as admissions avoided.

Total HF admissions and admissions avoided

In total, we identified 36 actual admissions for HF; in addition, 17 HIU periods met criteria for admission avoided, and 7 HIU periods occurring after hospital discharge also met criteria for admission avoided. There were thus a total of 60 potential HF admission events associated with HIU periods, and clinic intervention may have prevented 24 (40%) of potential HF admissions/readmissions. There were 72 clinic visits during HIU periods associated with admissions avoided. This represented 22% of clinic visits spent with the HIU cohort and 4% of all clinic visits during the analysis period.

Discussion

In this study, we identified a cohort of patients requiring periods of frequent and complex interactions with the ambulatory HF clinic. Almost one-fifth of visits to our ambulatory clinic were spent in the care of these individuals.

Not surprisingly, this cohort of patients demonstrated a high burden of comorbid conditions and was more likely to require admission to hospital for both HF and non-HF reasons during the entire analysis period. The selection of

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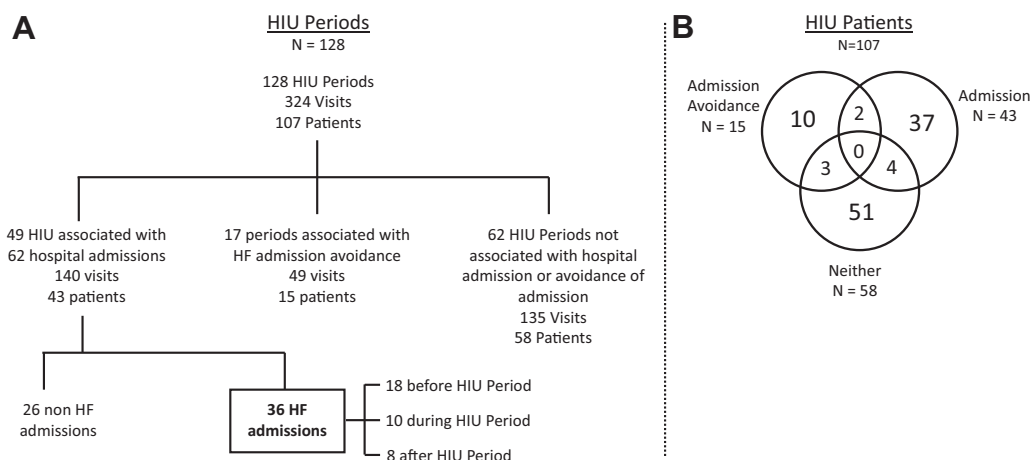
Figure 2. (**A**) High-intensity utilization period activity breakdown and (**B**) high-intensity utilization patient distribution (note the overlap).

controls was to provide context and description of age-matched patients who were otherwise seen in clinic on the same day by the same practitioner and that, by definition, did not have a high-intensity—use period. Selecting patients from the same clinic controlled for practice differences among care providers. It is well understood that patients with HF requiring admission to hospitals have more comorbid conditions.[4] As is often the case, resource utilization is disproportionately high, given the relatively small number of these patients,[5] and our study demonstrates that this applies to the ambulatory clinic setting as well as inpatient services. It is interesting that hospital admissions among this population associated with HIU periods were as likely to be related to HF as non-HF diagnoses,[6] attesting to the general frailty among these patients.

In this study, we were able to identify ambulatory clinic activity that fulfilled an *a priori* definition of an "admission avoided" and may have prevented up to one-third of potential HF admissions. In the ambulatory setting, decreases in body weight were achieved in some patients, similar to decreases observed in patients with HF admitted to hospitals and treated systematically with parenteral furosemide[7] within the **D**iuretic **O**ptimization **S**trategies **E**valuation (DOSE) trial. In our analysis, pharmacologic adjustment occurs frequently in the ambulatory setting, particularly escalation of oral loop diuretic dosage. In clinic encounters associated with avoided admissions, the response to oral loop diuretics was observed to occur rapidly, with the majority (88%) of these patients achieving weight loss ≥ 2 kg between the index visit and the first follow-up. We also observed approximately 15% of HIU periods that occurred within 30 days after a hospital discharge. A proportion of these patients continued to demonstrate weight loss. One interpretation of this observation is that some patients were not stable in the postdischarge phase and continued to require therapy for decongestion. This may further support the role of HF clinics, with the capacity to accommodate HIU periods, to prevent readmission in addition to admission avoidance.

