University of Alberta

Impact of Recall Visits on Hospitalization Rates in a Heart Failure Clinic

by

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Dedication

This thesis is dedicated to my husband and furry family, who tolerated a prolonged period of competing demands for my time and attention with patience and grace.

Abstract

Many heart failure (HF) hospital admissions are avoidable with appropriate surveillance and self-care support that HF Clinics can provide. Previous studies conducted vary in approach to surveillance. The goal of this study was to assess the impact of frequency of HF Clinic recall visits on hospital admissions. A retrospective cohort of 110 patients enrolled in a HF Clinic was selected. Correlations were conducted among demographic characteristics, clinical variables, number of recall visits, and hospital admission rates. Significant variables were entered into multivariate regression analysis to determine predictors of frequency of recall visits and hospital admissions. HF clinic visit recall frequency was not predictive of hospitalization rates in this cohort. The main predictor of hospital admissions was the baseline Seattle Heart Failure Model score. Additional study of this composite score as a potential tool for determining HF Clinic recall frequency is required.

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CHAPTER ONE

Introduction

There are over 500,000 people in Canada with heart failure (HF), and 50,000 new cases diagnosed yearly (Ross et al., 2006). High morbidity and mortality characterize HF, as do quality of life issues around a heavy and variable symptom burden (Dickstein et al., 2008). Cost estimates of in-hospital patient care for HF are calculated at over 50% of the total healthcare funding spent on HF (Thom et al., 2006). Many HF hospital admissions are avoidable with appropriate treatment, symptom surveillance and self-care support (Dickstein et al., 2008).

Heart Failure Clinics are specialized multidisciplinary hospital based ambulatory care settings featuring trained physicians, nurses, and allied health care providers (eg. dietitians, pharmacists) who integrate skill sets to ensure guideline based follow-up for HF patients (Howlett et al., 2010). Fundamentals of HF Clinic care include detailed physical examination and history, laboratory and diagnostic testing, self-care education, surveillance around symptom recognition and management, and guideline based HF medication titration and monitoring (McMurray et al., 2012). HF Clinics feature in person pre-planned visits or "recall" as the predominant treatment modality, with telephone follow-up offered on a supplementary basis. This approach differs from other methods of HF disease management programs such as home based care, and telemonitoring (Yancy et al., 2013). Canadian HF guidelines (Howlett et al., 2010) recommend HF Clinics as current best practice for HF patients, and particularly for those at high risk for hospital admission (two or more admissions in six months).

Patterns of patient recall frequency differ from one HF Clinic to another, and from physician to physician, within any given clinic. This holds true

regardless of similarities in baseline patient characteristics such as symptom intensity measured by New York Heart Association Functional Class (NYHA FC) (Dickstein et al., 2008), left ventricular ejection fraction (EF), or other clinical status indicators. How differing recall patterns may impact on a patient's HF hospitalization risk is not clear. Obtaining evidence based guidance on frequency of recall visits within HF Clinics is of significant consequence in terms of optimizing patient health status and quality of life, avoiding costly hospitalizations, increasing access to this service, and optimizing efficiency within the healthcare system. HF Clinics have recently expanded in number throughout Alberta (McAlister et al., 2013), but remain a scarce resource. On review of the literature, there is little evidence or informed direction for HF Clinic recall frequency.

Purpose of the Study

The purpose of this study was to examine if frequency of HF Clinic recall visits affect hospital admission rates for patients attending a HF Clinic.

The research questions were:

1) What patient demographic and clinical factors predict the frequency of HF Clinic visits for patients attending a HF Clinic?
2) What patient demographic and clinical factors predict hospital admissions for patients attending a HF Clinic?
3) What is the effect of frequency of HF Clinic recall visits on All Cause, HF, Cardiovascular (CV), and Other hospital admissions for patients attending a HF Clinic?

Significance of the Study

A significant challenge within HF care lies in identifying evidence supported treatment strategies, which include the frequency of patient recall visits

required to optimize program effectiveness. Currently, eligible HF patients out-number specialty HF Clinic capacity. A strategy that maximizes HF Clinic benefit, while minimizing both patient and resource burden is needed. Moreover, it may assist in resource allocation, potentially allowing more HF patients access to this level of care. Determining the impact of HF Clinic recall frequency on hospital admission rates will assist in defining best practice for HF care delivery.

CHAPTER TWO

Literature Review

HF Clinics are effective at addressing HF morbidity and mortality (McAlister, Stewart, Ferrua, & McMurray 2004; Roccaforte, Demers, Baldassare, Teo, & Yusuf, 2005). HF Clinics are known to reduce hospitalizations (Howlett et al., 2010) for HF patients, as found in numerous randomized control trials (RCTs), non-randomized studies, and meta analyses done since 2000. The optimal method of program delivery favors HF care that is multidisciplinary in nature (ie. specialized nurses, physicians and allied health personnel), and utilizes in-person clinic visits over other HF disease management programs, such as home based nursing interventions and remote telemonitoring (Sochalski et al., 2009). Gustafsonn and Arnold (2004) highlighted the value of experienced nurse involvement in HF clinic patient care. Thomas et al. (2013) also identified key elements for successful multidisciplinary HF Clinics; trained specialist nurses in prominent roles, intensive HF education for patients and caregivers, and ready access to HF trained clinicians. In addition, Cardiologist or specialist involvement in a HF clinic program is preferable (Ezekowitz, van Walraven, McAlister, Armstrong, & Kaul, 2005; McAlister et al., 2004). Fourteen RCTs (Atienza et al., 2004; Azad, Molnar, & Byszewski, 2008; Capomolla et al., 2002; Doughty et al., 2002; Ducharme, Doyon, White, Rouleau, & Brophy, 2005; Jaarsma et al., 2008; Kasper et al., 2002; Ledwidge et al., 2003; McDonald et al., 2002; Mejhert, Kahan, Persson, & Edner, 2004; Pugh, Havens, Xie, Robinson, & Blaha, 2001; Schou et al., 2013; Stromberg et al., 2003; Stewart et al., 2012); 9 non-randomized prospective studies and retrospective data reviews (Albert et al., 2010; Feldmann et al., 2011; Galatius, Gustafsson, Nielsen, Atar, & Hildebrandt, 2002; Gouya et al., 2011; Gustafsson et al., 2009; Howlett et al., 2009; Jain et al.,

2010; McAlister et al., 2013; Wijeysundera et al., 2013); 2 primary care based studies (Agvall, Alehagen, & Dahlstrom, 2013; Hershberger et al., 2005); 4 meta analyses (McAlister et al., 2004; Roccaforte et al., 2005; Sochalski et al., 2009; Thomas et al., 2013); and 2 systematic reviews (Gustafsson & Arnold, 2004; Takeda et al., 2012) give an overview of current HF Clinic care as it pertains to HF Clinic recall frequency and hospital admissions.

HF Clinic Recall Frequency

HF Clinic recall visit frequency varied widely amongst the RCTs reviewed, as did the reporting of detail regarding ad hoc (additional) patient clinic visits versus planned visits. The least frequent recall occurred in the Stromberg et al. (2003) trial in which the HF patients were seen once within 2 weeks of hospital discharge, repeat visits "if needed", and a return to their primary care physician when stable (28 patients had 1 visit, 12 patients had 2 visits, 8 patients 3-8 visits, and 4 patients had no visits). In the Mejhert et al. (2004) trial, patients were recalled to clinic for an average of 2.2 ± 2.3 visits over 18 months. The median frequency for this intervention was 1 visit, with a range of 0-10 visits. Patients had planned recall to clinic at 2 and 6 weeks post discharge in 2 studies (Ledwidge et al., 2003; McDonald et al., 2002), then ad hoc visits "as required". For the Pugh et al. (2001) trial, there was a minimum of 5 clinic visits for 31 patients over 6 months, with the first visit within 2 weeks of hospital discharge, and more frequent recall in the first 6 weeks. Doughty et al. (2002) averaged HF Clinic visits every 3 months over the 12 month study period, as did a larger study (N=338) by Atienza et al. (2004). Clinic visits were planned monthly for similar sized HF Clinic groups (N=98/115) in 2 trials (Ducharme et al., 2005; Kasper et al., 2002). The COACH trial (Jaarsma et al., 2008) was a two-tiered intervention that provided a lower (bimonthly clinic visits), and higher (monthly clinic visits)

intensity of HF clinic follow-up. In the recently published NORTHSTAR trial (N=461) (Schou et al., 2013), HF patients were recalled every 1 to 3 months over 2 years. Another recent Australian trial (N=143) (Stewart et al., 2012) gave no details on frequency of recall HF Clinic visits beyond the initial visit (study duration 18 months) which occurred within 2 weeks of hospital discharge. The most frequent recall and shortest duration of clinic visits were twice weekly for 6 weeks in the Azad et al. (2008) study. In a recent randomized open label study conducted in a primary health care setting (Agvall et al., 2013), patients were seen in clinic 3 times over 6 months, with 2 follow-up telephone contacts and ad hoc additional clinic visits as required.

Amongst the non-randomized studies reviewed, 5 documented frequency and pattern of HF Clinic visit recall. Two studies followed the HF patients with high frequency at time of referral (weekly to bi-weekly) over several months, then reduced frequency in stepwise fashion to every 3 months as patients “stabilized” (Hershberger et al., 2005; Jain et al., 2010). Similarly, a newly formed HF Clinic in Denmark (N=283) saw patients within 3 days of referral, conducted an 8 to 12 week medication titration and HF self-care education program, then discharged clinically stable patients back to their primary care physicians (Galatius et al., 2002). Gustafsson et al. (2009) conducted a prospective registry data collection of 18 HF Clinics (N=4012) detailing a median of 6 clinic visits over 18 months (range 3-10), with patients being recalled to clinic at “discretion of staff”. In a much larger population based study of 14,468 patients attending all existing HF clinics in Ontario, Wijeysundera et al. (2013) evaluated HF Clinics that had 3 distinct levels of intensity of patient clinic visit follow-up described as high (multiple visits), medium (>1 and <4 visits), and low (singly visit) over a 6 month period.

Many of the studies reported average visits per patient which reflected more frequent recall than was planned (Kasper et al., 2002, Jaarsma et al., 2008); less than was planned (Doughty et al., 2002); offered little information on ad hoc visits (Agvall et al., 2013; Atienza et al., 2004; Ducharme et al., 2005; McDonald et al., 2002; Pugh et al., 2001) or no information on planned visit frequency (Albert et al., 2010; Feldmann et al., 2011; Gouya et al., 2011; Howlett et al., 2009; McAlister et al., 2013). Capomolla et al. (2002) stated clinic visits were done according to individual patient need, guided by a "risk ratio" score. This score was based in part on clinical indicators such as New York Heart Association Functional Class (NYHA FC), left ventricular ejection fraction (EF), laboratory values, and peak vital capacity (VO2) measurements. No further detail on how the score was tabulated, or what score resulted in what level of recall frequency was provided. Many trials that did document the total number of clinic visits over the study duration did not give details around the timing of either the initial visit, or follow up visits (Agvall et al., 2013; Schou et al., 2013; Stewart et al., 2012; Wijeysundera et al., 2013). Trials that reported recalling patients for ad hoc visits based on individual condition and stability (Gustafsson et al., 2009; Hershberger et al., 2005; McDonald et al., 2002; Pugh et al., 2001; Stewart et al., 2012; Stromberg et al., 2003), did not elaborate on what patient or clinical factors influenced these. One of the randomized trials (Agvall et al., 2013) and 3 non-randomized studies (Galatius et al., 2002; Hershberger et al., 2005; Jain et al., 2010) applied a prospective approach to a HF Clinic recall pattern that was based on increased intensity of clinic visit frequency for new patients (weekly to biweekly), that tapered off once guideline medication goals were met, and as increased clinical stability (decrease in HF symptoms) was achieved for each patient.

