Analysis of Treatment Compliance Level and The Relationship with Quality of Life, New York Heart Association (NYHA) Classification, and Rehospitalization in Chronic Heart Failure Patients

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ABSTRACT

Background: Patient non-compliance with heart failure treatment is associated with increased rehospitalization, deteriorating symptoms, decreased quality of life, and death. Therefore, this study aimed to examine compliance with chronic heart failure treatment and the relationship with quality of life, New York Heart Association (NYHA) classification, and rehospitalization.

Method: A cross-sectional study of chronic heart failure patients was carried out at Airlangga University Hospital (RSUA) from April to June 2023. The inclusion criteria include patients aged >18 years, signed informed consent, able to read, write, and had no difficulty communicating. Meanwhile, the exclusion criteria were chronic heart failure patients with no known history of rehospitalization.

Results: The results showed that 41% of heart failure patients were compliant with RAASi, beta-blockers, MRA, and furosemide. Compliance with RAASi had a positive relationship with NYHA classification. However, a negative relationship was found between overall medication compliance and rehospitalization. There was no relationship between RAASi, beta-blockers, MRA, and furosemide compliance with the incidence of rehospitalization.

Conclusion: A positive relationship was found between compliance and RAASi medication with NYHA classification, while medication compliance to the incidence of rehospitalization showed a negative relationship.

Keywords: *Chronic Heart Failure, Compliance, Quality Of Life, Nyha Classification, Rehospitalization.*

1. INTRODUCTION

Heart failure is a condition characterized by structural and functional abnormalities, resulting in the inability to adequately fill ventricles or pump blood sufficiently to meet the body oxygen needs. Typical symptoms of heart failure include shortness of breath and fatigue [1, 2]. Furthermore, heart failure is included in the group of cardiovascular diseases and considered a global health problem [3]. It is associated with increased morbidity, mortality, and a large burden for health services. According to estimates, 64.3 million people worldwide are living with heart failure, and in developed countries, the prevalence ranges from 1% to 2% of the general adult population. The number of cases is 29.5 million in males and 34.8 million in females, while in Indonesia the prevalence is estimated at 5% [3, 4, 5 6]. The burden imposed by heart failure is not only significant in hospitalization and mortality rates but also in direct and indirect costs related to treatment [7]. Globally, the prevalence has doubled since 1990, increasing in 2017 from $33. 5 million to $64. 3 million [3].

According to *European Society of Cardiology*, risk factors for heart failure include *sedentary* lifestyle, smoking habits, obesity, microbial infections, use of cardiotoxic drugs, hypertension, chest radiation, diabetes mellitus, *coronary artery disease*, and influenza [1]. In Asia, heart failure patients with diabetes and hypertension are the highest compared to European countries, with the highest risk burden in Southeast Asia compared to South and North [8].

Heart failure treatment aims to reduce mortality rates, prevent recurrent hospitalizations due to deteriorating heart failure, improve clinical, functional capacity, and quality of life [1]. Patients receive combination treatment with ACE inhibitors, ARBs, or ARNIs along with β-blockers and aldosterone antagonists. Diuretics should be given when there is evidence of fluid retention. Other treatments may be considered in certain patients. In addition, heart failure treatment is also adjusted to the stage of patient heart failure [1, 2, 9].

Non-compliance with heart failure is associated with recurrent hospitalizations, worsening symptoms, decreased quality of life, and death [6, 10]. Compliance contributes to achieving therapeutic outcomes for chronic diseases. Identification of heart failure compliance can be useful for healthcare providers to map patients who are compliant and non-compliant in a hospital. Therefore, this study aimed to analyze the level of compliance and the relationship with quality of life, *New York Heart Association* (NYHA) classification, and rehospitalization at Airlangga University Hospital (RSUA), Surabaya.

2. METHOD

This study was conducted using a time-limited sampling method on a sample of chronic heart failure patients following KRS (Interim Care Control) at a single center, specifically the outpatient cardiac polyclinic of RSUA, Surabaya between June and August 2023. Data collection was carried out prospectively with a *cross-sectional* design, and *observationally* by conducting *interviews*, filling out ARMS-7 and SF-36 questionnaires, as well as *analyzing* the level of compliance and the relationship to quality of life, NYHA classification, and rehospitalization.

