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Review Article

Consensus and development of document for management of stabilized acute decompensated heart failure with reduced ejection fraction in India



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ABSTRACT

Aim: Ensuring adherence to guideline-directed medical therapy (GDMT) is an effective strategy to reduce mortality and readmission rates for heart failure (HF). Use of a checklist is one of the best tools to ensure GDMT. The aim was to develop a consensus document with a robust checklist for stabilized acute decompensated HF patients with reduced ejection fraction. While there are multiple checklists available, an India-specific checklist that is easy to fill and validated by regional and national subject matter experts (SMEs) is required.

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Heart failure with reduced ejection fraction
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Methodology: A total of 25 Cardiology SMEs who consented to participate from India discussed data from literature, current evidence, international guidelines and practical experiences in two national and four regional meetings.

Results: Recommendations included HF management, treatment optimization, and patient education. The checklist should be filled at four time points- (a) transition from intensive care unit to ward, (b) at discharge, (c) 1st follow-up and (d) subsequent follow-up. The checklist is the responsibility of the consultant or the treating physician which can be delegated to a junior resident or a trained HF nurse.

Conclusion: This checklist will ensure GDMT, simplify transition of care and can be used by all doctors across India. Institutions, associations, and societies should recommend this checklist for adaptability in public and private hospital. Hospital administrations should roll out policy for adoption of checklist by ensuring patient files have the checklist at the time of discharge and encourage practice of filling it diligently during follow-up visits.

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1. Introduction

The prevalence of heart failure (HF) in India is around 1% of the total population,¹ whereas globally, it is around 1–2%, increasing to $\geq 10\%$ among patients aged > 70 years.² Currently, the incidence of HF in India is not clear, and has been estimated to be anywhere between 1.3 and 23 million. As per the data published in the Trivandrum Heart Failure Registry (THFR), HF with preserved ejection fraction represents 25% of the total HF burden, which indicates that HF with reduced ejection fraction (HFrEF) is more predominant.^{3,4} The profile and characteristics of Indian patients with HF is different as compared to patients worldwide; they have younger age of onset (mean age reported was 61.8 ± 13.4 years in the Trivandrum Heart Failure Registry (THFR),⁵ 59.1 ± 11.8 years in the Medanta Registry,⁶ and 56 ± 15 years in the International Congestive Heart Failure (INTER-CHF [Indian population subset]) study,⁷ compared to 69.8 ± 14.4 years in United States [Acute Decompensated HEart Failure National REgistry {ADHERE}]),⁸ rheumatic heart disease is an important etiology, male:female ratio is 70:30 compared to 50:50 in West.^{3,5,6,9} It has been estimated that post-hospitalization events such as death and re-admission are 27.3% among patients with HF in India.¹⁰ Among Indian patients, adherence to medication ranges from 25% to 50%, and compliance to guideline-directed medical therapy (GDMT) is low.¹¹ In Indian patients, the prognosis of HF is very poor. As per the THFR data, the in-hospital mortality rate reported was 8.4% as compared to 4% in the ADHERE of USA. The INTER-CHF study also reported a mortality rate of 37% in Indian patients.³

High readmission and mortality rates in HF need to be reduced with focus on the reasons for readmission and how to prevent these. Factors leading to higher readmission rates and mortality in India as per literature are lack of GDMT, poor education, lack of adherence to guidelines, poor treatment compliance, older age, New York Heart Association (NYHA) functional class IV status, and increased serum creatinine.⁴ Many of the above factors can be checked and addressed by using a checklist.

Few strategies that can be used for decreasing readmission for patients hospitalized with HF are¹¹:

1. Use of GDMT
2. Patient education about their disease, treatments and dietary interventions. Education on how to respond to various symptoms of HF.
3. Follow-up: Majority of readmission cases occur within 30-days. Hence, a follow-up should be scheduled within 7 days after discharge.
4. Disease Management Programs can improve the medication adherence and quality of life (QoL) of patients with HF.