Given this lack of detail on the total number of HF Clinic visits per patient, the timing (clinic visit pattern), and rationale for both planned and ad hoc visits, no correlation between clinic visit recall pattern and study outcomes was presented by the majority of these studies and meta analyses.

Impact of Frequency of HF Clinic Recall

Despite a complex combination of demographic and clinical characteristics within each study sample, a seemingly arbitrary, "one size fits all" approach to the planned recall pattern was applied to patients within most RCTs. Moreover, HF Clinic recall frequency between trials did not appear to correspond in a predicable way to improved patient outcomes in HF hospital admission rates. The studies that presented HF Clinic recall frequency as a direct variable in terms of patient outcomes had either multiple levels of HF Clinic recall "built in", or provided detailed descriptions of recall pattern variation between studies reviewed.

The COACH trial (Jaarsma et al., 2008) found a slight increase in HF admissions for the higher intensity HF Clinic group (N=134) over the usual care group (N=120), however, the median duration of admissions was shorter for both levels of HF Clinic care (basic: 8 days, intensive: 9.5 days) versus the usual care group (12 days). Wijeysundera et al. (2013) found those patients seen most frequently (> 4 clinic visits) showed a reduced rate of All Cause hospitalization (HR 0.69, p=0.039), which differed from the neutral results of the medium and low intensity groups.

Within the non-randomized studies, 2 reported an increase in HF admission rates associated with HF Clinic follow up. Gouya et al. (2011) (N=474) found patients who were newly referred to the HF Clinic (N=344) (< 1 year follow up) to have an increase in HF hospital admissions over 1 year. In the 14, 468

patient evaluation of existing, non-RCT, HF Clinic outcomes (Wijeysundera et al., 2013), HF admission rates were also higher in the 2 lower intensity HF Clinic cohorts versus usual care (58.7% vs 47.3%).

Three of the 4 meta analyses reviewed (McAlister et al., 2004; Roccaforte et al., 2005; Sochalski et al., 2009) did not address the relationship between patient clinical status, HF Clinic recall frequency, and hospitalization rates. A more recent meta analysis (Thomas et al., 2013) out of the United Kingdom, looking at 10 RCTs, did exam the pattern of HF Clinic visits, concluding that the optimal recall pattern for best readmissions outcomes involved a high frequency of clinic visits soon after hospital discharge (weekly to biweekly) that gradually reduced over time. The authors reported a 58% relative risk reduction in unplanned HF hospital admissions in the trials that recalled HF patients to clinic more frequently in the first 2 months post hospital discharge, with neutral results found for HF Clinics that recalled patient every 1 to 3 months. Of interest, the RCT (Azad et al., 2008) that had the most frequent clinic recall had a negative result, with a trend to increased All Cause hospital admissions, and decreased quality of life scores.

Few of the studies appeared to apply a prospective approach to planned HF Clinic recall based on recognized predictors of a poor HF prognosis and increased risk of hospitalization such as age, NYHA FC, EF, or HF etiology (Dickstein et al., 2008). Some of the most symptomatic patients with NYHA 3 and 4 FC, were recalled to clinic monthly to every 3 months (Doughty et al., 2002; Ducharme et al., 2005; Kasper et al., 2002). The NORTHSTAR RCT (Schou et al., 2013) did assert that HF Clinics should focus visit recall frequency on up-titration of HF medications, and that long term follow-up of optimally treated, functionally stable patients was not associated with improved outcomes,

as did Gouya et al. (2011), but neither trial suggested a clinical definition of "instability", or a pattern of HF Clinic visit recall to facilitate this.

Impact of HF Clinics on Hospital Admissions

All Cause admissions. Of the 9 RCT citing All Cause hospital admission rate outcomes, 6 reported positive results (Atienza et al., 2004; Capomolla et al., 2002; Doughty et al., 2002; Ducharme et al., 2005; Kasper et al., 2002; Stromberg et al., 2003). A 26% reduction in All Cause hospital admissions for the HF Clinic group was reported by Doughty et al. (2002), a 16% reduction noted by Atienza et al. (2004), while Stromberg et al. (2003) found a 42% decrease after 3 months (adjusted for time of survival, All Cause admissions rates were reduced by 31%). Stromberg also noted a 45% reduction in hospital days for the HF Clinic group. An earlier study (Kasper et al., 2002) reported fewer overall hospital admissions over a 6 month period, as did a Canadian trial (Ducharme et al., 2005) which reported an All Cause hospital admission rate of 39% for the HF Clinic group versus 57% for patients assigned usual care. The Ducharme study also reported 514 and 815 total hospital days, for the HF Clinic and usual care groups, respectively. In a study by Capomolla et al. (2002), the hospital admission rates were lower in the HF Clinic group (14%) than in the usual care group (86%). A randomized prospective open label study conducted within a primary care based HF Clinic (Agvall et al., 2013), showed both fewer All Cause hospital admissions (36 vs 51) and days admitted (265 vs 423) in the HF Clinic cohort.

The remaining 3 RCTs (Doughty et al., 2002; Mejhert et al., 2004; Stewart et al., 2012) found no difference in All Cause admission rates. Of interest, Doughty et al. (2002) found that for All Cause hospitalization rates, the first readmission (both time to and length of hospital stay) were similar between the

usual care and HF Clinic groups. Subsequent hospital readmissions however, were less frequent, and shorter (fewer total bed days). This reduction in multiple admissions is a key element of interest in the care of a population that is prone to them. The WHICH trial (Stewart et al., 2012) was a head to head comparison between HF Clinic care and a home based nursing HF disease management program, which was a considerably enhanced level of intensity over the "usual care" of the other RCTs reviewed, possibly explaining this trial's neutral results.

Four non-randomized studies reported positive results with regard to All Cause admissions. The primary health care based HF Clinic (Hershberger et al., 2005) found a 40% reduction in All Cause admissions in a pre/post study evaluation. Feldman et al. (2011) also found lower rates of All Cause hospitalization over 3 years. In an outcome evaluation (McAlister et al., 2013) using interrupted time series (10 year span) conducted in Alberta following augmentation of province wide HF Clinic capacity, the authors found a reduction in All Cause readmission or death 30 days post discharge (18.6% vs 22.2%). Lastly, the retrospective analysis of the Improving Cardiovascular Outcomes in Nova Scotia (ICONS) registry (N=8731) (Howlett et al., 2009) reported HF Clinics to be associated with reductions in All Cause readmissions (HR 0.27; 95% CI 0.21-0.36, $p<0.0001$; NNT 4).

Gouya et al. (2011) reported neutral results for All Cause admissions in a cohort study for both newly referred (< 1 year) and long term HF clinic patients. A negative result was found in the Wijeysundera et al. (2013) population study (N=14, 468), with All Cause admissions increased slightly in patients followed by lower intensity HF Clinics than usual care (87.4% vs 86.5%), while the higher intensity HF Clinic showed a reduced rate of All Cause hospitalization over usual care (HR 0.69, $p=0.039$).

HF admissions. Nine RCTs (Atienza et al., 2004; Azad et al., 2008; Doughty et al., 2002; Jaarsma et al., 2008; Kasper et al., 2002; Ledwidge et al., 2003; McDonald et al., 2002; Pugh et al., 2001; Schou et al., 2013) presented results pertaining to HF hospital admission rates. A small (N=98) single site trial (McDonald et al., 2002) reported a 3.9% hospitalization rate for the HF Clinic group versus 25.5% for the usual care group, a five-fold decrease. Another identically sized study (Ledwidge et al., 2003) reported 2 HF admissions in the HF Clinic group, and 12 in the usual care group over a 3 month period. Ledwidge also reported 17 days of hospitalization in the HF Clinic group, compared to 195 days in the usual care group at 3 months. A larger trial (N=200) (Kasper et al., 2002), noted 59 HF admissions for the 35 patients in the usual care group, contrasted with 43 admissions for the 26 patients in the HF Clinic group. The largest RCT (N=338) (Atienza et al., 2004) reporting positive outcomes on HF admission rates found a 19% reduction in the HF Clinic group. Doughty et al. (2002) found first readmissions for HF similar between HF Clinic and usual care groups, similar to previously cited All Cause admissions, however, subsequent admissions were fewer, with less total bed days in the HF Clinic cohort.

Amongst non-randomized studies, Galatious et al. (2002) reported a 23% reduction in HF admissions over 1 year for 283 patients attending a newly formed HF Clinic. Similarly a retrospective chart review of 138 patients found fewer HF readmissions, including a 60% reduction in HF admission rates for those patients who crossed over to the HF Clinic side over the 16 month study period (Jain et al., 2010). In contrast, Pugh et al. (2001) found no difference in HF admission rates between the HF Clinic and usual care group in a small (N=58) pilot study, citing sample size as a factor. Three additional studies (Azad et al., 2008;

Jaarsma et al., 2008; Schou et al., 2013) found no significant difference in HF hospital admissions between the HF Clinic and usual care groups. The first of these studies (Azad et al., 2008) was small (N=91), had a relatively short intervention period of 6 weeks, with outcomes measured at 6 months (long after the intervention was discontinued). Moreover, this study had the least symptomatic patient cohort, with 66% at NYHA FC status 1 or 2. The authors cite sample size, program design, and suboptimal target population as contributing factors in a false negative trial. The COACH trial (N=1023) (Jaarsma et al., 2008) found a slight increase in HF admissions for the high intensity HF Clinic group over the usual care group, however, the "usual care" standard included a baseline visit and at least twice yearly follow up by a Cardiologist, with most of the patients being seen more frequently by this specialty service throughout the study duration. This is a significantly enhanced level of usual care compared with other studies reviewed, most of which assigned patients in usual care groups to Primary Care Providers. Specialist follow up is known to improve HF admission rates (Ezekowitz et al., 2005), and thus may explain why there was no intervention related improvement. The authors noted this potential offset of results, as well as a need to more specifically tailor the HF Clinic to individual patient requirements. The NORTHSTAR RCT (Schou et al., 2013) looked at extended follow-up (2 years) of stable HF patients (89% NYHA FC 1 or 2) on optimal medical treatment, and found no reduction in HF admissions, the authors suggesting this category of patient may not benefit from ongoing HF Clinic care.

The studies reviewed had a wide range in sample size (N=58-14, 468), patient characteristics, and HF Clinic program structure and duration (6 weeks to 4 years). This presents a challenge when confronted with the variable results in terms of hospital admissions. Three meta analyses were subsequently reviewed.

The first (McAlister et al., 2004) reviewed 29 RCTs done between 1995 and 2004, of which 7 had a HF Clinic program configuration. This analysis revealed a 27% reduction in HF hospitalizations (total HF admissions reduced 43%), and a 20% reduction in All Cause admissions for the multidisciplinary HF Clinic group. Roccaforte et al. (2005) reviewed 33 RCTs (9 HF Clinic models included) and cited a 31%, and 14% reduction in HF and All Cause admissions with this HF disease management program, respectively. The third meta analysis (Sochalski et al., 2009) pooled and re-analyzed data from 10 RCTs (N=2028) featuring the HF Clinic model exclusively. The authors reported 25% fewer All Cause hospital admissions, and 30% fewer All Cause hospital admission days in the HF Clinic group.

In a Gustafsonn and Arnold (2004) European Society of Cardiology (ESC) systematic review, 18 RCTs and 13 non-randomized trials comparing HF Clinics with nursing interventions showed both fewer All Cause hospital admissions and fewer days in hospital. Most recently, a Cochrane systematic review on clinic service organization in HF (Takeda et al., 2012), found “specialty HF Clinics” did not reduce All Cause hospital admissions for patients recently discharged for HF exacerbation. This neutral result may reflect the small specialty HF Clinic sample (6 RCTs), and poor differentiation (many overlapping program elements) among the 3 HF care models reviewed, which included case management (trained nurse telephone follow up) and multidisciplinary (trained clinical teams).

