Multidisciplinary Group Clinic Appointments
The Self-Management and Care of Heart Failure (SMAC-HF) Trial

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Background—This trial tested the effects of multidisciplinary group clinic appointments on the primary outcome of time to first heart failure (HF) rehospitalization or death.

Methods and Results—HF patients (n=198) were randomly assigned to standard care or standard care plus multidisciplinary group clinics. The group intervention consisted of 4 weekly clinic appointments and 1 booster clinic at month 6, where multidisciplinary professionals engaged patients in HF self-management skills. Data were collected prospectively for 12 months beginning after completion of the first 4 group clinic appointments (2 months post randomization). The intervention was associated with greater adherence to recommended vasodilators (P=0.04). The primary outcome (first HF-related hospitalization or death) was experienced by 22 (24%) in the intervention group and 30 (28%) in standard care. The total HF-related hospitalizations, including repeat hospitalizations after the first time, were 28 in the intervention group and 45 among those receiving standard care. The effects of treatment on rehospitalization varied significantly over time. From 2 to 7 months post randomization, there was a significantly longer hospitalization-free time in the intervention group (Cox proportional hazard ratio=0.45 [95% confidence interval, 0.21–0.98; P=0.04]. No significant difference between groups was found from month 8 to 12 (hazard ratio=1.7; 95% confidence interval, 0.7–4.1).

Conclusions—Multidisciplinary group clinic appointments were associated with greater adherence to selected HF medications and longer hospitalization-free survival during the time that the intervention was underway. Larger studies will be needed to confirm the benefits seen in this trial and identify methods to sustain these benefits.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00439842.

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Key Words: clinical trial ■ heart failure ■ survival analysis

Heart Failure (HF) affects ≈5 million Americans and is expected to have a 23% increase in prevalence by 2030.1 HF is the most frequent cause for hospitalization among Medicare beneficiaries. Accordingly, Medicare has adopted new reimbursement policies with penalties to hospitals for higher readmission rates after a HF discharge.2 This has created a pressing need to develop better strategies for minimizing rehospitalizations. Indeed, current guidelines emphasize the importance of implementing systems to coordinate and deliver effective care.3 Yet, recent meta-analyses and clinical management reviews have found that most HF interventions are resource intensive, difficult to replicate, and do not improve the high rate of repeat hospitalizations.4,5 One strategy that still holds promise for reducing HF readmissions is to improve patients’ abilities to self-manage their disease. This requires that HF patients learn how to use specific HF home-care skills and implement complex daily self-care tasks.4 Notably, patients are often discharged from the hospital with unresolved HF symptoms and with few HF self-management skills.7 In fact, many HF patients lack the basic knowledge needed for appropriate dietary management,8 are unsure of basic weight and fluid self-monitoring practices, and delay seeking treatment for HF symptoms, all of which can result in frequent rehospitalizations.9

Group clinic appointments, also known as shared medical appointments, can provide more extensive education than is usually offered...
in traditional office visits, can provide more face time with healthcare providers, and perhaps most importantly, can give patients the opportunity to identify self-management issues and engage in shared problem-solving with multidisciplinary professionals and fellow patients.\textsuperscript{11} For patients with diabetes mellitus and other chronic illnesses, group clinic appointments have been associated with better treatment adherence.\textsuperscript{12} However, the effect of group clinic appointments on HF clinical outcomes has rarely been studied in controlled trials.\textsuperscript{5} Two small pilot studies suggested that HF group appointments could improve HF knowledge, decrease HF rehospitalizations, and promote greater satisfaction with treatment.\textsuperscript{13,14}

To examine the effect of an efficient, standardized group clinic program in HF, we developed the Self-Management and Care of Heart Failure (SMAC-HF) program and prospectively tested its effect on HF-related rehospitalizations in a randomized controlled trial.

Methods

Between March 2007 and April 2011, we enrolled patients hospitalized for an exacerbation of HF into a randomized controlled clinical trial of multidisciplinary group clinic appointments. After giving written informed consent, patients were randomized to receive either standard care or the SMAC-HF group appointment intervention. Patients were prospectively followed for 12 months after randomization. The study was reviewed and approved by the Institutional Review Board of the University of Kansas Medical Center. In addition, the study progress was reviewed and approved annually by an external Data Safety and Monitoring Board comprised of a cardiologist, a statistician, and an Institutional Review Board representative.

