

Quality Improvement Collaborative to optimize Heart Failure care in patients from a Network of Clinics in Argentina during COVID-19 pandemic

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Abstract

Background: Heart failure (HF) is a major clinical and public health problem associated with significant mortality, morbidity, and healthcare costs. Despite the existence of evidence-based guidelines for the optimal treatment of HF, the quality of care remains suboptimal. Our aim was to increase the use a care bundle in 50% of enrolled subjects during their hospitalization and discharge, and to reduce their readmission for heart failure causes by 10%.

Methods: We conducted an uncontrolled before-after study in eight hospitals in Argentina to evaluate the effect of a quality improvement intervention on the use of a HF care bundle in patients with HF NYHA class II-III. The HF bundle of care included medication, continuum of care, lifestyle habits, and predischage exams. Training and follow-up of multidisciplinary teams in each center were performed through learning sessions and plan-do-study-act (PDSA) improvement cycles. Data collectors reviewed bundle compliance in health records of recruited patients after their hospital discharge and verified readmissions through phone calls to patients within 30 to 40 days after discharge.

Results: We recruited 200 patients (83 before and 127 during the intervention phase), bundle compliance increased from 9.6% to 28.3% (OR 3.71, 95% CI [8.46; 1.63]; $p=0.002$). Despite a slow improvement during the first months, bundle compliance gained momentum near the end of the intervention surpassing 80%. We observed a non-significant decreased readmission rate within 30 days of discharge due to HF in the postintervention period (8.4% vs 5.5%. OR 0.63, IC95 [1.88; 0.21]; $p=0.410$). Qualitative analysis showed that members of the intervention teams acknowledged the improvement of work organization and standardization of care, teamwork, shared mental model, and health records completeness as well as the utility of training fellows.

Conclusion: Despite the challenges related to the pandemic, better care of patients with HF NYHA class II-III was possible through simple interventions and collaborative work.

Graphical abstract

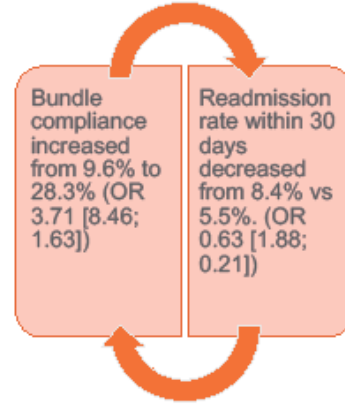
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Quality Improvement Collaborative to optimize Heart Failure care in patients from a Network of Clinics in Argentina during COVID-19 pandemic

Despite the challenges related to the pandemic, better care of patients with HF NYHA class II-III was made possible through simple interventions and collaborative work.

- Heart failure (HF) is a major clinical and public health problem associated with significant mortality, morbidity, and healthcare costs.
- Despite evidence-based guidelines for the optimal treatment of HF, the quality of care remains suboptimal.
- Our aim:
 - increase use of a care bundle in 50%
 - reduce their readmission by 10%.

- Uncontrolled before-after study
- 8 🏠 in Argentina
- Patients with HF NYHA class II-III
- HF bundle of care include:
 - medication
 - continuum of care
 - lifestyle habits
 - predischage exams



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BACKGROUND

Heart failure (HF) is a major clinical and public health problem associated with significant mortality, morbidity, and healthcare expenditures (1). Despite progress in reducing HF-related mortality, hospitalization and readmission rates continue rising (1). The illness and the complexity of its treatment demand much from the patient; unfortunately, adherence to medication and self-care behaviors are difficult to achieve (2,3). Notwithstanding the availability of evidence-based guidelines for the optimal HF treatment, quality of care for HF remains inadequate (4–6). Although some studies have shown decreased readmissions of patients with HF (5,6), replicating complex interventions is difficult and the specific component associated with the improvement is not always clear.

In this complex scenario, the use of a bundle of interventions together with other strategies, such as quality improvement collaboratives (QIC), could contribute to the optimization of the treatment of patients with HF (7,8). QICs have been used to improve healthcare for decades. They involve care teams from several sites or institutions working to improve performance in a specific area by collecting data and testing ideas in plan-do-study-act (PDSA) cycles supported by training and learning sessions (8,9). QICs are underpinned by the idea that leaders and institutions can leverage peer learning to accelerate improvement in healthcare performance and potentially achieve large-scale outcomes in a short time (10). Also, health system coordination could facilitate systematic group learning among similar health facilities at all health system levels.