There are many contributing factors to the varied success, and mixed results of the studies reviewed previously. The HF patient population served by these clinics varied widely in demographic and clinical characteristics. Many of the earlier RCTs had exclusion criteria that precluded HF Clinic participation of many patients that are now served by existing HF clinics (Gustafsson & Arnold,

2004), thus limiting the ability to extrapolate data to the general HF Clinic population. HF Clinic program design, staffing complements (disciplinary mix), interventional content (educational support, telephone follow-up), and recall visit pattern and frequency (where reported) were also highly heterogeneous across the trials (Gustafsson & Arnold, 2004). This heterogeneity ensures that interpreting trial results, as well as applying generalizations across the HF Clinic landscape remains a challenge (Abrahamyan et al., 2013).

Sochalski et al. (2009) further asserts that strategies to optimize HF Clinic program delivery are stymied by the "tremendous variability in program design" (p. 185), necessitating actionable evidence to support development of the best care approach. Many authors of both recent trials and national HF guidelines call for standardization of this care process, along with the initiation of a quality assessment structure (Gustafsson & Arnold, 2004; Hauptman et al., 2008; Howlett et al., 2010). To this effect, (Riegel, Lee, & Sochalski, 2010), have undertaken the development of an instrument to measure HF disease management program intensity (including timing and frequency of recall) as well as complexity to facilitate ease of direct comparison across HF Clinic programs. Wijeysundera et al. (2013) recently used this scoring tool to evaluate HF Clinics across Ontario for individual service components, and found programs with more intensive HF medication management component reduced both All Cause and HF readmission rates.

Risk Factors for HF Hospital Admissions

Lack of clarity around optimal HF Clinic recall frequency for patients relates in part to the myriad risk factors across physiological, comorbid, behavioral and socioeconomic domains that influence this complex and clinically unpredictable condition. HF patients may be completely asymptomatic (NYHA

FC 1), to unable to complete basic activities of daily living without marked to severe dyspnea, fatigue, and/or fluid congestion (NYHA FC 3-4). Symptom status may also fluctuate over time, throughout syndrome progression. Only 4% of HF patients have HF alone (Giamouzis et al., 2011). Comorbidity burden is associated with both a poorer prognosis and increased risk for hospitalization for any cause (Ross et al., 2008). Despite many additional factors being closely associated with increased HF admission risk, such as age, EF, blood pressure (BP), heart rate (HR), electrocardiogram (ECG) parameters, laboratory values (sodium, creatinine, hemoglobin), medication use, and psychosocial status, along with many others, none are reliably predictive (Giamouzis et al., 2011; Ross et al., 2008; Smith et al., 2010). In addition to being numerous, any of the factors associated with increased hospital admission risk can be more or less powerful based on subgroups of HF, such as NYHA FC, ischemic etiology, timing of appearance in syndrome course, or strength of association with certain outcomes (Giamouzis et al., 2011).

Two recent registry data collections have augmented the scarce evidence that exists for hospitalization risk factors for patients in existing HF Clinic populations. Gustafsson et al. (2009) (N=4012) found advanced age, NYHA FC, poor renal function and prior hospitalization to be prominent predictors of both All Cause hospitalization and death. In addition, Howlett et al. (2009) showed independent predictors of mortality and All Cause hospitalization include age, sex, diabetes mellitus (DM), ischemic etiology, weight, hemoglobin, serum creatinine, systolic blood pressure, and EF, across a large (N=8731) HF Clinic population. One additional risk factor indicative of poor outcomes across the literature is clinical vulnerability in the transition period from hospitalization to discharge home (Howlett et al., 2010; McAlister et al., 2013; Takeda et al., 2012).

This finding allows for certainty in enrolling new patients, and recalling established patients to the HF Clinic in a timely manner post hospital discharge, but does little to assist in efforts to optimize extended HF follow-up.

In the face of this clinical uncertainty, one of these factors, NYHA FC, may be of potential value to guide HF Clinic recall frequency. Clinical deterioration from NYHA FC 2 to NYHA FC 3-4 is one of the more robust associated factors for increased HF hospitalization rates (Dickstein et al., 2008; Gustafsson et al., 2009). Second, NYHA FC is the cut off at which symptoms such as fluid retention and congestion become both more bothersome, and eligible for treatment via HF guideline based therapies (Howlett et al., 2010). NYHA FC may as a result, signal the point at which increased clinical surveillance, paired with timely HF Clinic intervention, may provide the largest margin of benefit to resource allocation for the HF patient, but this is largely anecdotal. Three of the RCTs (Pugh et al., 2001; Capomolla et al., 2002; Kasper et al., 2002), and one randomized open label trial (Agvall et al., 2013) reported an improvement in NYHA FC for HF Clinic groups, but none presented an analysis of NYHA FC subgroups as they related to hospital admissions.

In addition to NYHA FC, another potential indicator for HF patients at high risk for hospitalization is the Seattle Heart Failure Model score. The Seattle Heart Failure Model (SHFM) is a validated multivariate risk model used to estimate survival of HF patients with the use of clinical, pharmacological, device and laboratory parameters. The overall receiver operating characteristic area under the curve obtained was 0.729 (95% CI, 0.714-0.744) in a cohort of 1125 HF patients (Levy et al., 2006). The SHFM score ranges from -1 to 4. Stratification for risk of pump failure death is predicted at a 4-fold higher risk for a score of 1, 15-fold for a score of 2, 38-fold for a score of 3, and 88-fold higher risk

for a score of 4 ($p<0.001$ for all comparisons; 1 year area under the receiver operating curve, 0.85). Current use of this model in the literature appears to be limited to predicting HF related survival, with no studies reviewed utilizing the scores (-1 to 4) to represent a continuum of HF related severity of illness, and subsequent risk for hospitalizations. As this model's score increases with worsening of clinical parameters such as NYHA FC, EF, and laboratory values, it is reasonable to speculate that this score may also reflect severity of patient illness. One recent study (Li et al., 2013) did examine the SHFM score in relation to health utility levels (mobility, self-care, usual activity, pain/discomfort, and anxiety/depression), and found that higher SHFM scores indicated a lower level of health utilities, and a more rapid decline in these areas over time.

HF Clinic recall visit frequency was not identified as a singular risk factor for hospitalization in any of the studies reviewed, except where lower and higher intensity (visit frequency) interventions were compared (Jaarsma et al., 2008; Wijeysundera et al., 2013) or where higher frequency of HF Clinic recall was associated with higher hospital admission rates (Azad, Molnar, & Byszewski, 2008; Gouya et al., 2011; Wijeysundera et al., 2013).

Thus, from the literature, it is difficult to ascertain meaningful relationships between specific HF patient characteristics, frequency of HF Clinic recall visits, and rates of hospitalization across the non-standardized level of care provided in current HF Clinics. HF has a variable and unpredictable clinical course that is highly amenable to treatment and self-care strategies aimed at avoiding clinical de-compensation (Dickstein et al., 2008). HF Clinics provide this support, along with the symptom surveillance required for early intervention required to prevent hospital admissions. A logical assumption is that patients exhibiting indicators of worsening HF clinical status, such as a higher NYHA FC, or SHFM scores will

derive the most benefit from a more intensive clinic recall visit pattern, with an expected reduction in HF and All Cause hospital admissions. How often should a HF patient be recalled to the HF Clinic to derive benefit? Which factors influence frequency of HF Clinic recall visits?

CHAPTER THREE

Methods

Design

A retrospective cohort study using a health record review of patients enrolled in one HF Clinic was undertaken. The Mazankowski Alberta Heart Institute Heart Function Clinic (HFC) is located within a tertiary center at the University of Alberta Hospital. It serves a wide range of patient demographics and HF acuity. The HFC employs a multidisciplinary team consisting of HF specialized physicians (cardiologists or general internists), registered nurses (RNs), clinical pharmacists, and a registered dietitian (RD). This clinic sees patients in person, with both physician and RN interacting with patients each clinic visit. The dietitian consults on an as needed basis after completing an assessment on a patient's initial clinic visit, as does the clinical pharmacist. Patients enrolled are followed on a continuous long-term basis. At each visit, the HFC nurses and physicians conduct a focused physical examination and history, laboratory and diagnostic testing review, self-care education, surveillance around symptom recognition and management, and guideline based HF medication titration and monitoring. Additional monitoring between planned clinic visits is done via nursing office telephone follow-up on both a planned and ad hoc basis, according to individualized patient need. Both planned and ad hoc recall to clinic is at the HFC physicians' or nursing staff's discretion in response to a patient's general clinical status, a specific clinical requirement (ie. HF medication titration, testing), or a deterioration in health status.

Sample

The sample was 110 selected HF patients who were enrolled in the HFC. The total patient enrollment in the HFC was approximately 1000 patients at the

time of health record review. HFC patients were identified per HFC list produced by the clinic manager with assistance from the HFC information system designate. Three hundred and thirty-eight patients were identified as attending the HFC for a minimum of 3 years, from which 110 patients had HFC visits within the 3 designated study time intervals (baseline, 18 months, 36 months). These intervals were chosen to provide a temporal prospective for data analysis.

The study inclusion criteria were:

1) confirmed HF diagnosis
2) enrolled in the HFC for a minimum of 3 years
3) NYHA FC 1 to 4
4) HFC visits falling within 3 time intervals over 3 years (baseline, 18 months, 36 months)

These criteria were chosen to maximize the variability of the patient sample, as well as facilitate consistent examination of the study variables over time. Patients who had died or dropped out of the HFC program during this period were excluded, due to unavailability of HFC health records.

Data Collection

Patient HFC health record data. Data from December 31, 2008 to December 31, 2011 were obtained from the patient's HFC health record. Data were collected at the HFC site by the investigator. Variables collected included:

- Demographic Indicators (baseline):
    - Age (Years)*
    - Sex (Male, Female)*
    - Marital status (Married, Single, Widow, Partner)
    - Time enrolled in HFC (Months)
    - HF clinic physician

- Mortality (dead/alive)

- Clinical Health Status Indicators (baseline, 18 months, 36 months):
  - Comorbidities (DM, COPD, atrial fibrillation)
  - HF etiology (ischemic yes/no)*
  - HF etiology if non-ischemic (idiopathic, post-partum, myocarditis)
  - Device type (ICD, CRT, ICD/CRT, none)*
  - Left ventricular ejection fraction-EF (%)*
  - New York Heart Association Functional Class-NYHA FC (1 to 4)*
  - Weight (Kg)*
  - Systolic blood pressure-SBP (mm/Hg)*
  - Heart rate (bpm)*
  - QRS (>120 yes/no)*
  - Lab values (serum hemoglobin [g/L]*, lymphocytes [%]*, uric acid [mmol/L]*, total cholesterol [mmol/L]*, sodium [mmol/L]*, creatinine [µmol/L], potassium [mmol/L] , MDRD eGFR [ml/min])
  - Medications (yes/no)*: Ace inhibitor (ACEI), Beta blocker (BB), Angiotensin receptor blocker (ARB), Statin, Allopurinol, Aldosterone antagonist
  - Medications (yes/no, dosage)*: Furosemide, Metolazone, Hydrochlorothiazide (HCTZ)
  - Seattle Heart HF Model (SHFM) score (-1 to 4) (Levy et al., 2006)
- HFC Recall Visit Frequency (18 months, 36 months):
  - Number of HFC recall visits
- Hospital Admissions (18 months, 36 months):
  - Number of All Cause hospital admissions
  - Number of HF hospital admissions

- Number of CV hospital admissions
- Number of Other hospital admissions

Variables making up the SHFM score for each patient (noted by * in variable list) were converted to case numbered (de-identified) data, encrypted, and sent to Dr. Levy at the University of Washington, Seattle, to compute the score. Dr. Levy consented to compute the SHFM score, as the Web based calculator only allows for calculation of estimated survival. Some of the laboratory values were missing from patient health records as tracked over 3 points in time (lymph %, uric acid, total cholesterol, sodium, and hemoglobin). These values were imputed (using each patient's available adjacent values, the average cohort value, or predicted value based on other variables for each patient) within the excel spreadsheet by Dr Levy.