The inclusion criteria for this study were chronic heart failure patients who were outpatients aged >18 years and signed *informed consent*, as well as patients and families who could read, write, and had no difficulty communicating. Chronic heart failure patients with no known history of rehospitalization were excluded. The level of compliance was the independent variable, while the related variables included quality of life, NYHA classification, and rehospitalization.

Analysis was performed *univariately* to describe sociodemographic characteristics, compliance, quality of life, and rehospitalization, while *bivariate* analysis was performed using IBM SPSS software, Statistics used *Mann Whitney* Test and *Independent-T* test to explain the relationship between medication compliance and quality of life as well as between medication compliance and NYHA classification. *Chi-square* and *Fisher-Exact* tests were used to examine the relationship between medication compliance and rehospitalization. This study received approval from the ethics committee of Airlangga University Teaching Hospital, Surabaya, and was declared ethically feasible based on the certificate of passing the ethical review 1751/UN3.RS/PT/2023.

3. RESULT

A total of 39 heart failure patients who met the inclusion and exclusion criteria were interviewed in a structured manner according to the demographic, ARMS-7 (medication compliance *questionnaire*), and SF-36 *questionnaire* (quality of life *questionnaire*).

3.1. Sociodemographic and Medication Characteristics of Heart Failure Patients in Compliant and Less Compliant Groups

Sociodemographic and medication characteristics showed that 56.4% were male aged 60 years, most of whom were married, the highest level of education was high school, and a significant proportion had retired from jobs. The average BMI (Body Mass Index) in 53.8% of patients was *normal weight*, while hypertension was the most common comorbidity and dominated by groups with an ejection fraction of less than 50%. Table 1 shows data related to sociodemographics according to compliant and less compliant groups. The grouping was carried out to determine the presence of *confounding factors* that can affect quality of life, NYHA classification, and rehospitalization. The results showed that most characteristics had no significant difference between compliant and less compliant groups (p>0.05) except for dyslipidemia comorbidity (p-value = 0.002).

Table 1. Data on sociodemographic characteristics of heart failure patients in compliant and less compliant groups (N=39)

No	Variable	Compliant N (%)	Less Compliant N (%)	*p-value*
1	**Age (mean ± SD)**			
	≤60 years	10 (62,5)	9 (39,1)	0,338[a]
	>60 years	6 (37,5)	14 (60,9)	

No	Variable	Compliant N (%)	Less Compliant N (%)	*p-value*
2	**Gender**			
	Male	11 (68,7)	11 (47,8)	0,333[b]
	Female	5 (31,3)	12 (52,2)	
3	**Marital Status**			
	Married	12 (75)	15 (65,2)	
	Widower/ Widow/ Unmarried	4 (25)	8 (34,8)	0,726[c]
4	**Education Level**			
	Elementary School	3 (18,8)	9 (39,1)	
	Junior High School	2 (12.5)	2 (8,7)	
	Senior High School	5 (31,2)	10 (43,5)	
	College	6 (37,5)	2 (8,7)	0,65[a]
5	**Occupation**			
	Private	2 (12,5)	1 (4,4)	
	Self-Employed	0 (0)	1 (4,4)	
	Civil Servant/Police Officer	1 (6,3)	0 (0)	
	Not Working	13 (81,2)	21 (91,3)	0,383[b]
6	**BMI Category**			
	Underweight	1 (6,2)	3 (13,0)	0,621[a]
	Normal	9 (56,3)	12 (52,2)	
	Overweight	3 (18,8)	4 (17,4)	
	Obesity I	3 (18,7)	4 (17,4)	
7	**Comorbid**			
	DM	6 (37,5)	10 (43,5)	0,966[b]
	HT	8 (50)	14 (50,9)	0,730[b]
	Dyslipidemia	0 (0)	10 (43,5)	0,002[c]
	AF	0 (0)	3 (13,0%)	0,255[c]
	Stroke	1 (6,3)	0 (0%)	0,410[c]
8	**LVEF**			
	<50%	13 (81,3)	16 (69,6%)	
	>50%	3 (18,3)	7 (30,4%)	
9	**Patient Duration (n (%)**			
	≤1 years	13 (81,2)	16 (69,6%)	
	2-5 years	2 (12,5)	3 (13,0%)	0,580[b]
	>5 years	1 (6,3)	4 (17,4%)	