Subjects

Hospitalized HF patients were prospectively identified by reviewing the daily admission records of all patients at a single academic medical center. Eligible patients had to have been hospitalized with New York Heart Association class III or IV HF, but were not required to have a reduced left ventricular ejection fraction (EF). Exclusion criteria were evidence of transient, reversible HF, a planned heart transplant, end-stage renal disease (creatinine $>4$ mg/dL), unresected malignancy or other terminal illness, or discharge to a nursing home, rehabilitation unit, or extended care facility. Patients were also excluded if they had a condition that would preclude them from engaging in the group clinic intervention, including blindness, deafness, dementia, cognitive deficiency, or could not write and speak in English.

Nurses who were trained on trial enrollment procedures, informed consent, and baseline data collection then enrolled patients during or within 2 weeks of their index hospitalization. Of the 774 patients identified with HF and meeting the criteria for enrollment, 198 (26\%) were enrolled in the study (Figure 1). The primary reasons for patients not enrolling in the study were either those patients were not interested or that study staff failed to reach the patient within 2 weeks of discharge.

Randomization

To form groups of patients for the clinic appointments in a timely fashion, blocks of patients were randomized rather than individual patients. Block sizes ranged from 4 to 8 participants. Depending on the rate of subject recruitment, it typically took $\leq 3$ weeks to form a group, randomize the group, and initiate the group visits. The initial group clinic schedule was a series of 4 weekly appointments; thus, the intervention clinics typically did not finish until 8 weeks post randomization. Thus, randomization plus 8 weeks (month 2) was the time prespecified to begin observation for HF-related end points. The same observation period was prespecified for both comparison groups.

After 4 to 8 participants had consented, that whole block of patients was randomly assigned to receive either the intervention or standard care. Randomization was blinded so that no patient or project staff was aware of the allocation until after that block of patients was randomized. We enrolled 32 blocks containing a total of 198 study subjects, of whom 106 (53\%) were in blocks that were randomized to standard care and 92 (47\%) were in blocks randomized to receive the SMAC-HF intervention.

Standard Care and Intervention Descriptions

Standard Care

Patients in both treatment arms received HF care from their existing treatment team both during and after hospitalization. This care typically included education from a discharge nurse that addressed the national HF core measures requirements, a postdischarge phone call from an NP within 3 to 7 days after discharge and a follow-up at outpatient MD clinic visit within 1 month of discharge, with many patients seen sooner depending on their clinical status. Patients’ HF-related medications were initiated or up-titrated per their provider based on clinical need. There were no differences in the percentage of patients seen by NP under the direction of a cardiologist versus an MD only between subjects in the intervention and control group ($\chi^2=1.25, P=0.32$).

SMAC-HF Intervention

The SMAC-HF intervention began with 4 weekly group visit appointments followed by a 5th booster appointment held 6 months after randomization. The first series of 4 weekly group clinic appointments was completed within 8 weeks after randomization. Transportation vouchers were provided for travel to each group clinic appointment. The patient-centered SMAC-HF intervention was based on empirically verified clinical management and pedagogical educational theory.\textsuperscript{13} The pedagogy approach used with patients was based on the American College of Physicians’ Family Home Care Management Guide\textsuperscript{8} and the Chronic Care Model, which emphasizes engaging

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{flowchart.png}
\caption{Flowchart of Self-Management and Care of Heart Failure enrollment, randomization, and follow-up to first heart failure (HF)-related rehospitalization or death.}
\end{figure}
patients in self-management partnerships with multiple professionals. Each group clinic visit included multidisciplinary health professionals: a nurse practitioner with extensive clinical experience in HF management, a mental health clinical nurse specialist, a social worker, and a diabetes. At the beginning of each group clinic appointment, the patients’ weight, vital signs, and HF symptoms were assessed, medications were reviewed, and depression screening conducted. Group appointment participants were shown how to complete daily self-monitoring/checklist diaries with spaces to daily record weight, fluid/sodium intake, physical activity, emotions and moods, and HF symptoms.