In Argentina, reported results of HF treatment (11) suggest that there is a good opportunity to combine two quality approaches to improve care: empirical use of an evidence-based care bundle (12) and implementation of QIC to generate cross-learning within a healthcare network. We conducted a before and after study in eight hospitals in Argentina to provide a standardized bundle of interventions to assure quality of care in patients with newly diagnosed or known HF (NYHA class II-III, LVEF <40%). Our aim was to increase the use of HF care bundle by 50% and to reduce the readmission rate of HF patients by 10%.

METHODS

We used an uncontrolled before and after design to assess the effect of a QIC in the treatment of HF patients between August 2020 and July 2021, with a preintervention period from August 2020 to December 2020 and an intervention period from January 2021 to August 2021. We included patients who were admitted to participating hospitals with HF (adults in class II-III of the NYHA classification of HF) with reduced ejection fraction (LVEF <40%).

Prior to the study, we used a modified RAND-UCLA Delphi consensus method (12,14) to select the set of care practices that would be part of the HF patient care bundle during hospitalization.

The study consisted of 3 phases: 1) Formative phase, in which the barriers and facilitators for the intervention were identified based on the theory of the normalization process (13), 2) Preintervention phase, where baseline HF care was measured; and 3) Phase of implementation, where the study HF care bundle was implemented. We also used evaluative interviews at the end of the intervention to assess the implementation from a qualitative perspective.

Settings

The participating clinics were selected for convenience and belonged either to the Argentine public (4) or private health systems (7). They had a coronary unit that attended in the pre-pandemic period at least two HF patients per week. Six of them were teaching hospitals. All of them had limited experience in implementation science and quality improvement projects. None of them had established quality improvement departments.

Formative phase and qualitative evaluation

We performed a formative phase with a qualitative component with semi-structured, individual, remote interviews. We conducted fifteen interviews with the project coordinators. We used the Normalization Process Theory to facilitate data collection and analysis. This theory focuses on the work that individuals and organizations must do for a new practice to become embedded and sustained in routine practice. For the qualitative evaluation of the implementation of the HF care bundle made by the end of the study, we conducted 20 interviews with key stakeholders and participants in different cadres involved in the study. Interviews were audio recorded and transcribed verbatim. Data were analyzed using the theoretical framework approach with *a priori* developed set of codes. For the formative phase, we placed emphasis on the identification of potential difficulties so that the intervention could be adjusted before implementation; whereas in the evaluative interviews, we focused on the barriers and facilitators experienced by participants in the implementation of the care bundle. We used Atlas.ti v8.4 qualitative data management software to facilitate the data coding process.

Bundle of care

We used a HF evidence based care bundle developed by an Argentine group of experts(12). The bundle covered four categories: medication, continuum of care, lifestyle habits, predischage tests. Inside each category these were specific measures: 1) medication: beta-blockers, angiotensin receptor neprilysin inhibitors or ACE-inhibitors, furosemide, and anti-mineralocorticoids; 2) continuum of care: follow-up appointment, daily weight monitoring; 3) lifestyle habits: smoking cessation counselling and low-sodium diet; 4) predischage tests: renal function, ionogram, blood pressure control, echocardiogram, and determination of decompensating cause (Table 1).

Outcomes

We pursued two outcomes: a) the percentage of complete HF care bundle compliance, and b) 30 day-HF readmissions. After hospital discharge, data collectors reviewed the patients' health records to ascertain the use of the care bundle during the hospital stay. The use of the bundle was measured as the percentage of recruited cases in which the use of all the bundle components were stated in the patient's health record. Whenever a single component was missing, the bundle was classified as noncompliant.

Heart failure hospitalization was defined, according to previous trials (14,15), when all of the following criteria were met: 1) worsening of heart failure signs or symptoms (presenting at least 1 of the following: dyspnea on exertion, orthopnea, nocturnal dyspnea, pulmonary edema, increasing peripheral edema, increasing fatigue or decreasing exercise tolerance, raised jugular venous pressure, and radiological signs of heart failure); 2) inpatient hospitalization; and 3) any addition or increase of any heart failure intra- venous treatments including diuretics, inotropes, or afterload-reducing vasodilator drugs(16).