Data were abstracted from patient health records to a case report form. Data at baseline, 18 months and 36 months were collected within a 2 month window on either side of the designated time intervals. Collection was done over a 3 week consecutive period, representing a one time acquisition of pertinent data from the patient health record. HFC health records were pulled and secured in a mutually agreed upon, designated area within the HFC nursing office by the investigator in batches for each data collection day. Health records were kept within this area while in use, and returned to the HFC health record area nightly. HFC staff had full access to the health records when required for patient care. Investigator presence in the HFC nursing office ensured a minimum of inconvenience for HFC staff, as well as an opportunity to acquire any data potentially missing from the health record. To ensure study rigor, data collection was done by the investigator who is knowledgeable in HF, thus increasing the consistency and accuracy of recorded information. Every tenth record was

audited for accuracy by the investigator, with 2 errors corrected prior to data analysis.

Patient hospitalization data. The Alberta Health Services (AHS) Data Integration and Measurement Reporting (DIMR) repository was accessed via an online application process to access All Cause, HF, CV, and Other hospital admission data for the specified study time periods. Once secured, these data were merged with patient HFC health record data.

The DIMR online process is detailed at:

http://insite.albertahealthservices.ca/1766.asp.

The DIMR online request tool is found at:

http://dimr1.albertahealthservices.ca:8080/ahs/auth/login?targetUri=%2F .

Data Analysis

Descriptive statistics were utilized to assess data patterns, describe the sample, clinical variables, as well as frequency of HF recall visits and hospital admission rates. To examine change over time for clinical and physiological status indicators, one-way repeated measures ANOVA was used; for HFC visits and hospitalizations, paired t-tests were used. Change scores were also calculated for NYHA FC and SHFM scores (the difference between scores from baseline to 18 months, and from 18 months to 36 months), to reflect change in patient clinical status over each period. Univariate analysis (Pearson's r) was used to determine significant associations between variables ($p \leq 0.05$). Significant variables were then entered into multivariate regression models to determine predictors of frequency of HFC recall visits and hospital admission rates.

Ethical Considerations

Ethical approval was obtained from the Health Research Ethics Board (HREB), University of Alberta. To ensure appropriate access to individual patient records, permission to access the HFC health records was obtained from the Director and local administrators of the HFC. AHS data was accessed and reported in accordance with the process outlined above. To ensure patient confidentially, all data were collected in accordance with institutional privacy policies. Patient names and hospital identification numbers were kept secure in a password protected master excel data sheet to minimize exposure of identifying patient information. Variables required to compute the SHFM scores were sent de-identified and encrypted to Dr. Levy, University of Washington.

CHAPTER FOUR

Results

Characteristics of the Patients

Demographic parameters. The HFC sample included 110 patients whose age ranged from 28 to 97 years, with a mean of 73.24 ±13.33 years. Seventy-five percent of the patients were over 65 years of age; 55% were over 75 years; with only 5.5% being <50 years of age. Males comprised 68.8% of the sample. The majority of the patients were married (66.4%), with 70.9% of patient health records having documented presence of "live in" support. The patients had attended the HFC from 3 to 20 years, with an average of 6.4 ±3.53 years. Patients were distributed evenly amongst 6 of the 7 HFC physicians, with those physicians following 15-21% of the patients (one physician followed 5%). Ischemia was the dominant HF etiology, comprising 53.6% of the sample (see Table 1).

Comorbidities. Of the 110 patients reviewed at baseline, 27.3% had none of the 3 comorbidities tracked, which were Type II Diabetes Mellitus (DM II), chronic obstructive pulmonary disease (COPD), and Atrial Fibrillation (AF). Thirty-one percent of the patients had DM II, 48.2% had AF, and 9.1% had COPD at baseline. Half of the HF patients had one co-morbidity; 19.0% had 2, and 4.0% of the HF patients had all 3 co-morbidities. The co-morbidities did not vary widely over 3 years. At 36 months, 2 additional patients had been diagnosed with DM II, 1 patient with AF, and 2 patients with COPD (see Table 2)

Table 1. PATIENT CHARACTERISTICS ***N=110***

Characteristics	Mean ±SD	Median	Number	(%)
Age (years)	73.24 ±13.33	76.5		
Sex				
Male			75	(68.8)
Female			35	(31.8)
Support				
Live in support			78	(70.9)
No live in support			32	(29.1)
Years in HFC* (Range 2.5-20.4)	6.4 ± 3.53	5.25		
HF Etiology				
Ischemic			59	(53.6)
Non ischemic			51	(46.4)
HFC Physician				
A			21	(19.1)
B			20	(18.2)
C			17	(15.5)
D			16	(14.5)
E			16	(14.5)
F			15	(13.5)
G			5	(4.5)

**HFC= Heart Function Clinic*

Devices. The majority of patients (74.5%) did not have any type of device at baseline. Over 36 months, this further decreased to 64.5%. Thirty-six percent of the patients at 36 months had an internal cardiac defibrillator (ICD), a cardiac re-synchronization pacemaker (CRT), or a combination unit (ICD/CRT) in situ (see Table 2).

Table 2. PATIENT COMORBIDITIES* ***N=110***

Co-morbidity	Baseline Number (%)	18 Months Number (%)	36 Months Number (%)
DM II	34 (30.9)	34 (30.9)	36 (32.7)
AF	53 (48.2)	53 (48.2)	54 (49.1)
COPD	10 (9.1)	11 (10.0)	12 (10.9)
HF + 1 co-morbid**	55 (50.0)	54 (49.0)	52 (47.2)
HF + 2 co-morbid**	21 (19.0)	22 (19.9)	25 (22.7)
HF + 3 co-morbid**	4 (3.6)	4 (3.6)	4 (3.6)
None of above***	30 (27.3)	30 (27.3)	29 (25.3)
Devices implanted			
ICD	13 (11.8)	16 (14.5)	16 (14.5)
CRT	5 (4.5)	6 (5.5)	5 (4.5)
ICD/CRT	10 (9.1)	14 (12.7)	18 (16.4)
None	82 (74.5)	74 (67.3)	71 (64.5)

DM II= Type 2 Diabetes; AF= Atrial Fibrillation; COPD= Chronic Obstructive Pulmonary Disease

**Co-morbidities included in chart review were restricted to DM II, AF, & COPD*

***HF + co-morbid: Patient had heart failure plus 1, 2, or all 3 co-morbid conditions included*

****None of above: Patient had no documented DM II, A-Fib, or COPD*

ICD: Internal Cardiac Defibrillator; CRT: Cardiac Resynchronization Therapy

ICD/CRT: Combination device

Physiological parameters. The weight of the patients averaged 86.4 ±20.9 kg at baseline, ranging from 48.7 to179.5 kg. Although the average weight for this cohort did not vary significantly (*F*= 2.73, *p*= *.083*) over the 3 points in time observed, the upper weight range was 225.6 kg and 240.5 kg at 18 and 36 months, respectively. This is likely due to one patient whose weight increased 61.0 kg over 3 years. Heart rate (HR) averaged 69.1 ±12.76 bpm at baseline, with no significant variation (*F*= 1.02, *p*= *.356*) over the 3 year period. Systolic and diastolic blood pressures averaged 120.6 ±19.23 mmHg (Md= 120 mmHg) and 69.6 ±10.53 mmHg (Md= 70 mmHg), respectively. Mean arterial pressure (MAP) for this cohort averaged 87 ±11.91 mmHg (Md= 86 mmHg). Across the 3 year period, there was a small but significant change in SBP (*F*= 2.96, *p*= *.054*), DBP (*F*= 6.02, *p*= *.003*), and MAP (*F*= 5.67, *p*= *.004*). Sixty-one percent of the patients reviewed had a QRS width that was at or under 120 milliseconds (ms) at baseline, with no significant variation over 3 years (*F*= 1.00, *p*= *.370*) (see Table 3).

Clinical parameters. EF was widely distributed in this cohort from under 10% to over 50%, with 82.1% of patients showing an EF less than 50%, and 38.7% with an EF less than 30% at baseline. Nineteen percent of patients at baseline showed HF with preserved EF (> 50%). The median EF was 30-35%. Over 3 points in time, the EF did vary significantly (*F*= 6.64, *p*= *.002*), with a modest increase to the median EF to 35-40% at 3 years. The NYHA FC scores showed the majority of patients to be in NYHA FC 1 or 2 (79.1%) at baseline, and only 1 patient (0.9%) being in NYHA FC 4 at 3 years (none at baseline). Both median and mode reveal a NYHA FC of 2 across the 36 month period. Twenty-one percent of the cohort scored NYHA FC 3 at baseline, with a significant increase within that scoring category to 32.7% at 36 months (*F*= 5.32,

Table 3. PATIENT PHYSIOLOGICAL PARAMETERS ***N=110***

Physiological Parameters	Baseline	18 Months	36 Months	*p value*
Weight (kg)**				
M±SD	86 ±20.9	88 ±23.34	88 ±24.9*	*.083*
Median	84.0	85.4	85.4	
Range	48.7-179.5	49.1-225.6	45.0-240.5	
HR (bpm)*				
M±SD	69 ±12.76*	67 ±12.84	68 ±10.64	*.356*
Median	66	64	67	
Range	47-110	47-104	46-100	
SBP (mmHg)				
M±SD	121 ±19.23	118 ±18.24	116 ±19.44	***.054***
Median	120	116	112	
Range	80-182	72-170	80-174	
DBP (mmHg)				
M±SD	70 ±10.53	66 ±10.03	66 ±10.62	***.003***
Median	70	66	64	
Range	33-100	50-96	46-100	
MAP (mmHg)				
M±SD	87 ±11.91	84 ±10.77	83 ±11.65	***.004***
Median	86	82	83	
Range	49-123	60-113	59-120	
QRS (ms)				
number (%)				
>120	42 (38.2%)	43 (39.1)	45 (40.9%)	.370
≤120	68 (61.8%)	67 (60.9%)	65 (59.1%)	

HR= Heart Rate; SBP= Systolic Blood Pressure; DBP= Diastolic Blood Pressure
MAP= mean arterial pressure; QRS= QRS interval
**N=109 for HR @ baseline*
***N=109 for weight @ 36 months*

Table 4. PATIENT CLINICAL PARAMETERS

Clinical Parameters	Baseline N=110 Number (%)	18 Months N=110 Number (%)	36 Months N=110 Number (%)	*p value*
NYHA FC				
1	24 (21.8)	15 (13.6)	18 (16.4)	
2	63 (57.3)	69 (62.7)	55 (50.0)	
3	23 (20.9)	26 (23.6)	36 (32.7)	
4	0 (0)	0 (0)	1 (0.9)	***.006***
Md/Mode	2/2	2/2	2/2	
SHFM Score				
-1	23 (20.9)	16 (14.5)	16 (14.5)	
0	57 (51.8)	59 (53.6)	40 (36.4)	
1	26 (23.6)	26 (23.6)	47 (42.7)	
2	3 (2.7)	7 (6.4)	5 (4.5)	
3	0 (0)	2 (1.8)	1 (0.9)	
4	1 (0.9)	0 (0)	1 (0.9)	
M±SD	0.12±0.832	0.27±0.856	0.42±0.903	***.000***
Md/Mode	0.00/0.00	0.00/0.00	0.00/1.00	
EF (%)*	**N=106**	**N=110**	**N=110**	
<10	1 (0.9)	0 (0)	0 (0)	
10-15	6 (5.7)	5 (4.5)	6 (5.5)	
15-20	15 (14.2)	9 (8.2)	9 (8.2)	
20-25	10 (9.4)	10 (9.1)	11 (10.0)	
25-30	9 (8.5)	14 (12.7)	8 (7.3)	
30-35	14 (13.2)	15 (13.6)	19 (17.3)	
35-40	11 (10.4)	8 (7.3)	9 (8.2)	
40-45	16 (15.1)	10 (9.1)	9 (8.2)	
45-50	5 (4.7)	16 (14.5)	11 (10.0)	
>50	19 (17.3)	23 (20.9)	28 (25.5)	***.002***
Md/Mode	30-35/>50	35-40/>50	35-40/>50	

NYHA FC= New York Heart Association Functional Class (1 best → 4 worst)
SHFM score= Seattle Heart Failure Model Score (-1 best → 4 worst)
EF= Left ventricular ejection fraction
**The ejection fraction portion of the table uses discrete categories-where the occasional value fit 2 categories, it was assigned to the lower one (ie. 15%--coded 10-15%)*

p= *.006*). The Seattle Heart Failure Model (SHFM) scores showed a similar trend with 96.4% of the patients scoring within the "less at risk" categories from -1 to 1 at baseline, with a modal score of 0. At 3 years, 93.6% of the cohort were at -1 to 1, with a modal score of 1, for a small but significant increase in the SHFM scores over this period (*F*= 11.00, *p*= *.000*) (see Table 4).