Once the assessments were completed at each clinic appointment, the patients and the multidisciplinary health professionals sat at a round table to view and then discuss that clinics short HF digital video disc (DVD). This 5-part DVD series was produced under a National Institute of Health grant (SBIR-IR43AG1700701) and illustrated HF patients using the national American College of Cardiology Foundation/American Heart Association guideline–based HF self-management strategies. A different DVD was shown at each group appointment, with each DVD focusing on a different self-management topic. Control group participants who received standard care also received a copy of the HF DVD series. Thus, our short DVDs were used to standardize the educational information across groups, so that the primary difference between the study arms was exposure to group clinics.

At the end of each group clinic discussion, a 1-page, HF self-management summary was completed. This form provided patients with a personal report of their trends in weight, blood pressure, heart rate, and depression scores. In addition, on this form, patients wrote questions they wanted to ask and discuss with their healthcare provider. Also the patient self-management summary indicated whether the patients were receiving a β blocker, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, or an aldosterone receptor antagonist. (For black patients, the combination of hydralazine and a nitrate was considered equivalent to use of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker.) Although each group visit was supervised by a nurse practitioner, this nurse practitioner did not directly alter the clinical treatment plan during the group visit, but rather worked with the patient to adhere to their prescribed regimen, to identify issues to address with their primary providers and for early referral of HF exacerbation symptoms to physicians.

Data Collection and Follow-Up
Hospitals that occurred post randomization were identified by querying hospital electronic medical records at the academic medical center. Copies of medical records were also requested for any hospitalizations that data collection uncovered or subjects reported occurring outside of the medical center. The control patients had follow-up data collection on the same time schedule as the intervention group participants. Nurses, blinded to group assignment, conducted telephone follow-up quarterly on all participants to ensure that all rehospitalizations were identified. An experienced physician, blinded to treatment arm assignment, reviewed these medical records using a priori determined adjudication rules and classified each hospitalization as being HF-related or not related to HF. Comparable methods were used to identify deaths and adjudicate the cause of death from obituary/death and medical records.

Measurements
The a priori primary outcome was time, in days, to cardiovascular-related death or the first HF-related hospitalization with the start time lagged to commence 8 weeks post randomization. Measures collected at baseline included demographic variables (age and sex); measures of HF severity (including left-ventricular function and length of HF diagnosis); HF functional status as assessed by the Kansas City Cardiomyopathy Questionnaire score (KCCQ); depressive symptoms as assessed by the Center for Epidemiological Studies Depression Scale; and patients’ current HF-related medications. At the end of each group appointment, patients assigned to the intervention arm also rated each multidisciplinary group clinic and each DVD on a 5-point Likert scale ranging from 1=not helpful to 5=very helpful.

Statistical Analysis
Means (standard deviations) and frequencies (percentages) of baseline characteristics were calculated for the 2 treatment arms and compared using χ² or Student’s t tests, as appropriate. Survival analysis methods were used to analyze the primary outcome of time-to-first HF-related hospitalization or death, with censoring at 12 months post randomization, which included the 8 weeks lag time for intervention completion. Kaplan–Meier survival estimates were calculated by treatment group, and a Cox proportional hazards regression model was used to determine whether treatment was significantly associated with the hazard (ie, risk) of HF-related death or rehospitalization. Tests for statistical assumptions were performed before performing the planned analyses. Thus, before conducting the Cox proportional hazard model, tests were conducted to verify the assumption that hypothesized treatment effects did not vary over time. However, these tests showed violation of the assumption that the hazards were independent of time. Specifically, the hazard functions crossed at month 7 (which is 1 month past the 6-month booster group appointment), indicating the effect of treatment was changing with time (Figure 2). When such a violation of statistical assumptions occurs, the Cox model does not provide a valid (unbiased) estimate of the treatment effect because these analyses require constant hazard ratios (HRs) for group comparisons across the entire time period. In this circumstance, a HR produced by such a model would be indicative of the average effect of treatment for the entire period of interest and would not produce meaningful information about effects that change over time.