Readmissions were expressed as the percentage of patients readmitted with a diagnosis of HF among all recruited patients. Readmission and its diagnosis were verified through phone calls to patients within 30 to 40 days after discharge and the review of health records. The deployment of the intervention was evaluated at the end of the study using qualitative research methods. Presentation, etiologies, precipitating factors, comorbidities, and in-hospital outcomes were defined by the investigators according to the corresponding guidelines.

Intervention

We adapted the collaborative model "Breakthrough Series" (BTS) (17), a QIC focused on shared learning with the Model for Improvement (18) to promote the adoption and adaptation of best practices for the treatment

of HF through virtual learning sessions and continuous feedback. The BTS model is based on the idea that quality improvement teams working collaboratively towards a common goal are likely to be more effective than those working in isolation(19). In each of the HF clinics, an improvement team was formed including at least one data collector, one intervention facilitator and a team leader. Most of the teams had two or more physicians and at least one educational nurse. During the implementation phase of the BTS, learning sessions (LS) were held virtually every two weeks. In these sessions, participants shared progress, best practices, barriers, facilitators, and lessons learned during the implementation of the project. LS were followed by periods of action (PA) during which teams tested and documented ideas of change using the model of QI and PDSA cycles. Teams also collected and reported data on key measures monthly. A driver diagram was used to organize and suggest topics on which teams should work to achieve the common objective of the study. These were expressed in the primary and secondary drivers, and each team had to complete it with the ideas of change, adapting the project according to their local resources and assets (Supplementary appendix).

Using the driver diagram as a roadmap, ideas of change were implemented including training on improvement methods, mapping and standardization of processes and concepts on teamwork, shared mental model, and identification of tasks and better definition of roles. The dissemination of baseline results raised awareness about the gap between the care theoretically provided and the one provided, which was widely underestimated. Communication campaigns about the project and its bundle were carried out in hospital units; additionally, the importance of registering practices, indicators and recommendations made to patients was stressed. The provision of post-discharge follow-up appointment processes was redefined, and in some cases, new professionals were assigned for this task. Day-to-day registries and the discharge note format in medical records were reviewed, and in some cases, a new template was created to complete the bundle key points, which served as a reminder checklist and an improvement of registration process. Regarding medication, basic concepts of therapeutic conciliation were reviewed. The importance of educating the patient and their environment was emphasized, encouraging an active attitude in getting to know and managing the patient's condition.

Data management and statistical analysis

The study data flow is shown in the supplementary appendix. Data was collected with REDCap®, and the LifeQI platform was used for the interaction, the recording of the results and the visualization of the improvement model (driver diagram, PDSA cycles, run chart) for each center. All data collected for this study was managed by the Institute for Clinical Effectiveness and Health Policy (IECS) data department, always

preserving confidentiality. A description of the characteristics of the individuals who were hospitalized during the pre- and postintervention periods was performed (table 2).

For categorical variables, frequencies and proportions were reported, and for continuous variables mean and SD were used. For hospital stay, the median and interquartile range were calculated. Pharmacological treatment at discharge and causes of heart failure decompensation were also reported by group. To assess the effect of the intervention on the primary and secondary outcomes, we used a logistic regression. As a measure of effect, the odds ratio (OR) and the 95% confidence intervals were reported. The statistical package R version 4.0 was used (The R Foundation).

All participant sites submitted the study protocol to their own institutional review board, which approved them in all cases. An informed consent was signed by all patients at hospital discharge.

RESULTS

Ten clinics treating patients with HF participated in the study, two sites left the project due to COVID-19 pandemic work overload. We recruited 200 patients, 83 in the preintervention period and 127 in the postintervention period. Patient characteristics were similar in both study periods (Table 2). The most frequent causes of HF decompensation were dietary noncompliance in the preintervention period and non-adherence to treatment in the postintervention period (Table 2). Regarding pharmacotherapy in HF, we observed increased use of angiotensin-converting enzyme (ACE) inhibitors and decreased use of neprilysin and angiotensin receptor inhibitor (ARNI) in the post-intervention period. We didn't observe changes in other drugs use between both periods (Table 3).

As regards the implementation of the HF care bundle, an increased adherence was observed in the postintervention period (9.6% vs. 28.3%, OR 3.71 (95 CI: 8.46; 1.63); $p=0.002$). We observed a trend of 5 ascending measures demonstrating a non-random pattern in the HF care bundle compliance run chart (figure 1) (20). During the first months of the intervention, improvement was slow; however, the adherence to HF care bundle gained momentum during the last months of the intervention reaching over 80%. We showed individual observation of each HF care bundle category (medication, continuous care, lifestyle habits, predischarge goals) in the supplementary appendix.