5. Use of a checklist.

Checklists help improve patient care, medication compliance, reduce post-discharge readmissions, save cost of medical expenses, prevent human errors, and standardize medical care.⁹ A structured discharge protocol can help improve QoL and HF knowledge in patients with stabilized acute decompensated heart failure (ADHF).¹⁰ The checklists currently available are American College of Cardiology (ACC) consensus,¹² Target HF checklist,¹³ Heart Failure Checklist from National Heart, Singapore,¹⁴ All India Institute of Medical Sciences (AIIMS) HF critical care unit Checklist,⁹ ABCD checklist,⁹ HF passport (Hriday Card),⁹ and HF Toolbox.¹⁵

While there are multiple checklists available in literature, it was important to formulate an India specific checklist taking clues from all the recommended checklists to adapt in a way that is easy to fill, standardized and validated by both regional and national subject matter experts.

An ideal India specific checklist must:

1. Ensure continuum of care in stabilized ADHF patients from intensive care unit (ICU) to out-patient follow-ups.
2. Easy to fill and contain all important parameters required for monitoring patients with HF
3. A one-two page checklist should reinforce and encourage adherence to GDMT and necessary diagnostic tests at appropriate follow ups.
4. A multidisciplinary team (led by the treating physician) should be able to complete the checklist.

2. Methodology

Subject matter experts from India with expertise in decision making in the management of HF were identified. Seven cardiologists across the country constituted a core committee and 18 other cardiologists were identified for regional meetings taking into consideration diversity in different parts of India. Data and existing guidelines/literature were searched and analyzed, and then presented for deliberations in the first core committee meeting, followed by the four zonal meetings (East/West/North/South). All of these meetings were attended by cardiologists. Published Global and Indian literature was shared with each member prior to every meeting. After each meeting, minutes were recorded, documented and circulated to the attendees.

After compilation of the minutes of all zonal meetings, findings were shared in the final core committee meeting to arrive at this consensus document.

3. Recommendations

The following points and parameters were added in the checklist after due consideration to make it robust. We have described each point that has been included in the checklist and the reasons for doing so. A single checklist is recommended for maintaining continuum of care for all patients with stabilized ADHF with reduced ejection fraction (HFrEF) and better follow-up allows compliance that reduces the chance of readmissions. This checklist is the responsibility of the consultant or the treating physician. He/she can delegate it to a junior resident or HF nurse (trained) to fill the checklist and make sure it is completed. Heart failure nurses play a crucial role during post-discharge. Appropriate follow up of patients with HFrEF either in person or telephonic can be maintained by HF nurses. This could help regular enquiry about patient's health, documentation of weight, heart rate, blood pressure findings and advise on diet and lifestyle modifications.

The focus of this article is on providing consensus recommendations for the management, treatment care optimization, and education for a patient with stabilized ADHF with reduced ejection fraction (HFrEF). It is important that we define at the outset what we mean by a patient with stabilized ADHF with reduced ejection fraction (HFrEF). Below are the criteria that were defined by the panel for the same:

- off intravenous inotropes since last 24 h
- off intravenous diuretics since last 24 h
- Stable haemodynamic parameters defined as systolic blood pressure (BP) > 90 mm Hg and heart rate (HR) < 100 beats per minute

The following points were recommended by the panel:

Demographics and contact number: to capture the essential information about the patient.

Weight at discharge: In order to compare during follow-up monitoring.

Date of assessments or visits: Should be captured for record purpose along with the name of the hospital specialist, can be the treating physician or nurse who is checking the parameters and filling the checklist.