[a]The test was conducted using the *Mann Whitney Test*
[b] The test was conducted using the *Chi-square Test*
[c]The test was conducted using the *Fisher-Exact Test*

3.2 Use of drugs and dosage in heart failure patients in compliant and less compliant groups

This study showed the use of drugs and the average dosage of heart failure patients, who all received RAAS-inhibitor drugs, namely lisinopril, ramipril, candesartan, and ARNI. The results also showed patients who received beta-blocker drugs such as bisoprolol, as well as MRA drugs, namely spironolactone and Furosemide. The average dose received by patients

was smaller than the standardized dose. The overall average of drugs received by patients was 6.7 drugs from a range of 4 to 12 drugs.

Table 2 shows data on the use of drugs and dosage among heart failure patients in compliant and less compliant groups. A difference test was carried out between the two groups to determine the presence of confounding factors in patient drug use. The results showed that there was no difference in the type of drug and dosage consumed between compliant and less compliant groups (p-value> 0.05).

Table 2. Data on drug use and drug dosage in heart failure patients in compliant and less compliant groups

No	Variable	Compliant N (%)	Less Compliant N (%)	*p-value*
1	Number of drugs	6,75±1,77	5,61±1,47	0,904
2	RAAS inhibitor dose			
	Lisinopril (n = 4)	5,00 ± 0,0	8,3 ± 2,9	0,317
	Ramipril (n = 10)	3,00 ± 1,1	6,0 ± 3,8	0,155
	Candesartan (n = 24)	12,3 ± 2,2	9,5 ± 3,2	0,780
	ARNI (n = 1)	50		*
3	Beta-blocker dose			
	Bisoprolol (n = 38)	2,7 ± 0,1	2,7 ± 0,9	0,917
4	MRA dose			
	Spironolactone (n = 23)	28,8 ±9,4	30,0 ± 10,5	0,777
5	Loop Diuretics dose			
	Furosemide (n = 22)	40,0 ±0,00	45,0 ± 20,0	0,540

*The test was conducted using the *Mann-Whitney Test*
*The difference test cannot be performed because the sample is only 1

3.3 Distribution of ARMS-7 Questionnaire Questions

In the frequency distribution of items from ARMS-7 questionnaire, under *Compliance to Refill indicator*, which includes questions regarding delays in cardiac polyclinic follow-up appointments exceeding 30 days, despite patients receiving only 30 days worth of medication, and the regularity of daytime use, the highest percentage of respondents did not forget to refill prescriptions. Conversely, the lowest compliance was related to medication shortages with some patients occasionally running out of RAASi, beta-blockers, MRAs, and furosemide. This suggests that a primary cause of non-compliance was the unavailability of medication. Under c*ompliance to medication indicator*, the reason for non-compliance with treatment as a whole was that patients never forget to take medication, except for furosemide. Several reasons expressed regarding non-compliance with treatment include being preoccupied with work, families forgetting to prepare medicine, or patients taking

medicine according to the drug label only, as well as not taking medicine due to disturbing side effects or only when symptomatic.

3.4 Relationship of Heart Failure Patient Compliance Level to Quality of Life

This study used SF-36 questionnaire based on 8 dimensions with a value range of 0-100 to assess the quality of life. The results showed that 7 of the 8 dimensions of quality of life had a value of 50, and the highest was social function and the lowest was physical role.

To assess the relationship between heart failure patient compliance and quality of life, a bivariate test was carried out. The results in Table 3 showed that the overall level of treatment compliance was significant in the physical role dimension (p-value <0.05). More specifically, compliance with RAAS inhibitors was significantly associated with physical role and vitality. Compliance with MRA and *beta-blockers* showed a significant relationship to physical role (p-value <0.05). This suggests that patients who are compliant with the overall treatment, namely RAAS-inhibitors, MRA, and beta-blockers, tend to have higher scores on physical role than those who are not compliant, while patients with low vitality are associated with non-compliance with RAASi treatment. Furosemide did not show a significant relationship with the 8 dimensions of quality of life (p-value >0.05).