Consequently, a time-varying treatment effect was added to the Cox model to first test and then account for the changing effect of treatment for the period of interest. Based on the crossing hazards at 30 days after the final booster visit, an interaction term, z, was added to the model, where z was set to treatment group assignment if the event occurred before 30 days postintervention booster visit and set to zero otherwise. A test of this treatment–time interaction within the Cox model showed a significant change in the treatment effect 30 days after the postintervention booster visit (P=0.03), providing
empirical evidence of the change in the hazard functions over time. In our primary analysis, we used hospital medical records to track outcomes on all patients, including those who did not complete telephone follow-ups.

Because telephone follow-ups and obituaries were our primary means of identifying hospitalizations and deaths that might have occurred outside of the academic medical center, we performed another analysis in which subjects were censored on the date of last completed follow-up. We also compared recurrent or multiple HF-related rehospitalizations between treatment arms using a counting process approach with the proportional means model using a robust sandwich covariance estimator.21 Changes in medication usage over the course of the trial (baseline to 12 months post randomization) were compared between treatment arms using generalized estimating equations. All statistical analyses were completed using SAS® version 9.3.

Results

Of the 198 participants who enrolled in the study, 106 (53%) were randomized to the standard care control arm and 92 (47%) into the intervention arm. Of the 198 enrolled, 180 (91%) completed 12-month follow up data; deaths and dropouts were similar across arms (Figure 1). The randomization process was successful in creating comparable groups (Table 1). The mean age of participants was 62.3 years (SD=13.2 years); 76 (38%) were women; 87 (44%) were black; 105 (53%) were white; and 6 (3%) were other or >1 race. Participants reported having had a diagnosis of HF for an average of 6.2 years before study enrollment (SD=7.6 years; median=3.3 years); the mean Charlson comorbidity index score was 6.7 (SD=2.8) and the mean left ventricular EF was 30% (SD=16.1). There was no significant difference between intervention and control arm patients on left ventricular EF (\(\chi^2=0.69; P=0.41\)), with 94% in the control arm and 91% in the intervention arm having a left ventricular EF\(<40\). In this sample, there were 14 patients with EF\(\geq40\). There was no difference in percentage of these patients with EF\(\geq40\) between the intervention and standard care patients (\(\chi^2=0.69; P=0.41\)). Between the intervention and standard care arms, there were no statistically significant differences on these measures at baseline (Table 1).

The intervention patients attended on average 4.6 of the 5 available intervention group clinic appointments. There were a total of 72 group clinic appointments held during the study, and each group clinic appointment on average was rated by participants as 4.8, where 5 indicates very helpful. Participants rated the helpfulness of each DVD as 4.5 on a 5-point Likert scale. The intervention group reported watching the DVD series 2.7x plus the times watched during each group clinic visit. The standard care control participants reported viewing the DVD series 3.6x on average. There was no significant difference in the viewing time or exposure to the DVD series (\(\chi^2=3.27; P=0.71\)) between groups. No formal evaluation of DVD helpfulness was collected about individual DVDs from the control arm to avoid a potential cointervention effect.

At baseline, the majority of patients were receiving treatment with recommended vasodilators (angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, or hydralazine/nitrate combination) and \(\beta\)-blockers (Table 2). Use of recommended vasodilators declined more in the standard care group (−15%) than in the intervention group (−5%) at 12 months (\(P=0.04\)). There was a similar, although nonsignificantly higher decline in the use of \(\beta\)-blockers in the standard care arm (−9%) than in the intervention arm (−1%; \(P=0.06\)).