Clinical assessment:

- **Etiology:** Identifying etiology is first and an important step for providing optimal management in patients with HF. The important etiologies can be ischaemic, non-ischaemic and valvular in nature.
- **Comorbidities:** Generally, patients with HF have 3 or more comorbidities.¹⁶ Hence, to reduce the chances of mortality and readmission, these co-morbidities also need to be managed.
- **Reason for decompensation:** Infections, anaemia, arrhythmia, ischemia, and pulmonary embolism could be the common causes of acute decompensation.
- **Weight:** One of the easiest ways of monitoring patients of HF is to keep a close watch of patient's body weight. Increases of more than 1 kg per day are early warning signs of fluid retention.
- **Resting heart rate:** Heart rate should be monitored at each visit and the trend or variation should be checked
- **Respiratory rate:** Respiratory rate is an important clinical assessment that needs to be monitored at each visit.
- **Blood pressure:** need to be measured for medication dosage adjustments, lowering dose of medications like diuretics in case of hypotension.
- **Signs of fluid overload:** Presence of pedal edema, chest congestion, and weight gain is important to monitor.

- **NYHA class:** The NYHA classification can be used as an assessment tool to measure the functional status for the patient post discharge
- **Laboratory measurements:**
 - o **Electrocardiogram (ECG):** may suggest an acute tachyarrhythmia or bradyarrhythmia, acute myocardial ischemia or infarction that may give cues of etiology of HF. Also, it can give clues of electrolyte imbalance and chamber enlargement.
 - o **Left ventricular ejection fraction (LVEF):** LVEF values measured by 2-D echo or 3-D echo can help in understanding the severity of HF. A LVEF <40% and worsening from previous values necessitates prompt action.
 - o **Hemoglobin:** Anemia may be a cause for acute decompensation of HF
 - o **Electrolytes**
 - o **Sodium and Potassium:** should be monitored at each visit
 - o **Creatinine:** Worsening of creatinine levels may strongly contribute to HF progression and worsen the patient's survival
 - o **Blood Urea Nitrogen (BUN):** A high or steadily increasing level of BUN is associated with a higher mortality risk in patients with acute HF. During hospitalization, return of BUN levels to normal range may improve long-term clinical outcomes.¹⁷ A high blood urea level may also indicate overuse of diuretics.
 - o **Estimated glomerular filtration rate (eGFR):** As a measure for kidney function may be done
 - o **N-terminal fragment of ProB-type Natriuretic Peptide (NT-proBNP):** represent the gold standard for biomarkers in HF. For patients presenting with ADHF, the risk increases if > 300 pg/mL for NT-proBNP and >100 pg/mL for BNP.¹⁸ The blood level of these biomarkers reduces with treatment of HF and correlates with improved clinical outcomes. A pre-discharge NT-proBNP is desirable to predict the prognosis. The tests should be repeated during follow-up as per availability and physician's discretion.
 - o **Iron studies:** In HF patients, iron deficiency can be defined as ferritin <100 mg/L (absolute iron deficiency, related to depletion of iron stores), or 100–300 mg/L with transferrin saturation <20%.¹⁸

Patient education: A multi-disciplinary team (HF nurse, dietitian, HF educator, counsellor) led by the treating physician should spend enough time for patient and care giver counselling. The following points should be discussed:

- **Salt and water intake plan:** Usually, sodium restriction (intake < 2 gm per day) reduces hospitalization of HF. Urinary sodium levels can be checked by using spot check devices. Instead of down-titrating dose of medications like angiotensin receptor blocker neprilysin inhibitor (ARNi), it is recommended to increase fluid and salt intake during summers.
- **Personalized diet plan:** Educate the patient for any special nutritional recommendations, frequency and size of meal. This should be done in-hospital prior to discharge.
- **Exercise plan:** Physical exercise improves functional aerobic capacity, health related QoL and hospitalization rate in patients with HF.¹⁸ Patient should be educated about importance of daily exercise for improved outcomes and how the exercises should be done.
- **Weight monitoring:** Weight can be a good indicator of fluid overload.
- **Warning symptoms:** Patients should be instructed to report to the treating physician or nurse in case there are any changes in the frequency or severity of existing symptoms or any new symptoms. Patients must be made aware of the following

warning symptoms: difficulty in breathing with physical activity (exertional dyspnea), difficulty in breathing while lying flat (orthopnea), episodes of waking up from sleep gasping for air (paroxysmal nocturnal dyspnea), frequent dry hacking cough, swelling in lower body, sudden weight gain (monitored by the HF nurse), new or worsening dizziness or confusion.