Table 3. Relationship between the level of compliance with heart failure treatment and quality of life

Overall medication compliance (n=39)			
Dimensions of quality of life	Compliance (mean±SD) n=16	Uncompliance (mean±SD) n=23	p-value
Physical Function	56,56±27,67	45,22±30,69	0,237[a]
Physical Role	37,5±34,16	17,39±28,64	**0,038[b]**
Pain	69,06±27,90	70,43±29,73	0,779[b]
General Health	61,46±16,28	60,68±19,66	0,897[a]
Social Function	85,94±22,30	84,02±28,01	0,648[b]
Emotion	54,17±29,50	63,95±36,58	0,376[b]
Vitality	79,38±15,90	70,43±19,89	0,144[a]
Metal Health	73,75±21,96	76,83±17,02	0,796[b]

[a] The relationship test was conducted using the *Independent T-test*
[b] The relationship test was conducted using the *Mann-Whitney Test*

3.5 New York Heart Association Classification in Heart Failure Patients

NYHA classification of heart failure patients showed a general improvement when patients were checked into heart polyclinic. Most patients were categorized as NYHA class II, followed by Class 1 and Class III. This indicates a shift in NYHA Class between the time of KRS and the follow-up visit. Table 4 shows that compliant group experienced

rehospitalization in NYHA II classification at the time of KRS, while in NYHA III classification, compliant group experienced rehospitalization.

Table 4. Number of rehospitalized patients based on NYHA classification at the time of KRS

NYHA Classification at KRS	Rehospitalization N (%)	Not Rehospitalized n (%)	Total N (%)
NYHA I	0	0	0
Compliant	0	0	0
Not Compliant	0	0	0
NYHA II	7 (25,9)	20 (74,1)	211 (100)
Compliant	5 (45,5)	6 (54,5)	7 (100)
Not Compliant	2 (12,5)	14 (87,5)	16 (100)
NYHA III Compliant	5 (41,7)	7 (58,3)	12 (100)
Not Compliant	3 (60)	2 (40)	5 (100)
	2 (28,6)	5 (71,4)	7 (100)

3.6. Relationship of Heart Failure Treatment Compliance Level to New York Heart Association Classification

The relationship between the level of compliance and changes in NYHA classification was analyzed, as shown in Table 5. The results showed that compliant group experienced a general improvement in NYHA class as indicated by the difference in NYHA values of 2 and 3. In contrast, non-compliant patients were more likely to show no change in NYHA between KRS and follow-up visits. Additionally, 1 patient showed a deterioration in functional status, shifting from NYHA Class II at discharge to NYHA Class III at follow-up, indicating a negative change (a difference of 1). The results showed that overall treatment compliance was related to the difference in NYHA classification (p-value = 0.014). Based on the relationship between treatment compliance per drug with the difference in NYHA classification, only RAASi compliance was related to NYHA classification (P-value = 0.004), while treatment compliance with beta-blockers, MRA, and furosemide had no relationship (p-value>0.05).

Table 5. Relationship between compliance level and NYHA classification differences

Overall medication compliance (n=39)			
NYHA Difference	**Compliant (n,%)**	**Less Compliant (n,%)**	**P-value**
-1	0(0)	1 (4,34)	0,014
0	4 (25)	13 (56,52)	
1	10 (62,5)	9 (39,1)	
2	2 (12,5)	0 (0)	
Total	16 (100)	23 (100)	

3.7. Rehospitalization After Discharge

Figure 1. shows that patients were rehospitalized due to *cardiovascular disease events* in 30-45 days post-KRS. Most of the incidents were due to *Acute Decompensated Heart Failure* (ADHF) and *Acute Coronary Syndrome* (ACS).