A decrease in patients' readmissions due to HF within 30 days of discharge was observed in the post-intervention period compared to readmissions in the pre-intervention period, however it didn't reach

statistical significance (8.4% vs. 5.5%, OR 0.63 (IC95: 1.88;0.21); $p=0.410$). We didn't observe any pattern in the patients' readmissions due to HF within 30 days of discharge run chart (figure 2)(20).

Participants described barriers and facilitators in the formative phase. The main barriers mentioned were the changes in care practices brought by the COVID-19 pandemic, limited human, and material resources in some of the facilities, and the low attendance at group meetings and LS. Other barriers were lack of cooperation between/within areas or departments, resistance to change, insufficient time for activities, lack of commitment by some team members, under-registration of practices in health records, difficulty in requesting diagnostic tests, and problems in implementation of counselling. Regarding the facilitators to QI implementation, interviewed staff recognized the intervention was simple, low-cost, and aligned with standard practices intervention; they also mentioned high commitment of some site coordinators and improvement facilitators, readiness of frontline professionals, and the availability of materials and education resources.

The qualitative analysis of data obtained in the interviews carried out at the end of the study revealed that according to the perception of the participants, the bundle was adequate, complete, and simple, and the interventions were feasible to implement.

The support provided by the coordinating team and the quality of educational materials produced for the study were highlighted. The main barriers to the implementation of the bundle were the health emergency due to COVID-19 with a decrease in human resources and patient flow, for example, lack of material resources and lack of coordination between departments in the centers. Other identified barriers included certain resistance to change from senior professionals, low participation of improvement teams in the study general meetings, low participation of nurses and lack of clarity in communicating the objectives among study participants. As regards the improvements obtained, the participants perceived that the project brought systematization of routine practices, improvement of medical records, better organization of patient care, identification of care that was not being provided, and improvement knowledge and skills that they also applied to the care of other illnesses. The opportunities for improvement identified by the participants for future initiatives were more feedback on the results, incentive for greater participation in meetings, greater participation of nurses, clearer objectives, and improvement of communication between site departments.

DISCUSSION

Statement of principal findings

Our findings demonstrated an increased implementation of a HF patient care bundle of evidence-based practices, previously identified in an expert consensus (12). It was possible to improve the compliance level, from 15% in the first month of the study to 80% at the end of the study. The run chart showed a non-random pattern, consisting of an ascending trend, suggesting that the intervention may explain the increase in the bundle compliance (Fig. 1). Our study showed that a low-cost intervention, based on the best practices identified by local experts, achieves better acceptance, and can be successfully implemented in centers that treat patients with HF in an LMIC setting during the COVID-19 pandemic.

Our results showed a low readmissions rate within 30 days of discharge, with a non-significant decrease between periods. We identify a non-random pattern in the readmissions rate run chart, suggesting the descent may be due to chance (Fig. 2).

Strengths and limitations

To our knowledge this is the first study that evaluate the implementation of a HF patient bundle of care in LMICs. Despite the COVID-19 we could deploy an intervention to sustain an evidence-based care in these HF clinics. In the qualitative analysis, most professionals recognized the benefits of the simple and low-cost components of the care bundle. The educational materials produced, the clear roles, the improved processes, training, and the consolidated teams could provide the basis for sustainability.

Some limitations should be acknowledged. First, the study was entirely done in pandemic times, which made it impossible to audit the sites. In this scenario, we maintained biweekly exchange meetings between sites and near weekly follow up on-to-one calls between sites and a QI advisor to keep dated. Second, we initially expected to recruit 40 patients per site, totaling 320 patients. Anticipating difficulties to reach this number, 10 sites were included; however, two of these withdrew from the study. The reason for withdrawing was losing their project leader and other team members. Only two centers exceeded 40 recruited patients. The smaller sample only allowed pooled data analysis. Third, we had planned to measure outcomes every 15 days, but due to the reasons described, measurements were made every 30 days. At last, due to the pandemic there were high rate of staff turnovers.