- **Home BP monitoring:** Periodic checking of BP at home is suggested. The values can be noted down by the patient in a diary and can be informed to the treating physician or nurse. Any drastic change in the BP values should be informed to the treating physician. Patient should be warned that the resting BP could be as low as 90 mm Hg or even little lower.
- **Medication adherence:** Not adhering to GDMT and not taking the drugs as prescribed by the physician increases the risk of readmission and poor survival or mortality.⁴
- **Quality of life:** At follow-up questions about QoL related to daily routine activities should be asked to every patient. For example: patient able to do household work, walk and go to bathroom, go for morning walk, go to the local market etc.

Optimization of HF Treatment: The use of GDMT plays an important role in halting or preventing progression of HF.^{4,11}

The administration of therapies should be individualized, taking into account the BP, potassium, serum creatinine, and sodium levels, any co-morbidities and contraindications. It is important that the drugs are prescribed at the right dose and ensured that the patient continues the therapy. If any drug is not prescribed, the reason should be documented. The patient should not stop the treatment unless directed by the physician.

At the time of discharge, the physician should ensure that the patient is on essential HF medications.

- **Angiotensin Receptor Blocker Nephilysin Inhibitor (ARNi):** Results from PARADIGM trial demonstrated that the use of sacubitril/valsartan diminished the risks of mortality and hospitalization, as compared to enalapril.¹⁹ Evidence from the TRANSITION and PIONEER-HF trials supports in-hospital initiation of sacubitril/valsartan, titrated to target dose based on algorithms incorporating systolic BP and laboratory values, as first-line therapy in the management of acute decompensated heart failure with reduced ejection fraction (HFrEF). An expert consensus of Heart Failure Association of the European Society of Cardiology (ESC) have recommended initiation of sacubitril/valsartan rather than an angiotensin converting enzyme inhibitors (ACEi) or an angiotensin receptor blockers (ARB) for patients hospitalised with new-onset (de novo) HF or decompensated congested heart failure to reduce the short-term risk of adverse events and to simplify management (by avoiding the need to down-titrate ACEi first and then switch to sacubitril/valsartan) since these patients are already at high risk of events. The recommendation also suggests that there is no need to check plasma concentrations of natriuretic peptides (BNP, NT-proBNP) prior to initiating sacubitril/valsartan.^{20–22}
- **Angiotensin-converting-enzyme inhibitors (ACEi)/Angiotensin-receptor blockers (ARBs) (only when neprilysin inhibitor with ARB is contraindicated):** If the patient has stable renal function, an ACEi or ARB can be administered. Angiotensin-converting-enzyme inhibitors (ACEi) have been the cornerstone of treatment for HF, since enalapril's efficacy to diminish the risk of mortality was reported in the two trials.^{23,24} The results of ARBs on mortality have not been consistent.^{25,26} ARBs are recommended in patients with HF who have adverse effects like cough arising from administration of ACEi.¹⁹
- **Beta-blockers:** reduces the risk of all-cause and cardiovascular mortality but increase the risk of bradycardia and hypotension.

Once BP is stable, beta-blockers can be safely administered.¹⁸ The dose should be carefully increased to reduce the heart rate to around 70 beats per minute.