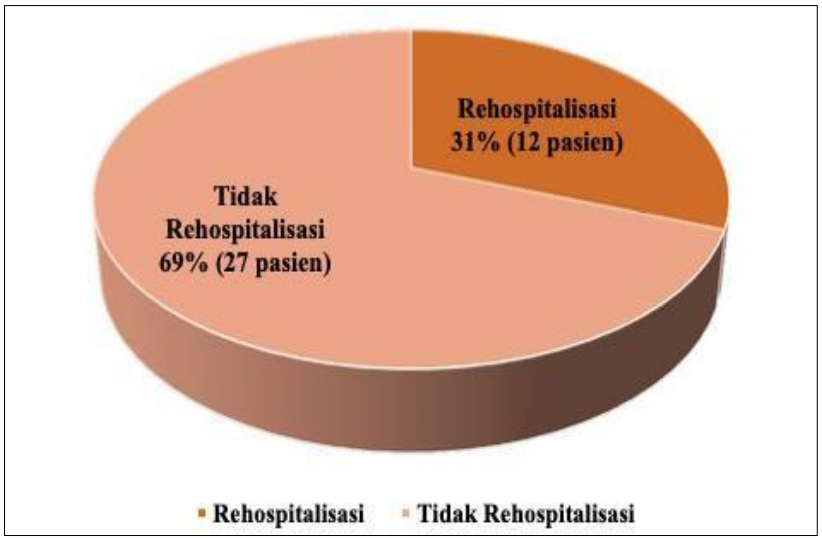

Figure 1. Rehospitalization incidents due to *cardiovascular disease events*

3.8 Relationship between Heart Failure Treatment Compliance Levels and Rehospitalization

Table 6 shows that for the relationship between heart failure treatment compliance levels and rehospitalization, compliant patients experienced more rehospitalization than those who were less compliant. This occurred in compliance per drug, showing that the percentage of rehospitalization in compliant patients was higher than in non-compliant. From the analysis results, overall medication compliance was related to rehospitalization (p-value = 0.014), but the relationship was negative because more rehospitalized patients were in compliant group. This implies that compliant patients tend to experience rehospitalization in 37-45 days post-KRS. Therefore, there is no relationship between medication compliance and rehospitalization (P-value>0.05).

Table 6. Relationship between the level of heart failure medication compliance and rehospitalization

Compliance rate	**No rehospitalization (n,%)**	**Rehospitalization (n,%)**	**Total (n,%)**	***P-value***
Total Compliance (N=39)				
Less Compliance	19 (82,6)	4 (17,4)	23 (100)	
Compliance	8 (50)	8 (50)	16 (100)	
Total	27 (69,2)	12 (30,8)	29 (100)	
				0,041[b]

[a] The relationship test was performed using the *Chi-square Test*

[b] The relationship test was performed using the *Fisher's Extract Test*

Treatment compliance was described following the type of drug, quality of life with 8 indicators, and NYHA classification based on the difference between KRS and outpatients in the cardiac polyclinic. This comprehensive approach aims to obtain the overall relationship between treatment and NYHA classification as well as the relationship between the incidence of rehospitalization in 45 days after discharge from the hospital in chronic heart failure patients at RSUA.

The results showed that chronic heart failure patients were dominated by males. This is in line with studies in Asia in which heart failure was more predominant in males than females [11]. This is because females have the hormone *estrogen* as a protective effect on heart including inhibition of RAAS activity and myocardial fibrosis, mitochondrial biogenesis, calcium regulation in cardiomyocytes, and stimulation of nitric oxide release [1, 6]. The average age of patients is 60 years, and age is one of the factors in the occurrence of heart failure. Cardiovascular changes in elderly affect chronotropic and inotropic responses, improve intracardiac pressure with ventricular filling, and increase *afterload* [12]. Elderly patients are included in the non-productive age category and accompanied by physical limitations. This study similarly observed that most patients were not working or retired. The majority of patients with higher education levels are Senior High School graduates. Most of BMI was *normal weight*, as also reported by studies conducted in Japan and India where the average BMI was 24 kg/m² [13]. Elderly patients tend to have a relatively stable body weight while muscle mass decreases and body fat increases [14, 15].

The highest comorbidities were hypertension and diabetes mellitus, in line with previous studies that reported hypertension, hyperlipidemia, diabetes mellitus, and atrial fibrillation [16, 17]. Approximately 74.4% of patients had LVEF ≤50%, indicating that most were experiencing chronic heart failure for less than or equal to 1 year. Studies from [18] explained that the duration of chronic diseases such as heart failure was related to compliance with taking medication. Patients who have had heart failure for more than 4 years will tend to be non-compliant [19].

All patients in this study received RAASi, *beta-blocker*, MRA, and furosemide drug classes, in line with other studies showing that the combination of RAASi, *beta-blocker*, and MRA drugs provides benefits by reducing *all-cause mortality*, cardiovascular death, *all-cause hospitalization*, and hospitalization for heart failure [1, 20]. The dose of each heart failure drug received by patients was lower than in the previous study [7]. Several factors

are responsible for lower doses such as advanced age, kidney function, hyperkalemia, and hypotension.