Laboratory parameters. Sodium, potassium, and hemoglobin values all showed little fluctuation over time, with medians of 140.0 mmol/L, 4.5 mmol/L, and 136 to 133 g/L, respectively. Creatinine values for this cohort varied widely from 42 µmol/L to 514 µmol/L, however the median values ranged from 101.5 µmol/L to 111.5 µmol/L over this 3 year period. Estimated glomerular filtration rate (eGFR) ranged from 10% to 148%, with a median eGFR 61.5% to 54.0% from baseline to 36 months (see Table 5). Missing laboratory values imputed for SHFM score tabulation (lymph %, uric acid, total cholesterol) were only analyzed within the SHFM score.

HFC Visit Frequency

This cohort of 110 patients was seen in the HFC from 4 to 19 times over the course of 36 months. The majority of patients (75%) had 5 to 9 visits for this period, while only 4 patients had more than 12 visits. The average total number of visits (0-36 months) to the HFC was 8.2 ±2.85 (Md= 8 HFC visits). When contrasting the 0-18 month and 18-36 month periods, HFC visits significantly decreased from 4.22 ± 1.77 to 3.98 ±1.48 (t= 2.176, *p*= *.032*). Only 4.5% and 6.4% patients were seen in the HFC over 6 times in the 0-18 month and 18-36 months periods, respectively (see Table 6).

Table 5. PATIENT LABORATORY PARAMETERS

Laboratory Parameters*	Baseline	18 Months	36 Months
Sodium (mmol/L)	***N=110***	***N=110***	***N=110***
M±SD	139.72±2.9	139.06±2.44	138.95±2.89
Median	140.00	139.00	139.00
Range	128-149	130-144	125-145
Potassium (mmol/L)	***N=105***	***N=106***	***N=99***
M±SD	4.53±0.42	4.55±0.44	4.47±0.41
Median	4.50	4.60	4.50
Range	3.7-6.1	3.4-6.5	3.0-5.2
Creatinine (umol/L)	***N=110***	***N=106***	***N=100***
M±SD	108.51±37.60	118.52±49.28	125.83±68.91
Median	101.50	111.50	107.50
Range	61-306	42-398	52-514
eGFR (MDRD) (%)	***N=110***	***N=106***	***N=100***
M±SD	63.27±21.54	58.36±21.54	58.03±24.40
Median	61.50	56.00	54.00
Range	18-121	14-120	10-148
Hemoglobin (g/L)	***N=107***	***N=107***	***N=107***
M±SD	133.66±21.12	134.28±17.99	132.49±18.93
Median	136.00	135.00	133.00
Range	84-184	96-184	91-184
Lymph (%)	***N=110***	***N=110***	***N=110***
M±SD	24.27±3.09	23.83±3.32	23.34±3.29
Median	24.30	23.80	23.15
Range	9.5-31.2	9.1-31.0	14.0-30.9
Uric Acid (umol/L)	***N=110***	***N=110***	***N=110***
M±SD	7.31±0.99	7.36±1.02	7.47±1.08
Median	7.40	7.35	7.60
Range	4.8-9.8	5.2-10.3	5.0-9.9
Tot Chol (mmol/L)	***N=98***	***N=100***	***N=101***
M±SD	4.05±0.97	4.05±1.00	3.98±1.00
Median	3.90	3.88	3.76
Range	2.04-6.74	2.34-7.58	2.40-7.46

eGFR (MDRD)= estimated GFR calculated with patient age, gender, serum creatinine & ethnicity
Lymph:percentage lymphocytes
Tot Chol= total cholesterol
** Missing values for Sodium, Hemoglobin, Lymph, Uric Acid & Total Cholesterol imputed per SHFM scoring table via Dr Levy where program able to calculate them*

Table 6. HFC VISIT FREQUENCY ***N=110***

HFC visits	0-36 Months Number (%)	0-18 Months Number (%)	18-36 Months Number (%)	*p value*
2	0 (0)	11 (10.0)	14 (12.7)	
3	0 (0)	27 (24.5)	35 (31.8)	
4	3 (2.7)	32 (29.1)	33 (30.0)	
5	12 (10.9)	22 (20.0)	15 (13.6)	
6	11 (10.0)	13 (11.8)	6 (5.5)	
7	22 (20.0)	1 (0.9)	5 (4.5)	
8	21 (19.3)	1 (0.9)	2 (1.8)	
9	17 (15.5)	1 (0.9)	0 (0)	
10	7 (6.4)	1 (0.9)	0 (0)	
11	5 (4.5)	0 (0)	0 (0)	
12	7 (6.4)	1 (0.9)	0 (0)	
13+*	4 (3.6)	0 (0)	0 (0)	
M±SD	8.20±2.85	4.22±1.77	3.98±1.48	
Md/Mode	8/7	4/4	4/3	
Range	4-19*	2-12	2-8	***.032***

**4 patients had over 12 total HFC visits in 36 months (1-13, 1-14, 1-17, 1-19)*

Factors Associated with HFC Visits

Univariate analysis revealed that age, gender, live in support status, years in HFC, and HFC physician were not correlated with the total number of HFC visits at 0-18 months, or at 18-36 months. Baseline comorbidities (DM II, COPD, and AF), weight, HR, BP, MAP, and QRS at baseline, 18 months, and 36 months were also not associated with the number of HFC visits. Baseline creatinine showed a small correlation to total HFC visits (r= .227, *p= .017*). Amongst the clinical parameters, only baseline NYHA FC was significantly correlated to total HFC visits (r= .223, *p= .019*) and to HFC visits at 0-18 months (r= .276, *p= .003*).

SHFM scores at baseline showed a small correlation with HFC visits at 0-18 months (r= .325, *p= .001)*, 18-36 months (r= .221, *p= .020)*, and total HFC visits (r= .332; *p= .000*). SHFM scores at 0-18 months also were correlated with HFC visits at 18-36 months (r= .246, *p= .009*) and 0-36 months (r= .323, *p= .001*). Total HFC visits had the strongest correlation to total HF hospital admissions (r= .480, *p= .000*). HFC visits during 0-18 months showed a significant relationship to HF admissions at both 0-18 months (r= .442, *p= .000*) and 0-36 months (r= .357, *p= .000*). Finally, HFC visits during 18-36 months were correlated with HF admissions at 18-36 months (r= .364, *p= .000*) and total HF admissions (r= .454, *p= .000*).

Hierarchical multiple regression was then used to identify predictors of total HFC visits from 18-36 months (see Table 7). All Cause hospital admissions from 0-18 months explained 33.4% of the variance in HFC visits from 18-36 months [*F*(1, 108)=13.535, *p= .000*], being the strongest predictor. Baseline SHFM score, plus the SHFM score for 0-18 months, then baseline NYHA FC and NYHA FC change scores over 0-18 months were added, followed by years in HFC, but were not significant predictors of HFC visits from 18-36 months. In the final model, HFC visits at 0-18 months added to the All Cause hospital admissions (0-18 months) explained a total variance of 47.4% [*F*(7, 102)=4.212, *p= .000*].

In an additional hierarchical multiple regression conducted, HF, CV, and Other hospital admissions were explored as predictors (see Table 8). HF hospital admissions from 0-18 months explained 29% of the variance in HFC visits from18-36 months [*F*(1, 108)= 9.924, *p= .002*]. CV hospital admissions from 0-18 months, as well as HFC visits from 0-18 months remained significant

Table 7. PREDICTORS OF HFC VISITS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			3.617	.143		25.224	.000
	AC* admissions 0-18	**.334**	**.111**	**.511**	**.139**	**.334**	**3.679**	**.000**
2	Constant			2.865	.368		7.792	.000
	AC admissions 0-18	**.390**	**.041**	**.460**	**.140**	**.300**	**3.291**	**.001**
	SHFM score baseline			**.348**	**.161**	**.211**	**2.164**	**.033**
	SHFM ∆ score 0-18			-.272	.201	-.129	-1.349	.180
3	Constant			2.949	.470		6.274	.000
	AC admissions 0-18	**.407**	**.014**	**.466**	**.140**	**.304**	**3.328**	**.001**
	SHFM score baseline			.414	.210	.251	1.970	.051
	SHFM ∆ score 0-18			-.199	.230	-.095	-.868	.387
	NYHA FC baseline			-.121	.288	-.058	-.422	.674
	NYHA ∆ FC 0-18			-.236	.301	-.094	-.784	.435
4	Constant			2.442	.537		4.543	.000
	AC admissions 0-18	**.474**	**.058**	**.314**	**.147**	**.205**	**2.130**	**.036**
	SHFM score baseline			.317	.208	.192	1.526	.130
	SHFM ∆ score 0-18			-.174	.224	-.083	-.776	.440
	NYHA FC baseline			-.198	.285	-.095	-.694	.489
	NYHA ∆ FC 0-18			-.186	.295	-.074	-.630	.530
	HFC visits 0-18			**.233**	**.085**	**.277**	**2.752**	**.007**
	Years in HFC			-.005	.035	-.014	-.156	.877

1 Overall value of R^2 = .111, Adjusted R^2 = .103, F (1, 108) = 13.535, p= .000
2 Overall value of R^2 = .152, Adjusted R^2 = .128, F (3, 106) = 6.331, p= .001
3 Overall value of R^2 = .166, Adjusted R^2 = .126, F (5, 104) = 4.136, p= .002
4 Overall value of R^2 = .224, Adjusted R^2 = .171, F (7, 102) = 4.212, p= .000
**AC=All Cause*

predictors of HFC visits at 18-36 months explaining a total variance of 49.9% [*F*(9, 100)=3.682, *p= .001*].