Table 2. Summary of HIU period activity grouped by relationship to hospital admission

	Admission avoided (N = 17)	Admission ± 30 days (N = 49)	Neither avoidance nor admission (N = 62)
HIU details			
Duration (median IQR)	28 (23-46)	28 (22-46)	27.5 (19-28)[†]
Median number of visits	3 (2-4)	2 (2-4)	2 (2-2)*,[†]
Total number of visits	49	140	135
Medication changes			
% HIU with medication changes	100%	84%	80%
Number dose adjustments per HIU (median IQR)	3 (2-3.5)	2 (1-3)*	1.5 (1-2)*
Number medications changed per HIU	2 (2-3)	2 (1-2)*	1 (1-2)*
Loop diuretics			
% HIU with loop diuretic adjustment	88%	67%	39%
Number loop diuretic adjustments per HIU	1 (1-2)	1 (0-1)*	0 (0-1)*
Weights and weight changes during HIU period			
Weight at index (mean ± SD)	84.4 ± 16.7	80.7 ± 18.0	80.4 ± 16.3
Weight lost	4.5 ± 3.6	1.9 ± 3.4*	0.0 ± 1.0*,[†]
Maximum weight lost	4.9 ± 3.5	2.5 ± 3.6*	0.0 ± 1.0*,[†]
% of patients with any weight loss	100%	69%*	50%*,[†]
% of patients with weight loss ≥ 2 kg	100%	49.0%*	0%*,[†]

HIU, high-intensity utilization; IQR, interquartile range, SD, standard deviation.

* Significant when compared with admissions avoided (N = 17), $P < 0.05$.

[†] Significant when compared with admission ± 30 days (N = 49), $P < 0.05$.

Table 3. Details of admissions before and during and after HIU periods

	Admissions before HIU	Admissions during and after HIU
Number of admissions		
All-cause	25	37
Heart failure	18	18
Number of HIU periods/number of visits associated with admissions		
All-cause	24/59	31/93
Heart failure	18/42	16/49
Admission LOS, median (IQR)		
All-cause	5 (3.5-11)	5 (2.25-8)
Heart failure	5 (2.75-9.5)	5 (3-14.25)

HIU, high-intensity utilization; IQR, interquartile range; LOS, length of stay.

In this analysis, we also identified a group of patients who were admitted to hospital, despite a period of intensive ambulatory care. Admissions occurred despite escalation of diuretic dosages and evidence of fluid loss. It is likely important in planning optimal deployment of ambulatory clinic resources to determine the factors that identify patients who will and will not respond optimally to oral decongestion. Generally, renal insufficiency was uncommon in HIU patients who did not require hospital admission, but there was significant overlap between groups with respect to other comorbid conditions. In this experience, approximately half of admissions associated with HIU periods occurred within 2 weeks of the index HIU visit, suggesting relatively rapid recognition of unsuccessful treatment in the ambulatory setting.