The level of compliance was assessed in chronic heart failure patients using ARMS-7 questionnaire with an emphasis on 2 indicators, namely *compliance to refill* (compliance to redeeming drugs) and *compliance to medication* (compliance to taking drugs). The results showed that overall medication compliance has a lower percentage than those who are not compliant. Similarly, [21] and [22] showed that most heart failure patients had low medication compliance. In *compliance to refill indicator*, the reasons for non-compliance include patients running out of drugs, and the availability of drugs in health services. In *compliance to medication indicator*, non-compliance can be identified as related to control schedules that exceed 30 days including holidays, caregivers who forget to prepare drugs, forgetting the schedule for taking drugs according to the label, disturbing side effects, deciding only to take drugs when symptomatic and not having hypertension. The last reason was that patients were often preoccupied with work. This non-compliance causes patients to forget taking medication due to the absence of symptoms. Patient reluctance to take medication was caused by side effects such as diuretic effects. Pharmacists should provide education regarding the importance of returning for timely check-ups and taking medication continuously. By providing education and services, pharmacists can effectively identify problems experienced by patients in taking medication and improve compliance.

Quality of life is one of the *outcomes* of heart failure treatment, and the assessment in this study was carried out using SF-36 questionnaire. The score for each dimension on SF-36 is 100, where the lower the value, the worse the patient quality of life [23]. The highest dimension, namely social function, suggested mental health and social relationships were least affected due to the influence of a social culture that provides support from the family as a contribution to mentality. The results indicate that heart failure patients tend to experience physical decline rather than mental (psychological), followed by mental health, vitality, general health, pain, emotional role, physical function, and physical role. The overall score of compliance test on quality of life has a significant relationship with the physical role dimension (p-value = 0.024).

This study found a relationship between compliance to RAASi, *beta-blockers*, and MRA with the quality of life in the physical role dimension (p-value <0.05), suggesting compliant patients are better at carrying out daily activities compared to non-compliant. Meanwhile, RAASi compliance was related to the vitality dimension. A systematic review

showed that RAASi (ACEI/ARB/ARNI) and *beta-blockers* can improve the quality of life in heart failure patients, but may worsen compliance after 3 years of use or 1 year of *follow-up*.

The results showed a shift in NYHA classification between hospital discharge and follow-up visits. Some patients experienced improvement (decrease in NYHA classification), others showed no change, while a few experienced worsening functional status. Rehospitalization occurred in the treatment compliance group. Compliant patients tend to have NYHA difference of 1 or 2 which means a decrease in NYHA from the time of KRS and follow-up visits to heart clinic. Based on the bivariate test results, treatment compliance was related to the difference in NYHA classification (p-value = 0.014). This shows compliance with treatment leads to a decrease in NYHA class from the time of discharge to follow-up visits.

A significant relationship was found between RAASi treatment compliance and NYHA classification, while no statistically significant association was found with beta-blockers, MRA, and furosemide. Overall compliance showed a significant relationship with rehospitalization within 45 days. However, the relationship was negative, indicating that compliant patients were associated with recurrent hospitalizations in the period of 37-45 days. A study by [24] in Tanzania showed that poor compliance increased the risk of rehospitalization in 90 days. Based on the results, there was also no relationship between compliance with RAAS inhibitors, beta-blockers, MRA, and furosemide and rehospitalization. These results differ from previous studies which found a relationship between RAASi and furosemide treatment with the incidence of Rehospitalization but no significant association was observed with MRA. The differences in the results can be attributed to the patients level of education, attitudes, and beliefs, interactions between pharmacists or other health workers, and less-than-optimal health service systems. Further studies are needed to explore dose variations and guideline-directed medical therapy (GDMT) implementation among heart failure patients in Indonesia, with a focus on the weaknesses related to the quality of life questionnaire and a smaller sample than previous studies.

4. CONCLUSION

In conclusion, this study assessed the level of compliance with treatment and the relationship with the quality of life, NYHA classification, and rehospitalization in outpatient heart failure patients. Compliance with overall treatment was achieved by 41% of patients,

and there was a positive relationship between compliance with RAASi treatment, beta-blockers, and MRA in the physical role dimension. RAASi treatment compliance was also related to the vitality dimension and NYHA classification. In addition, there was a negative relationship with the incidence of rehospitalization.

5. FUNDING

This study was no specific funding was provided

6. CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest to report regarding the present study.

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