Of the 198 subjects, 48 (24%) patients had 1 or more HF-related hospitalizations during the observation period. There were 2 deaths in each group. Overall, a total of 52 (26%) patients experienced the primary outcome of HF-related hospitalizations or death, 22 (24%) in the intervention group and 30 (28%) receiving standard care. Based on examination of the treatment group hazard functions of time to first event, a time-varying treatment effect was identified. The hazard functions were approximately parallel up until month 7 (30 days after the 6-month booster group appointment) but crossed several times in the period thereafter, indicating the effect of treatment was changing with time (Figure 2). From the onset of the observation period, lagged 8 weeks to complete the intervention, up until month 7 (which is 30 days after the 6-month booster clinic), the time-dependent Cox model identified a significantly longer

![Table 1. Patient Baseline Characteristics Means and Comparison Between Groups](http://circheartfailure.ahajournals.org/Downloaded_from)
event-free time associated with the intervention (P=0.04). The HR for the a priori primary outcome (time to first HF-related rehospitalization or death) during this period of follow-up was 0.45 (95% confidence interval, 0.21–0.98). This model also demonstrated that beyond month 7, there were no significant differences between treatment groups (HR=1.7; 95% confidence interval, 0.7–4.1). To determine the sensitivity of these results to our a priori choice of censoring, another Cox model analysis that censored participants after their last completed follow-up was performed and provided similar results (Figure 3). In a secondary analysis, which looked at the total HF-related hospitalizations, including repeat hospitalizations during the observation period, there were 28 total hospitalizations in the intervention group and 45 among those receiving standard care (HR=0.68; 95% confidence interval, 0.37–1.24).

Discussion
Nationally, ≈25% of Medicare patients hospitalized with HF are readmitted within 30 days of discharge,1 and by 12 months, ≈40% to 60% of patients with HF are rehospitalized and 12% to 31% of patients die.1 To address this concern, a large number of studies have been undertaken to improve discharge planning for patients with HF and to enhance postdischarge support and follow-up care.24 Yet, case-management and disease management interventions, including follow-up programs, have not consistently demonstrated beneficial effects, improved outcomes, or reductions in healthcare costs.25 The SMAC-HF program was the first controlled trial to examine group clinic appointments on rehospitalizations related to HF and the effect of DVD HF self-management videos alone. In this study, a benefit for the group clinic appointments was seen, which lasted until month 7 or 30 days after the last booster group clinic appointment, but this benefit was not maintained afterward.

Although use of recommended HF medications was high in both arms, it is possible that some of the positive effect seen in this study could be caused by the intervention group patients’ medication adherence. There was higher adherence to recommended vasodilators in the intervention group compared with the standard care group and a statistically insignificant increase in use of β-blockers over time, also favoring the intervention group. The observed decline in use of HF-related medications over time may have been because of nonadherence, adverse effects, or to cost because numerous patients reported concerns about the costs of all their medications.26 The social worker did assist each patient who voiced concern with applying for cost-saving programs; however, these may take months to fill. Notably there were no significant differences on patients reporting stopping medications because of cost between groups across the trial (χ²=1.64; P=0.22).

A variety of factors may have influenced the small observed differences between groups in medication adherence. One of the group clinic appointments was devoted primarily to medication management and adherence. These patients also received written information on optimal HF medication use as part of the individualized patient summaries provided at the end of each weekly group clinic appointment with instructions to share these summaries with their primary providers. They worked with the group clinic multidisciplinary team to

Table 2. Changes in Medication Treatment Use Throughout the Course of the Trial Among 184 Subjects With a Baseline LVEF <40% (n=184)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Standard Care</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended vasodilator (ACE/ARB/ Hydralazine and Nitrate)</td>
<td>79 (79%) 54 (64%) −15%</td>
<td>72 (86%) 51 (81%) −5%</td>
</tr>
<tr>
<td>β-Blocker</td>
<td>97 (97%) 74 (88%) −9%</td>
<td>74 (88%) 55 (87%) −1%</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>37 (37%) 37 (44%) 7%</td>
<td>38 (45%) 30 (48%) 2%</td>
</tr>
</tbody>
</table>

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; and LVEF, left ventricular ejection fraction.

*Parameter estimates and P values based on generalized estimating equations.
list specific issues to monitor and discuss with their doctors, including questions related to their HF medications.