- **Mineralocorticoid-receptor antagonists (MRAs):** can be given safely in chronic kidney disease patients with hypokalemia. MRAs provide mortality benefit; however, one needs to monitor creatinine and potassium before administering an MRA and monitor periodically later as well.
- **Ivabradine:** reduces the risk of HF hospitalization or cardiovascular death in symptomatic patients with HFrEF. It should be administered in patients with sinus rhythm.¹⁸ Ivabradine is indicated when the beta blockers are contraindicated or when heart rate could not be controlled with beta-blockers without side effects.
- **Diuretics:** are used in patients with HFrEF who have evidence of fluid retention. Diuretics can be down titrated once the fluid retention is reduced and patient has been stabilized.¹⁸
- **Miscellaneous therapy/therapies:** may include digoxin, nitrate, hydralazine, aspirin, statins, antiplatelet agents, anticoagulant agents, sodium-glucose transport protein 2 (SGLT2) inhibitors.
- **Iron:** Iron deficiency is very commonly seen in 40% of Indian patients with HF.¹⁸ In such cases IV iron should be given.
- **Vaccination:** All patients with HF before discharge should be vaccinated for pneumococcal vaccine (every 5 years) and influenza vaccine (every year)
- **Medical Device:** An implanted device (cardioverter defibrillator or cardiac resynchronization therapy defibrillator) may be considered for patients with HF who are at risk of sudden cardiac death after optimized medical therapy.

Date of next visit: Close follow-up should be done. Patients should be called within 10 days of discharge to ensure compliance and health status, and later on case-to-case basis as required.

4. Discussion

Guidance in the form of checklists can be utilized to provide uniformity in the evaluation and management of HF patients. Checklists facilitate rapid and optimum commencement of the required treatment, care, and monitoring mechanisms.

This standardized consensus document developed by cardiologists across India provides a checklist for maintaining continuum of care for patients with stabilized ADHF. This checklist can be used by all the doctors treating HF patients across India.

The usage of this checklist should be initiated when the patient is transitioning from ICU to ward or prior to discharge from the hospital. This checklist would minimize the chances of missing out prescribing an essential medication. Usage of this checklist during follow-up can help triage patients who need urgent attention and referral accordingly.

The data collected by use of this checklist can help measure outcomes like prescription of GDMT, education and adherence. Standardization of the data collection tool across India can help set up registries for HF patients in India. This checklist can also be a tool used by HF clinics/HF disease programs to maintain data and monitor practices. It was suggested that institutions, associations, and societies could recommend this checklist for adaptability both in public and private sectors and facilitate policy making. The major challenge anticipated in implementing the checklist is limited time available to consultants. It was suggested that a policy be rolled out by hospital administrations for adoption of checklists. The authors recommend this checklist be attached to the patient file at the time of discharge and the practice of filling it be diligently continued during follow up visits.

The authors propose a follow-up study to verify the effectiveness of this checklist, to check if using this checklist leads to a reduction in the frequency of readmissions.

4.1. Limitations

This article is for the management and monitoring of patients with stabilized ADHF, and not for acute HF or an acute decompensation of chronic HF. The selection of cardiologists was based on their interest and willingness to draft the consensus document.

5. Conclusion

Factors leading to higher readmission rates and mortality in India can be addressed through various strategies, the most important and promising one being the use of a checklist. The author's proposed checklist is consistent with international guidelines. The authors believe that this checklist would simplify management of patients with stabilized ADHF and can therefore be used by all healthcare professionals across India. A multidisciplinary team (HF nurse, dietitian, HF educator, counsellor) led by the treating physician should be able to complete the checklist. The checklist can support the management from in-hospital transition from ICU to general ward, at discharge and follow-up outpatient setting, and thus support continuum of care needed by patients with HF.

Conflicts of interest

Development of the checklist, writing/editorial support were funded by Novartis Healthcare Pvt Ltd, India. The Sponsor reviewed the initial draft and subsequent versions of the manuscript for own data accuracy and for proprietary evaluation. The authors were advisors of National and Regional Steering Committee Meetings across India to formulate the consensus document and received honoraria from Novartis.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ihj.2020.09.007>.

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