The care of patients with HF is complex, and the majority of HIU periods were neither associated with admission nor admission avoided. Eighty percent or more of these visits included adjustments to diuretic or nondiuretic medical therapy, reflective of contemporary HF management. Pharmacotherapy is only a single aspect of care delivered in the ambulatory setting, which is increasingly multidisciplinary and includes adequate patient education on adherence and self-care, selection of candidates for device therapy, mechanical support and transplantation, and conversations regarding goals of care and shared decision making.[8]

Our experience illustrates the complex role of the HF clinic. It has been demonstrated in a systematic review that

management by multidisciplinary HF clinics is associated with a lower incidence of HF hospitalization and mortality.[9] However, it has also been demonstrated in a Canadian experience that HF clinics may also increase hospital admissions.[10] Our study supports the existence of several mechanisms by which these conflicting observations may arise. We identified clinic activities that result in decongestion and that may pre-empt admission for some patients. However, we also identified clinic activities that may conceivably delay admission or perhaps facilitated recognition of the need for admission or readmission in appropriate patients. A strategy that may enhance the effectiveness of ambulatory care for treatment of congestion is the administration of intermittent parenteral furosemide to patients demonstrating inadequate decongestion with oral therapy.[11] The safety of the ambulatory approach to decongestion requires further study. Timeliness is likely also a key attribute dependent on both the clinic and patient availability for contact at short-interval clinical and biochemical surveillance.

In this study, we focused on frequent in-person patient encounters within a subspecialized ambulatory clinic with physiologic monitoring of congestion. Since these data were extracted, remote daily physiologic monitoring of pulmonary artery pressure has become more widely available and has been demonstrated to reduce the rate of hospital admissions.[12] It is possible that the in-person aspect of clinic follow-up with experienced HF practitioners may facilitate more comprehensive assessments of patients' overall clinical, physiologic, and psychosocial status and more aggressive adjustment of therapy. More intensive individualized support may, in turn, enhance patient engagement and compliance with recommended treatments. As such, the combination of remote monitoring and telehealth evaluation[13] may achieve the same outcome of decreasing admissions and readmissions. The relative availability of resources and patient factors, such as mobility and location, may determine the specific services offered by chronic HF disease-management programs. It will also be useful to develop tools that identify patients at higher risk of hospitalization in addition to mortality risk scores.

Study limitations

This study was limited by the single-centre retrospective design in an urban academic HF clinic and relatively modest sample size. Telephone and telehealth contacts were not captured in our data extraction, a limitation that may further underestimate the impact of the HF clinic. Patients may have also sought urgent evaluation in primary care or emergency departments, which was not systematically identified. The intent was to approach our centre as a case study and to examine activities with some granularity. The majority of patients were located proximate to the large metropolitan area of Toronto, Ontario. There is great variation in service models for HF in Ontario, and there may be barriers to access equivalent levels of care, especially in rural areas.

Conclusions

We identified periods of intensive ambulatory clinic activity dedicated to patients with high burdens of comorbidities and associated with both HF and non-HF—related hospital admissions. These periods were also associated with episodes
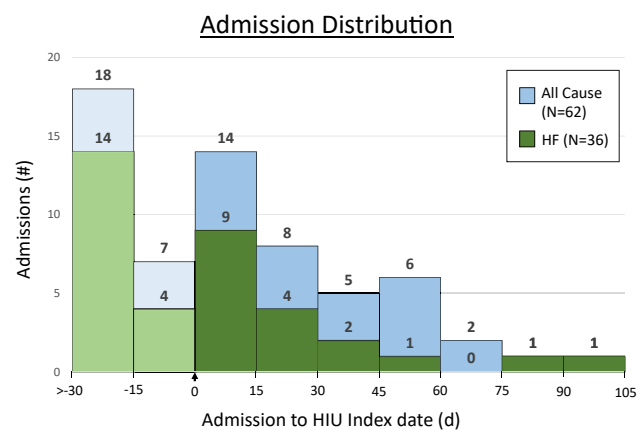
Figure 3. Temporal relationships between high-intensity utilization periods and associated hospital admissions.

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of successful decongestion with oral diuretics, resulting in avoidance of admission. Identifying patients with HF who can be treated successfully or who are likely to require admission may be helpful for allocating clinic resources.

Funding Sources

Disclosures

The authors have no conflicts of interest to disclose.

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