The SMAC-HF intervention was well-received by the participants as evidenced both by the positive evaluations from participants and by high rates of attendance to the group clinic appointments. Other investigators have also observed positive responses from patients participating in group appointments. The success of group appointments for other disease conditions, however, has been difficult to replicate, possibly because of lack of standardization of the information delivered or lack of a patient-centered approach such as that used in SMAC-HF group discussions. Information variation was controlled in the SMAC-HF group clinics by the DVD series. The DVD audiovisual media may be particularly supportive to patients with neurological or cognitive decline, different learning styles, or lower health information literacy levels. Use of the DVD during the group clinic appointment allowed standardization of the overall self-management theme, but still allowed patients to discuss their own concerns with the oversight of multidisciplinary professionals input.

Although improvements in outcomes were noted up until month 7 or 30 days after the last intervention booster group appointment, these positive outcomes were not sustained. This suggests that there may be a need for continuing the booster interventions after this time or a need to reinforce specific HF self-management skills, such as using the pill organizer box for adhering to daily medications or clarifying low sodium in food labels. However, other programs for HF have also shown decrements in the effectiveness of the tested intervention in the follow-up period. Also, it has been shown that in these New York Heart Association Class III and IV HF patients, the overall poor prognosis may limit the effect of many treatments.

Limitations
One limitation of this study is that the overall HF-related rehospitalization or death event rate in this study was much lower than anticipated. In our total sample, 24% of patients had a rehospitalization for HF during 12 months of follow-up. The low rates of rehospitalization or death could also have reduced our ability to detect a persistence of the intervention effect beyond the last booster session. The relatively low event rate seen in this study could be related to the high levels of guideline concordant medications seen at baseline (Table 2); it also may reflect underappreciated benefits of the DVD educational videos alone. The low rates of readmission also reduced our ability to detect a difference in all rehospitalizations, where a 32% reduction in total HF hospitalizations was nevertheless not statistically significant. This reinforces the preliminary nature of the finding from this study. The length of time needed to set up the group clinic appointment enrollment also limited our ability to affect hospital readmissions that might happen early after the index hospitalization. Finally, this was a single-center study with unique features of an academic health center patient population; results might differ in settings where HF care was either more or less regimented. These characteristics limit the generalizability of the observed benefits. A future, multi-center study of a longer duration of patient support would help further clarify the potential benefits of the multidisciplinary group clinic approach.

Conclusions
Our findings suggest that group clinic appointments hold promise for reducing HF rehospitalizations, but these findings from this small, single-site study need to be confirmed in a larger, multi-site study. The group clinic appointments were highly rated by patients and the multidisciplinary professionals involved. Emerging reimbursement policies could facilitate adoption of group appointments under the existing Current Procedural Terminology codes and Medicare rules. The effect of the group clinic appointments, however, seems to be limited to the period of group clinic exposure. To reduce earlier rehospitalizations, future studies could consider initiating parts of the intervention before hospital discharge. Future studies of group appointments for HF might also consider additional telephone follow-up reinforcement, home visits, or additional booster sessions to sustain positive effect.

Acknowledgments
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Disclosures
None.

References
Heart failure (HF) patients lack self-management skills that are critical to prevent repeat hospitalizations. Group clinics have helped diabetic and cancer patients acquire self-management skills, but there is little study in HF patients. In the Self-Management and Care of Heart Failure randomized trial, a group clinic was tested on rehospitalization or death in 198 HF patients. The group clinic consisted of 4 weekly appointments and a booster session at 6 months. The group clinics were led by an experienced nurse practitioner and included a mental health specialist, a social worker, and a diettian. After brief individual assessment, the group of HF patients watched 1 of 5 digital video discs (DVDs) that addressed a specific topic related to HF self-management. The DVDs helped stimulate the ensuing discussion among the HF patients and the multidisciplinary clinic team. The standard use of the standardized DVDs increased the consistency in intervention delivery as well as the potential for replication—a problem plaguing many disease management programs to date. After completion, the group clinic patients experienced a significantly longer event-free survival than the standard care patients (HR=0.45, P=0.04), but these differences were not maintained during follow-up. The group clinic patients also had higher rates of adherence to some HF medications. This study was limited by a much lower than anticipated rate of readmissions, indicating the need for a larger study that includes more intervention sites. Nevertheless, this study suggests that group clinics, supported by standardized materials, such as the American College of Cardiology Foundation/American Heart Association–based HF DVDs, could positively affect HF outcomes.
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