Interpretation within the context of the wider literature

Our results are aligned with the OPTIMIZE-HF study (5) showing that measuring adherence, providing baseline feedback and comparing institutions resulted in an increased use of evidence-based therapy, higher adherence

to performance measures and shorter hospital stays of HF patients. In particular, compliance in the medication category of the bundle surpassed 80% in the last months of the study, being even higher than the average compliance observed in the ARGEN-IC study (beta blockers 77.8%; ACE inhibitors, ARBs II or NRNAs 70.9%; and antialdosteronics 56.3%) (11). Sodium glucose cotransporter 2 inhibitors (SGLT2i's) were not included in the medication intervention since the bundle was designed before the publication of their impact in HF.

The ARGEN-IC study (11), conducted in Argentina, had a rate of readmission within 30 days much higher than the rate observed in our population even before the intervention (16.7% vs. 8.4%). In a cluster trial, Panella et al. (6) showed a reduction in mortality (5.6% vs. 15.4%; $p = 0.001$) and in unscheduled readmissions (7.9% vs. 13.9%; $p = 0.053$) after implementing clinical pathways for HF adapted by each hospital's staff. The slow increase in the adoption of the bundle components at the beginning of the implementation period might have been associated with the study timing which overlapped with most staff's annual leave. Also, COVID-19 pandemic posed a significant challenge for patient recruitment because many coronary care units had to be used for COVID hospitalizations—and staff was scarce because of COVID-19 infection and isolation. Compared to other epidemiological studies on HF carried out in Argentina, a lower age, greater comorbidity with diabetes mellitus, previous infarction and atrial fibrillation were observed in our study (11).

Implications for policy, practice, and research

The HF patient bundle of care was previously developed by key stakeholders from Argentina. The participants' perception of the bundle was positive, and the implementation was feasible. Our study can be scaled up in other settings since we could test the HF bundle of care in public and private clinics along the country.

Conclusions

Even facing difficulties related to the COVID-19 pandemic, better care of patients with HF NYHA class II-III was possible through simple interventions and collaborative work in a middle-income country; however, no changes were observed in readmission rates. Future studies should confirm the effect size of the bundle implementation as well as its use in other settings.

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Figure 1 Compliance with heart failure care bundle through study time.

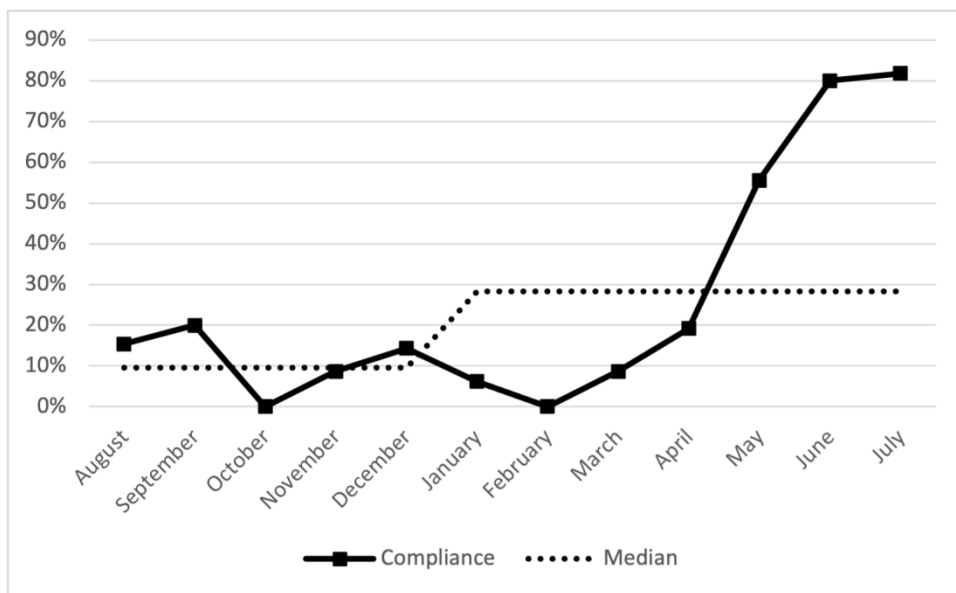


Figure 2 Readmissions rate within 30 days of discharge due to heart failure through study time.