Hospital Admissions

The number of hospitalizations for this cohort during 0-36 months was low for all admission categories reviewed. For All Cause admissions, 40% of the patients had no hospitalizations for this 3 year period, and 55% had between 1 and 3, with a range from 0 to 10 total All Cause hospitalizations. There was no significant increase in All Cause admissions between 0-18 and 18-36 months (t= -.950, *p= .344*). CV admissions ranged from 0 to 3 over 3 years, with most patients (94%) having 0 or 1 hospitalization. There was no significant difference in the number of CV hospitalizations between the 0-18 month and 18-36 month

Table 8. PREDICTORS OF HFC VISITS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			3.768	.131		28.785	.000
	HF admissions 0-18	**.290**	**.084**	**.832**	**.264**	**.290**	**3.150**	**.002**
2	Constant			3.593	.141		25.407	.000
	HF admissions 0-18	**.407**	**.082**	**.811**	**.256**	**.282**	**3.168**	**.002**
	CV admissions 0-18			**.865**	**.270**	**.285**	**3.210**	**.002**
	Other admissions 0-18			.104	.209	.044	.496	.621
3	Constant			2.876	.370		7.781	.000
	HF admissions 0-18	**.450**	**.037**	**.669**	**.262**	**.223**	**2.551**	**.012**
	CV admissions 0-18			**.883**	**.267**	**.291**	**3.302**	**.001**
	Other admissions 0-18			.090	.206	.039	.438	.662
	SHFM score baseline			**.326**	**.161**	**.197**	**2.027**	**.045**
	SHFM ∆ score 0-18			-.296	.199	-.141	-1.490	.139
4	Constant			2.929	.466		6.288	.000
	HF admissions 0-18	**.462**	**.011**	**.708**	**.265**	**.247**	**2.668**	**.009**
	CV admissions 0-18			**.846**	**.270**	**.279**	**3.132**	**.002**
	Other admissions 0-18			.095	.208	.041	.457	.648
	SHFM score baseline			.363	.210	.220	1.731	.087
	SHFM ∆ score 0-18			-.213	.229	-.101	-.932	.345
	NYHA FC baseline			-.074	.283	-.035	-.260	.796
	NYHA ∆ FC 0-18			-.245	.299	-.098	-.819	.415
5	Constant			2.460	.539		4.562	.000
	HF admissions 0-18	.499	.035	.463	.291	.161	1.589	.115
	CV admissions 0-18			**.677**	**.278**	**.223**	**2.431**	**.017**
	Other admissions 0-18			.082	.206	.035	.397	.692
	SHFM score baseline			.311	.209	.189	1.489	.140
	SHFM ∆ score 0-18			-.199	.226	-.095	-.880	.381
	NYHA FC baseline			-.160	.285	-.076	-.562	.576
	NYHA ∆ FC 0-18			-.182	.297	-.072	-.611	.543
	HFC visits 0-18			**.193**	**.089**	**.228**	**2.171**	**.032**
	Years in HFC			.002	.035	.005	.059	.953

1 Overall value of R^2 = .084, Adjusted R^2 = .076, F (1, 108) = 9.924, p= .002
2 Overall value of R^2 = .166, Adjusted R^2 = .142, F (3, 106) = 7.023, p= .000
3 Overall value of R^2 = .202, Adjusted R^2 = .164, F (5, 104) = 5.276, p= .000
4 Overall value of R^2 = .213, Adjusted R^2 = .160, F (7, 102) = 3.955, p= .001
5 Overall value of R^2 = .249, Adjusted R^2 = .181, F (9, 100) = 3.682, p= .001

periods (t= .315, *p= .735*). Eighty-five percent of the patients had no HF admissions over the 3 years, with 10% having 1 admission. Total HF admissions (0-36 months) ranged from 0 to 4 (M=0.24±0.65). There was no significant difference in the number of HF admissions from 0-18 months to 18-36 months (t= .601, *p= .549*). Other admissions ranged from 0 to 6 over the total 36

Table 9. HOSPITALIZATION RATES ***N=110***

Hospitalizations	0-36 Months Number (%)	0-18 Months Number (%)	18-36 Months Number (%)	*p value*
Heart Failure				
0	93 (84.5)	98 (89.1)	103 (93.6)	
1	11 (10.0)	11 (10.0)	4 (3.6)	
2	4 (3.6)	0 (0)	2 (1.8)	
3	1 (0.9)	0 (0)	1 (0.9)	
4	1 (0.9)	1 (0.9)	0 (0)	
M±SD	0.24±0.649	0.14±0.478	0.10±0.427	
Md/Mode	0/0	0/0	0/0	
Range	0-4	0-4	0-3	*.549*
Cardiovascular				
0	80 (72.7)	93 (84.5)	94 (85.5)	
1	23 (20.9)	14 (12.7)	14 (12.7)	
2	6 (5.5)	3 (2.7)	2 (1.8)	
3	1 (0.9)	0 (0)	0 (0)	
M±SD	0.35±0.627	0.18±0.453	0.16±0.418	
Md/Mode	0/0	0/0	0/0	
Range	0-3	0-2	0-2	*.735*
Other				
0	71 (64.5)	95 (86.4)	80 (72.7)	
1	26 (23.6)	10 (9.1)	22 (20.0)	
2	7 (6.4)	4 (3.6)	6 (5.5)	
3	4 (3.6)	0 (0)	1 (0.9)	
4	0 (0)	1 (0.9)	1 (0.9)	
5	1 (0.9)	0 (0)	0 (0)	
6	1 (0.9)	0 (0)	0 (0)	
M±SD	0.57±1.027	0.20±0.587	0.37±0.715	
Md/Mode	0/0	0/0	0/0	
Range	0-6	0-4	0-4	***.028***
All Cause				
0	44 (40.0)	73 (66.4)	69 (62.7)	
1	37 (33.6)	23 (20.9)	25 (22.7)	
2	16 (14.5)	11 (10.0)	9 (8.2)	
3	7 (6.4)	1 (0.9)	5 (4.5)	
4	2 (1.8)	1 (0.9)	1 (0.9)	
5	1 (0.9)	1 (0.9)	0 (0)	
6	0 (0)	0 (0)	0 (0)	
7	2 (1.8)	0 (0)	0 (0)	
8	0 (0)	0 (0)	1 (0.9)	
9	0 (0)	0 (0)	0 (0)	
10	1 (0.9)	0 (0)	0 (0)	
M±SD	1.15±1.581	0.52±0.896	0.63±1.139	
Md/Mode	0/0	0/0	0/0	
Range	0-10	0-5	0-8	*.344*

months, the majority of patients (64.5%) having none, with the remaining patients (34%) having between 1 and 3 admissions. Other hospitalizations had a significant increase in admissions (t= -2.233, *p= .028*) (see Table 9).

Factors Associated with Hospital Admissions

Factors associated with All Cause admissions. Demographical variables (age, gender, live in support status, years in HFC, and HFC physician), comorbid status (DM II, COPD, AF), physiological parameters (weight, HR, SBP, DBP, MAP, QRS width), and laboratory data (sodium, potassium, hemoglobin, creatinine, eGFR) were not found to be correlated to All Cause admissions over the 36 months in univariate analysis. Of the clinical parameters, baseline EF showed a small, inverse relationship to total All Cause admissions (r= -.196, *p=.044*). NYHA FC had no significant correlation to All Cause admissions. SHFM score at baseline was correlated to All Cause admissions at 0-18 months (r= .188, *p= .049*), as was the SHFM score at 36 months (r= .230, *p= .016*). Total HFC visits were significantly correlated to total All Cause admissions (r= .421, *p= .000*). Also, HFC visits at 0-18 months correlated to both 0-18 months (r= .409, *p= .000*) and total All Cause admissions (r= .285, *p= .003*). Lastly, HFC visits at 18-36 months showed significant correlation with All Cause admissions at 18-36 months (r= .336, *p= .000*) and total All Cause admissions (r= .431, *p= .000*).

Hierarchical multiple regression was then conducted for the dependent variable of All Cause hospital admissions during 18-36 months (see Table 10). The final model explained 35.8% of the total variance [*F*(7, 102)= 2.143, *p= .046*], with baseline SHFM and NYHA FC scores at baseline being the significant predictors of All Cause admissions over 18-36 months. HFC visits from 0-18 months, SHFM change score (0-18 months), NYHA FC change score (0-18

months), and years in HFC were not found to be independent predictors of All Cause hospital admissions from 18-36 months.

Factors associated with HF admissions. Univariate analysis of age, gender, live in support status, and HFC physician revealed no statistically significant correlations to HF admissions over 0-18 months, 18-36 months, or total admissions (0-36 months). Years in HFC did show a small, inverse relationship with total HF admissions (r=-.226, *p= .018*). Baseline comorbidities (DM II, COPD, and AF) were not correlated with HF admissions. No physiological parameters (weight, HR, SBP, DBP, MAP, and QRS width) were significantly related to HF admissions over any period of time. Creatinine showed a small correlation with total HF admissions (r= .199, *p= .037*), but sodium, potassium, hemoglobin, and eGFR (MDRD) did not. Amongst clinical parameters, EF at baseline, 18 months, and 36 months was not related to HF admissions. Baseline NYHA FC was significantly correlated to total HF admissions (r= .199, *p= .037*), however, NYHA FC at 18 and 36 months was not. SHFM score at baseline showed a small relationship to the total (r= .322, *p= .001*), 0-18 months (r= .259, *p= .006*), and 18-36 months (r= .199, *p= .037*) HF admissions. The SHFM scores at 18 months (r= .279, *p= .003*) and 36 months (r= .280, *p= .003*) also correlated to total HF admissions. Total HFC visits had the strongest correlation to total HF admissions (r= .480, *p= .000*).

Hierarchical multiple regression was then conducted to identify predictors of HF admissions from 18-36 months (see Table 11). In the final model, the baseline SHFM score remained the only independent predictor of HF admissions in the 18-36 month period, for a total variance explained of 26% [*F*(7, 102)= 1.055, *p= .398*].

Table 10. PREDICTORS OF ALL CAUSE ADMISSIONS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			.416	.304		1.369	.174
	HFC visits 0-18	.075	.006	.052	.067	.075	.777	.439
2	Constant			.218	.382		.570	.570
	HFC visits 0-18	.113	.007	.033	.072	.047	.460	.647
	SHFM score baseline			.124	.150	.091	.828	.410
	SHFM ∆ score 0-18			-.106	.181	-.061	-.586	.559
3	Constant			.874	.437		2.000	.048
	HFC visits 0-18	.298	.076	.058	.070	.083	.826	.411
	SHFM score baseline			**.456**	**.184**	**.333**	**2.475**	**.015**
	SHFM ∆ score 0-18			-.249	.199	-.143	-1.251	.214
	NYHA FC baseline			**-.729**	**.251**	**-.420**	**-2.906**	**.004**
	NYHA ∆ FC 0-18			.328	.261	.158	1.254	.213
4	Constant			1.052	.476		2.213	.029
	HFC visits 0-18	.311	.008	.051	.070	.073	.725	.470
	SHFM score baseline			**.441**	**.185**	**.322**	**2.378**	**.019**
	SHFM ∆ score 0-18			-.256	.200	-.147	-1.284	.202
	NYHA FC baseline			**-.695**	**.254**	**-.400**	**-2.736**	**.007**
	NYHA ∆ FC 0-18			.302	.263	.145	1.150	.253
	Years in HFC			.029	.031	-.091	-.952	.343
5	Constant			1.157	.473		2.447	.016
	HFC visits 0-18	.358	.031	-.001	.075	-.001	-.007	.994
	SHFM score baseline			**.433**	**.183**	**.316**	**2.366**	**.020**
	SHFM ∆ score 0-18			-.259	.197	-.148	-1.313	.192
	NYHA FC baseline			**-.711**	**.251**	**-.410**	**-2.834**	**.006**
	NYHA ∆ FC 0-18			.305	.260	.147	1.176	.242
	Years in HFC			-.024	.031	-.075	-.788	.433
	AC* admissions 0-18			.248	.130	.195	1.912	.059

1 Overall value of R^2 = .006, Adjusted R^2 = -.004, F (1, 108) = .604, p .439
2 Overall value of R^2 = .013, Adjusted R^2 = -.015, F (3, 106) = .459, p .712
3 Overall value of R^2 = .089, Adjusted R^2 = .045, F (5, 104) = 2.032, p .080
4 Overall value of R^2 = .097, Adjusted R^2 = .044, F (6, 103) = 1.843, p .098
5 Overall value of R^2 = .128, Adjusted R^2 = .068, F (7, 102) = 2.143, p .046
**AC=All Cause*

HFC visits from 0-18 months, SHFM change score over 0-18 months, NYHA FC at baseline, and NYHA FC change score over 0-18 months were not found to be predictors of HF admissions from 18-36 months.