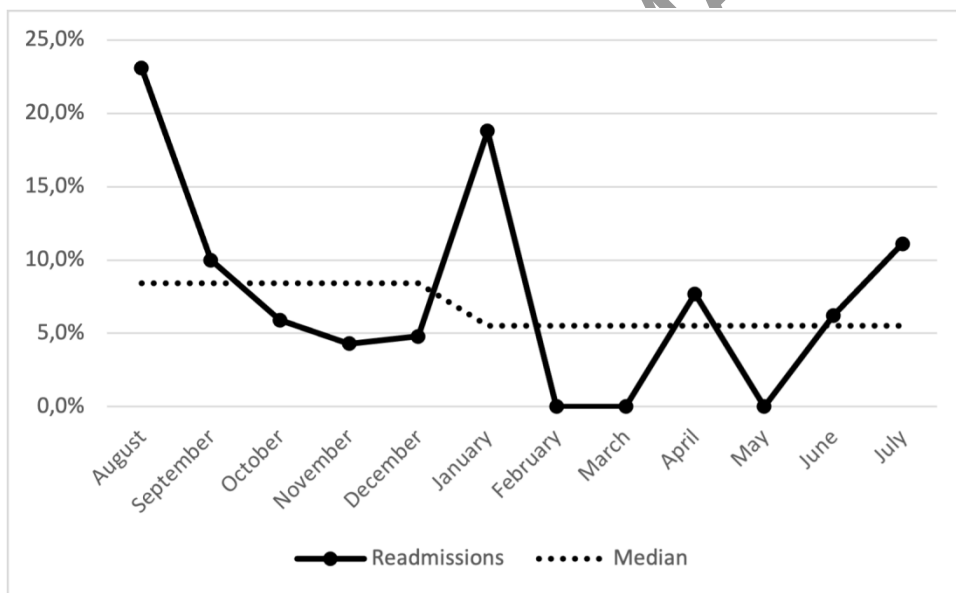


Table 1. Heart Failure Quality of Care Improvement care bundle.

Interventions	
Medications prior to discharge at the initial dose recommended by international and local clinical practice guidelines	Beta-blockers: try to reach the optimal dose
	ACE inhibitors or ARBs or RNAs: try to reach the optimal dose
	Anti-mineralocorticoids: try to reach the optimal dose
	Furosemide: try to reach the optimal dose
Ongoing care: pre-discharge objectives	Follow-up appointment with the specialist in the 7 days after discharge
	Daily weight under the same conditions and weight recording (the goal of recording weight during follow-up may trigger medication change or dose modification according to provider opinion)
Lifestyle pattern	Low-sodium diet: less than 2 g of daily sodium intake
	Smoking cessation advice
Pre-discharge objectives	Kidney parameters and ionogram evaluation
	Blood pressure control (pre-discharge)
	Echocardiogram during hospitalization
	Determination of the cause of HF decompensation

Table 2. Characterization of the population in the pre-intervention and post-intervention periods.

	Pre-intervention (N = 83)	Post-intervention (N=127)	P-value*
	n/N (%)	n/N (%)	
Age in years**	64.8 (12.8)	63 (13)	0.361
Female	27/83 (33.3%)	44/127 (34.6%)	0.751
Hospital stays in days ^β	8 (6-12)	9 (6-12)	0.663
Obesity	14/31 (45.2%)	12/40 (30.0%)	0.188
Hypertension	60/77 (77.9%)	88/124 (71.0%)	0.277
Smoking	22/74 (29.7%)	44/122 (36.1%)	0.363
Dyslipidemia	25/58 (43.1%)	32/92 (34.8%)	0.307
Diabetes mellitus	28/75 (37.3%)	50/125 (40.0%)	0.708
Atrial fibrillation	35/75 (47.7%)	41/124 (33.1%)	0.056
Previous hospitalizations for heart failure	40/75 (53.3%)	61/117 (52.1%)	0.871
Previous ischemic stroke [€]	3/69 (4.3%)	10/126 (7.9%)	0.388
Implantable cardioverter defibrillator [€]	4/72 (5.6%)	4/125 (3.2%)	0.467
Cardiac desynchrony therapy [€]	2/71 (2.8%)	1/125 (0.8%)	0.298
Aortic counter-pulsation balloon [€]	1/75 (1.3%)	0/126 (0.0%)	0.373
Ischemic cardiomyopathy	29/57 (50.9%)	39/107 (36.4%)	0.074
Left ventricular ejection fraction**	27.5 (6.6)	28.2 (6.6)	0.476
NYHA Functional Class (%)			
I	3/83 (3.6%)	5/127 (3.9%)	
II	47/83 (56.6%)	84/127 (66.1%)	
III	30/83 (36.1%)	37/127 (29.1%)	0.292
IV	3/83 (3.6%)	1/127 (0.8%)	
Systolic pressure (SBP)**	113.2 (20.1)	112.1 (17.9)	0.676
Diastolic pressure (DBP)**	69.0 (12.0)	69.1 (12.3)	0.971
Heart rate**	81.1 (17.8)	78.6 (15.3)	0.266
Causes of heart failure decompensation			
COVID-19 infection [€]	6/83 (7.2%)	1/127 (0.8%)	0.016
Other infection	5/83 (6.0%)	10/127 (7.9%)	0.611
Food transgression (%)	23/83 (27.7%)	23/127 (18.1%)	0.100
Hypertension	7/83 (8.4%)	12/127 (9.4%)	0.802
Lack of adherence to drug treatment	18/83 (21.7%)	38/127 (29.9%)	0.187
Arrhythmia	21/83 (25.3%)	24/127 (18.9%)	0.269
Ischemic event [€]	4/83 (4.8%)	8/127 (6.3%)	0.767
Disease progression	13/83 (15.7%)	21/127 (16.5%)	0.867

* Chi-squared test used to compare the pre-intervention and post-intervention periods

**The mean and (standard deviation) were reported. T-test used to compare the pre-intervention and post-intervention periods

^βThe median and the (Quartil 1 – Quartil 3) were reported. Wilcoxon test used to compare the pre-intervention and post-intervention periods

[€]Fisher test used to compare the pre-intervention and post-intervention periods

Table 3. Pharmacological treatment at discharge

	(N = 83)	Post-intervention (N=127)	P value*
	n/N (%)	n/N (%)	
Use of ACE inhibitor or ARA II	48/83 (57.8%)	91/127 (71.7%)	0.038
Use of ARB	15/83 (18.1%)	31/127 (24.4%)	0.278
Use of ARNI	28/83 (33.7%)	24/127 (18.9%)	0.015
Use of diuretics	73/83 (88.0%)	117/127 (92.1%)	0.314
Use of digitalis	7/82 (8.5%)	17/127 (13.4%)	0.283
Use of beta-blockers	69/83 (83.1%)	113/127 (89.0%)	0.223
Use of mineralocorticoid antagonist	65/83 (78.3%)	106/127 (83.5%)	0.348
Use of statins	41/83 (49.4%)	63/127 (49.6%)	0.976
Adjustment made to the dose of the drugs that the patient used prior to admission			
The dose of some drug was increased	13/83 (15.7%)	33/127 (26.0%)	0.077
The dose of some drug was lowered	11/83 (13.3%)	27/127 (21.3%)	0.141
Some drugs were discontinued	21/83 (25.3%)	33/127 (26.0%)	0.912
Added some drug	58/83 (69.9%)	80/127 (63.0%)	0.304
No changes were made	8/83 (9.6%)	13/127 (10.2%)	0.888
Unregistered**	2/83 (2.4%)	3/127 (2.4%)	1.000

ACE: angiotensin-converting enzyme; ARA II: angiotensin II receptor antagonists; ARB: Angiotensin receptor blockers ;ARNI: dual neprilysin and angiotensin receptor inhibitor

*Chi-squared test used to compare the pre-intervention and post-intervention periods

** Fisher test used to compare the pre-intervention and post-intervention periods

End matter: Supplementary information

“Quality Improvement Collaborative to optimized Care Provided to Heart Failure patients from a Network of Clinics in Argentina during COVID-19 pandemic”

BRICA: Bundle para la Reducción de las internaciones en pacientes con Insuficiencia Cardiaca en la Argentina

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All authors contributed to the conception or design of the work, or the acquisition of data, or analysis of data, or interpretation of data for the work. All authors participated in drafting the work or revising it critically for important intellectual content and have approved and are responsible for the final version submitted for publication.

Ethics and other permissions

- IRB Hospital Central, approval date 09/22/2020
- IRB Hospital de Clínicas, approval date 08/05/2020 (nº 4058)
- IRB Hospital del carmen, approval date 07/16/2020
- IRB Hospital Privado de Comunidad, approval date 08/06/2020
- IRB Hospital Italiano Garibaldi, approval date 08/05/2020
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Conflict of interests

F. Ditata: Modest; Employment in Novartis. **A. Fernández:** Modest; Speaker for Astra, and Boehringer.

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Data Availability Statement

All database and IRB approvals are storage in this link:

https://osf.io/rwzcu/?view_only=2ee4907f9e0148079df0d88a09e10d9e

The intervention materials are storage in the same link.

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