Factors associated with CV admissions. Age, gender, live in support status, years in HFC, and HFC physician showed no significant univariate correlations with CV admissions over the total 36 months.

Table 11. PREDICTORS OF HF ADMISSIONS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			.049	.114		.428	.669
	HFC visits (0-18	.046	.002	.012	.025	.046	.480	.632
2	Constant			-.108	.141		-.767	.445
	HFC visits 0-18	.200	.038	-.006	.027	-.022	1.222	.825
	SHFM score baseline			.109	.055	.213	1.968	.052
	SHFM ∆ score 0-18			-.009	.103	-.009	-.091	.928
3	Constant			.009	.167		.057	.955
	HFC visits 0-18	.241	.018	-.002	.027	-.006	-.064	.949
	SHFM score baseline			**.162**	**.070**	**.316**	**2.307**	**.023**
	SHFM ∆ score 0-18			-.059	.076	-.091	-.780	.437
	NYHA FC baseline			-.121	.096	-.187	-1.268	.208
	NYHA ∆ FC 0-18			.124	.100	.159	1.242	.217
4	Constant			.047	.185		.256	.799
	HFC visits 0-18	.260	.009	.003	.029	.011	.098	.922
	SHFM score baseline			**.163**	**.072**	**.318**	**2.277**	**.025**
	SHFM ∆ score 0-18			-.068	.077	-.103	-.878	.382
	NYHA FC baseline			-.112	.097	-.173	-1.155	.251
	NYHA ∆ FC 0-18			.124	.102	.159	1.218	.226
	Years in HFC			-.011	.012	-.090	-.904	.368
	HF admissions 0-18			-.060	.099	-.067	-.603	.548

1 Overall value of R^2 = .002, Adjusted R^2 = -.007, F (1, 108) = .230, p= .632
2 Overall value of R^2 = .040, Adjusted R^2 = .013, F (3, 106) = 1.479, p= .225
3 Overall value of R^2 = .058, Adjusted R^2 = .013, F (5, 104) = 1.288, p= .275
4 Overall value of R^2 = .068, Adjusted R^2 = .004, F (7, 102) = 1.055, p= .398

Comorbidities (DM II, COPD, and AF), physiological parameters (weight, HR, SBP, DBP, MAP, and QRS width) also did not reveal any significant relationships to CV admissions. Laboratory values were also not related to CV admissions. Furthermore, clinical parameters (EF, NYHA FC, and SHFM scores), were not related to CV admissions over the 36 months. Total HFC visits showed a small correlation to total CV admissions (r= .250, *p= .009*). HFC visits from 0-18 months were correlated with CV admissions at 0-18 months (r= .257, *p= .007*), as were HFC visits at 18-36 months with total CV admissions (0-36 months) (r= .293, *p= .002*).

Table 12. PREDICTORS OF CV ADMISSIONS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			.238	.112	2.134	.035	
	HFC visits 0-18	.069	.005	-.018	.025	-.069	-.714	.477
2	Constant			.187	.140		1.342	.183
	HFC visits 0-18	.139	.015	-.025	.026	-.098	-.960	.339
	SHFM score baseline			.042	.055	.084	.767	.445
	SHFM Δ score 0-18			.043	.066	.067	.649	.518
3	Constant			.396	.161		2.460	.016
	HFC visits 0-18	.292	.066	-.017	.026	-.067	-.664	.508
	SHFM score baseline			**.151**	**.068**	**.301**	**2.230**	**.028**
	SHFM Δ score 0-18			.010	.073	.016	.140	.889
	NYHA FC baseline			**-.237**	**.092**	**-.372**	**-2.565**	**.012**
	NYHA Δ FC 0-18			.065	.096	.085	.677	.500
4	Constant			.411	.176		2.341	.021
	HFC visits 0-18	.293	.000	-.018	.026	-.069	-.680	.498
	SHFM score baseline			**.150**	**.068**	**.298**	**2.191**	**.031**
	SHFM Δ score 0-18			.010	.074	.015	.131	.896
	NYHA FC baseline			**-.234**	**.094**	**-.367**	**-2.493**	**.014**
	NYHA Δ FC 0-18			.063	.097	.082	.648	.519
	Years in HFC			-.003	.011	-.022	-.226	.822
5	Constant			.411	.176		2.328	.022
	HFC visits 0-18	.295	.001	-.020	.027	-.079	-.753	.453
	SHFM score baseline			**.151**	**.069**	**.301**	**2.199**	**.030**
	SHFM Δ score 0-18			.006	.075	.009	.077	.939
	NYHA FC baseline			**-.233**	**.094**	**-.366**	**-2.478**	**.015**
	NYHA Δ FC 0-18			.066	.098	.087	.678	.500
	Years in HFC			-.002	.011	-.020	-.206	.837
	CV admissions 0-18			.035	.092	.038	.378	.706

1 Overall value of R^2 = .005, Adjusted R^2 = -.005, F (1, 108) = .510, p= .477
2 Overall value of R^2 = .019, Adjusted R^2 = -.008, F (3, 106) = .697, p= .556
3 Overall value of R^2 = .085, Adjusted R^2 = .041, F (5, 104) = 1.943, p= .093
4 Overall value of R^2 = .086, Adjusted R^2 = .033, F (6, 103) = 1.613, p= .151
5 Overall value of R^2 = .087, Adjusted R^2 = .025, F (7, 102) = 1.391, p= .217

Hierarchical multiple regression was then conducted for predictors of CV hospital admissions (see Table 12). Baseline SHFM and NYHA FC scores remained the only significant predictors of CV admissions at 18-36 months in the final model for a total variance explained of 29.5% [*F*(7, 102)= 1.391, *p= .217*]. HFC visits from 0-18 months, SHFM and NYHA FC change scores over 0-18 months and CV admissions in the 0-18 month period were not found to be predictors of CV admissions from 18-36 months.

Factors associated with Other admissions. Subject demographics (age, gender, live in support status, years in HFC, and HFC physician) revealed no significant correlations to Other hospital admissions. Physiological parameters (weight, HR, SBP, MAP, QRS width), comorbidities (DM II, COPD, AF), and laboratory data (creatinine, eGFR), likewise revealed no univariate relationships. None of the clinical parameters (EF, NYHA FC, SHFM scores) showed any relationships to Other admissions over the 36 months. However, total HFC visits correlated with total Other admissions (r= .193, *p*= *.044*). HFC visits from 18-36 months were also related to "Other" admissions at both 18-36 months (r= .242, *p*= *.011*) and 0-36 months (r= .198, *p*= *.038*), respectively.

Hierarchical multiple regression was then explored to determine predictors of Other hospital admissions at 18-36 months (see Table 13). NYHA FC at baseline, and Other admissions at 0-18 months remained the significant predictors of Other admissions at 18-36 months, explaining a total variance of 39.9% [*F*(7, 102)= 2.762, *p*= *.011*].

Table 13. PREDICTORS OF OTHER ADMISSIONS (18-36 months) ***N=110***

Model	Predictor variable	*R*	$R^{2\Delta}$	b	***SE***	β	t	*p*
1	Constant			.129	.190		.681	.498
	HFC visits 0-18	.131	.017	.058	.042	.131	1.377	.171
2	Constant			.139	.237		.585	.560
	HFC visits 0-18	.191	.019	.064	.044	.146	1.440	.153
	SHFM score baseline			-.027	.093	-.032	-.292	.771
	SHFM Δ score 0-18			-.137	.112	-.125	-1.218	.226
3	Constant			.469	.274		1.710	.090
	HFC visits 0-18	.297	.052	.077	.044	.175	1.743	.084
	SHFM score baseline			.143	.116	.166	1.234	.220
	SHFM Δ score 0-18			-.200	.125	-.183	-1.600	.113
	NYHA FC baseline			**-.371**	**.158**	**-.341**	**-2.356**	**.020**
	NYHA Δ FC 0-18			.139	.164	.106	.846	.400
4	Constant			.574	.299		1.922	.057
	HFC visits 0-18	.309	.007	.073	.044	.166	1.643	.103
	SHFM score baseline			.134	.116	.155	1.148	.254
	SHFM Δ score 0-18			-.204	.125	-.187	-1.631	.106
	NYHA FC baseline			**-.351**	**.159**	**-.322**	**-2.200**	**.030**
	NYHA Δ FC 0-18			.124	.165	.095	.750	.455
	Years in HFC			-.017	.019	-.085	-.892	.378
5	Constant			.607	.290		2.096	.039
	HFC visits 0-18	.399	.064	.067	.043	.153	1.566	.120
	SHFM score baseline			.142	.113	.165	1.259	.211
	SHFM Δ score 0-18			-.204	.121	-.187	-1.683	.095
	NYHA FC baseline			**-.387**	**.155**	**-.356**	**-2.498**	**.014**
	NYHA Δ FC 0-18			.139	.160	.107	.869	.387
	Years in HFC			-.020	.019	-.097	-1.049	.297
	Other admissions 0-18			**.311**	**.111**	**.255**	**2.786**	**.006**

1 Overall value of R^2 = .017, Adjusted R^2 = .008, F (1, 108) = 1.897, p= .171
2 Overall value of R^2 = .036, Adjusted R^2 = .009, F (3, 106) = 1.335, p= .267
3 Overall value of R^2 = .088, Adjusted R^2 = .045, F (5, 104) = 2.017, p= .082
4 Overall value of R^2 = .095, Adjusted R^2 = .043, F (6, 103) = 1.810, p= .104
5 Overall value of R^2 = .159, Adjusted R^2 = .102, F (7, 102) = 2.762, p= .011

CHAPTER FIVE

Discussion

The purpose of this study was to examine a HFC visit recall frequency and hospital admission rates, as well as identify predictors of both HFC visit recall frequency and hospital admission rates. This retrospective cohort's demographic parameters reflected a mostly male, elderly cohort, with ischemic HF etiology for just over half of the patients, similar to prior studies reviewed. Studies that differed included Azad et al. (2008) who enrolled female patients exclusively, and Camponolla et al. (2002), whose mostly male patients' (84%) mean age was younger (56±10). Most of the patients in this study were long term patients (6.4±3.5 years), corresponding closely to the Schou et al. (2013) study, with all of the other RCTs HF Clinic patients being "new to clinic". Comorbidity burden for this study's cohort was comparable to the literature (where documented), with DM II rates of 31%, AF 48%, and COPD 10%, with only 4% of the patients having DM II, AF, and COPD. Other comorbidities were not documented in this study. Device status in this cohort reflects current rates of implantation in this tertiary center for long term, stable patients, but was largely unreported in prior studies.

Clinical parameters revealed a stable cohort with weight, HR, BP, MAP, and QRS width, showing minimal change over time. Median EF for this cohort was 30-35%, congruent with most studies reviewed, which improved slightly over 3 years to 35-40%. NYHA FC scores reflected a less symptomatic cohort, with the majority of patients (79%) in NYHA FC I or 2, and none in NYHA FC 4, similar to trials done by Azad et al. (2008), Capomolla et al. (2002), Schou et al. (2013), Feldmann et al. (2011), and Gustafsonn et al. (2009). Most studies showed the majority of patients to be in NYHA FC 2 or 3 (Agvall, Alehagen, & Dahlstrom,

2013; Atienza et al., 2004; Galatius, Gustafsson, Nielsen, Atar, & Hildebrandt, 2002; Gouya et al., 2011; Hershberger et al., 2005; Jaarsma et al., 2008; Jain et al., 2010; Kasper et al., 2002; Mejhert, Kahan, Persson, & Edner, 2004; Pugh, Havens, Xie, Robinson, & Blaha, 2001; Stewart et al., 2012), with a smaller number reporting a very symptomatic cohort, having NYHA FC 3 or 4 (Doughty et al., 2002; Ducharme, Doyon, White, Rouleau, & Brophy, 2005; Stromberg et al., 2003), or NYHA FC 4 exclusively (McDonald et al., 2002). Similarly, the SHFM scores for this study's cohort reflect a "less at risk" cohort, with almost all of the patients (96%) scoring -1 to 1, the majority of these patients had a score of 0 (1 patient scored a 4). SHFM scores are not documented in any of the prior studies reviewed.

HFC Visits

HFC frequency of visits in this cohort ranged from 4 to 19 visits over the 3 year period (all patients were seen ongoing at the HFC), with all visits appearing to be individualized to the patient's current condition (HF de-compensation, hospital discharge), and anticipated clinical support (HF medication titration, self-care teaching, device screening, diagnostic testing), as evidenced by the chart documentation provided at each HFC visit. These follow-up visit intervals were decided on a visit to visit basis by the HFC physicians, or via nurse led HFC office patient communication.

HFC visits were heterogeneous for this cohort, with a fairly uniform range of visit frequency (75% patients had 5 to 9 visits). Visits averaged 8 ±2.9 over the 3 year period, representing a visit roughly every 4.5 months, with ongoing follow-up (ie., patients are not discharged from this clinic). The literature reviewed had a wider range and heterogeneity in terms of recall frequency (where documented), with visits reported from twice weekly (Azad et al., 2008), weekly-

biweekly (Hershberger et al., 2005; Jain et al., 2010; Pugh et al., 2001), monthly-bimonthly (Ducharme et al., 2005; Jaarsma et al., 2008; Kasper et al., 2002), every 3-4 months (Atienza et al., 2004; Doughty et al., 2002), as well as 1-2 total visits (Agvall et al., 2013; Ledwidge et al., 2003; Mejhert et al., 2004), and "individual" or "as needed" (Capomolla et al., 2002; Gustafsson et al., 2009; McDonald et al., 2002; Stromberg et al., 2003). Wijeysundera et al. (2013) had 3 levels of follow-up, which fell under "multiple contacts" at the high end, and "single visit" at the low end. For the majority or studies reviewed, it was impossible to ascertain an accurate total number of visits per patient over the study duration which also ranged widely from 6 weeks (Azad et al., 2008) to 4 years (Wijeysundera et al., 2013), however, it does appear that the cohort in this study had relatively less frequent HFC visits over time than was noted in the literature.

Factors Influencing HFC Visit Frequency

When patient demographic and clinical effects on HFC visit frequency were analyzed, the number of all cause hospital admissions at 0-18 months was the main independent predictor. HFC visits at 0-18months also remained predictive of HFC visits in the latter time period. HF admissions did not predict HFC recall, perhaps due to the low number of admissions in the study time period. No demographic or clinical factors were significant predictors in this patient cohort, perhaps, given the small patient sample, and low level of change in clinical status over the time period.

There was no evidence in the literature that any demographic or clinical parameters have been noted to contribute to HF Clinic frequency of recall, despite the existence of well established indices of HF illness severity, such as EF and NYHA FC (Dickstein et al., 2008; Ross et al., 2008). It is implied in many

of the studies that “individual patient factors” or “symptom stability” drove frequency of recall, but no specific clinical indicators are identified (Hershberger et al., 2005; McDonald et al., 2002; Pugh et al., 2001; Stromberg et al., 2003). One RCT (Capomolla et al., 2002) suggested using specific clinical indices of HF related illness (a risk ratio score) to guide HF Clinic recall. However, in the present study, no association was found among the EF, NYHA FC score, or SHFM score to the number of HFC visits, nor were any demographic variables related to differences in HFC visit recall.

As All Cause hospital admissions are perhaps the strongest indicator of chronic illness severity, the study results are not unexpected, and may be the predominant driver of frequency of HFC recall. In the Heart Failure Society of America Consensus Statement (Hauptman et al., 2008), recent HF admissions, as well as multiple active co-morbidities (ie., renal failure) are identified in patients most likely to benefit from HF Clinic care.

Hospital Admissions

Hospital admission rates for this cohort were very low in every category, with All Cause admissions occurring most frequently, with just under half of the patients having 1 to 2 All Cause admissions, with a median of 0 admissions ($M=1.15\pm1.58$) over 3 years. All Cause admissions have been reported at 39% over 6 months (Ducharme et al., 2005), 63% over 1 year (Stromberg et al., 2003), 49% over 1 year (Agvall et al., 2013), 55% over 18 months (Jaarsma et al., 2008), 87% over 4 years (Wijeysundera et al., 2013), 55% over 2.5 years (Schou et al., 2013), 14% over 1 year (Capomolla et al., 2002), and lastly, 14% over 6 months (Jain et al., 2010). Studies that reported mean All Cause hospital admissions included $0.89\pm.98$ per 100 days (Stewart et al., 2012), and $0.35\pm.62$ per year (Hershberger et al., 2005). Doughty et al. (2002) reported an All Cause

admission rate of 1.37 per patient year, Pugh et al. (2001) found a rate of 0.15 All Cause admissions per month, and Mehjert et al. (2004) reported 4.4 All Cause admissions per patient over the 18 month study duration.

Eighty-four percent of this patient cohort had no HF admissions over the 3 year period, with a median admission rate of 0 (M=0.24±0.65) over 3 years, which is lower than found in the literature. HF admissions have been reported at a rate of 24% over 3 months (Ledwidge et al., 2003), 42% over 6 months (Kasper et al., 2002), 58.7% over 4 years (Wijeysundera et al., 2013), and 22% and 6% over 1 year for new and long term patients, respectively (Gouya et al., 2011). Studies reporting mean HF admission rates included 0.52±.76 per 100 days (Stewart et al., 2012), 0.48 over 6 months (Azad et al., 2008), and 0.18 over 1 year (Atienza et al., 2004). Galatious et al. (2002) reported 306 HF admissions for 283 patients over 2 years, while McDonald et al. (2002) showed one HF admission over 3 months for 51 patients. The results for this study likely reflect a less ill HF cohort.

Factors Influencing Hospital Admissions

In this retrospective cohort study of patients attending a HFC, the number of HFC visits over 3 years was not predictive of hospital admission rates in any category. On review of the literature to date, no studies have reported this relationship. Predicting hospital admissions with HFC visit frequency, and demographic and clinical factors revealed that the baseline SHFM score was predictive of all categories of hospital admissions except Other admissions. For HF admissions, it was the only significant predictor. In addition to the baseline SHFM score, the baseline NYHA FC score also contributed to risk of all cause, CV, and Other hospital admissions. In the case of Other admissions, baseline NYHA FC was the main predictor. Prior literature revealed NYHA FC deterioration as significant for HF admission risk (Dickstein et al., 2008;

Gustafsson et al., 2009). HF comorbidity burden was previously noted as a significant risk factor for All Cause hospitalization (Gustafsson & Arnold, 2004; Howlett et al., 2009; Ross et al., 2008), as were advanced age, weight, EF, BP, HR, and select laboratory values for HF admission (Giamouzis et al., 2011; Gustafsson & Arnold, 2004; Howlett et al., 2009). None of the above were found to be significant in this cohort, perhaps due to small sample size, and relative clinical stability of the cohort. Prior hospital admissions have also been cited as a risk factor for subsequent hospitalization (Gustafsson & Arnold, 2004), and in this study, Other admissions at 0-18 months did predict Other admissions in the second period (18-36 months).

The SHFM score, as a composite indicator of risk, has been shown to predict HF mortality (Levy et al., 2006), but has not been used to predict hospital admissions in any of the studies reviewed. The recent study by Li et al. (2013) found that higher SHFM scores reflect a higher level of illness in 5 domains of health utility, which could result in a higher risk of hospitalization. This study's results indicate it may be a more reliable predictor of hospital admissions than the NYHA FC score, even for this less symptomatic HF cohort. This novel finding is not surprising, given the nature of the variables that compute this composite score, such as age, HF etiology, EF, NYHA FC, HF medication status, and laboratory values, all of which have been found to be individual predictors of hospital admissions in prior studies. Taken together, these variables may provide a more salient picture of HF illness related risk across this heterogeneous patient population.

What is notable is that the baseline SHFM score did not predict HFC visit recall. As the SHFM scores were consistently low for this cohort, it may be that this group of patients at lower risk, were evaluated as less ill, based on individual

assessment of variables contained within the SHFM score as above. If the SHFM score has potential to identify patients at higher risk of hospital admission, it has the potential to be a powerful indicator of HF patients who stand to benefit from increased level of HF Clinic planned surveillance.

Study Limitations

This was a convenience sample from an established HFC. In this retrospective cohort study, there was no comparison group, with some limitations on data available in the health record review. The cohort was small, consisting of long-term patients who were clinically stable throughout the 3 year study period. Comorbidity tracking was not comprehensive, nor was there analysis of HF medication use. Low hospitalization rates, and little fluctuation in both clinical parameters, and HF symptom status, provided a limited opportunity to contrast patients at risk across the HF continuum in terms of HFC visits and hospitalization rates. HFC specific recall patterns were not analyzed in detail in terms of interval between clinic visits or timing around important transition periods, such as hospital discharge. Intensity and complexity of visits in this HFC cohort were not explored. Emergency room visits and contacts with Primary Care Providers were also not available. Finally, multicollinearity was a concern throughout the multivariate regression analysis, as many of the variables were redundant, or closely correlated (eg. NYHA FC, SHFM).

Implications

In the HF Clinic literature, RCTs dominated the landscape throughout the early 2000s, with mostly smaller selected patient groups, nurse led clinics, and a “one size fits all” philosophy applied to program structure and patient follow-up. Later studies provide a broader view of “real world” HF Clinic practice in larger, more typical HF patient populations in terms of clinical status and comorbidity

burden. An evolution of focus to 2014 brings an interest in exploring the intensity and complexity of HF Clinic programs (Riegel, Lee, & Sochalski, 2010), as well as the pattern and timing of patient contact around periods of known risk (Howlett et al., 2010). Frequency of HF Clinic visits across a varied patient population must be studied within this context to provide the answers HF clinicians require to effectively care for this patient population.

HFC visit recall frequency did not predict hospital admissions in this patient cohort, rather, the baseline SHFM score was the strongest predictor of hospitalization. Traditionally, the NYHA FC has been a recognized risk factor for hospitalization based on HF symptom status. If the SHFM score can accurately identify HF patients at higher risk for follow-up, it could potentially be utilized at key intervals to determine the individual "dose" (Riegel, Lee, & Sochalski, 2010) of HF Clinic surveillance required. Moreover, HF Clinic patients who are at lower risk via the SHFM score could be seen less frequently, or potentially be discharged from clinic, allowing increased access for a larger patient population. The SHFM score has additional potential as a tool for standardization of HF Clinic care. Used in tandem with a HF disease management scoring instrument, as developed by Riegel, Lee, and Sochalski (2010), it could serially evaluate effectiveness of care across HF Clinics within a more level field of comparison. Lastly, the vast majority of HF patients are not cared for by specialty HF Clinics, secondary to general resource allocation issues, or individual patient and physician factors. The SHFM score may be an effective tool for Primary Care Providers to identify patients at higher risk for follow-up, maximize evidence based therapies (NYHA FC, EF, HF medication and device status embedded in score tabulation), and recognize those patients who may benefit from referral to a HF Clinic.

Conclusion

This retrospective cohort study found no impact of HFC recall frequency on hospital admissions for HF patients. HFC visits in this patient cohort were not driven by the SHFM score, but rather by All Cause hospitalizations. Baseline SHFM scores were a significant predictor of hospitalization rates for this cohort of HF patients. For HF hospital admissions, it was the sole predictor. For All Cause and CV admissions, NYHA FC contributed to the risk, while for Other admissions, NYHA FC was the main predictor. Additional study is required to examine the relationship of SHFM scores with hospitalization rates on a larger scale (ie. large samples, multiple HF Clinic sites), with the potential to expand the use of this composite scoring tool to HF hospitalization risk stratification, and planning of a more individualized HF Clinic frequency of visit recall.

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