ORIGINAL ARTICLE

A Prospective Observational Study to Determine Incidence and Outcome of Sepsis-induced Cardiomyopathy in an Intensive Care Unit

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Abstract

Introduction: Sepsis leads to left and/or right ventricular systolic and/or diastolic dysfunction resulting in adverse outcomes. Myocardial dysfunction can be diagnosed by echocardiography (ECHO) and early intervention can be planned. There are lacunae in Indian literature regarding the true incidence of septic cardiomyopathy and its influence on the outcome of patients admitted to intensive care unit (ICU).

Materials and methods: This prospective observational study was conducted on patients consecutively admitted with sepsis to the ICU of a tertiary care hospital in North India. In these patients, ECHO was performed after 48–72 hours to establish left ventricular (LV) dysfunction, in whom the ICU outcome was analyzed.

Result: The incidence of LV dysfunction was 14%. About 42.86% of patients had isolated systolic dysfunction, 7.14% of patients had isolated diastolic dysfunction, and 50.00% of patients had combined LV systolic and diastolic dysfunctions. The average days of mechanical ventilation in patients without LV dysfunction group (group I) was 2.41 $\pm$ 3.82 days as compared to 4.43 $\pm$ 4.27 days in patients with LV dysfunction (group II) ($p = 0.034$). Incidence of all-cause ICU mortality was 11 (12.79%) in group I and 3 (21.43%) in group II ($p = 0.409$). The mean duration of stay in ICU was 8.26 $\pm$ 4.41 days in group I as compared to 13.21 $\pm$ 6.83 days in group II.

Conclusion: We concluded that sepsis-induced cardiomyopathy (SICM) in ICU is quite prevalent and clinically significant. All-cause ICU mortality and length of ICU stay are prolonged in patients with SICM.

Keywords: Sepsis, Sepsis-induced cardiomyopathy, Septic cardiomyopathy.

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Highlights

This is the first study from India that has evaluated incidence and outcome of SICM. We have used ECHO as a standard for the diagnosis of LV dysfunction (systolic and diastolic). We have excluded any preexisting pathology of the myocardium by ECHO before considering them as a part of the study. Furthermore, the parameters used to assess systolic and diastolic dysfunctions are easily done on bedside and are reproducible.

Introduction

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection.[1] Sepsis results in a complex intramyocardial inflammatory response that leads to sepsis-induced myocardial dysfunction. Sepsis-induced cardiomyopathy (SICM) is defined traditionally as intrinsic and reversible systolic and/or diastolic dysfunction involving left and/or right ventricle.[2] Myocardial dysfunction results in to complications such as arrhythmias, congestive heart failure, ischemic events, valvular dysfunctions, and thrombus formation and these events further lead to worse outcomes. Routine screening with the use of bedside point-of-care tests like hemodynamics, electrocardiographic changes, and ECHO may lead to an early diagnosis. Likewise early intervention with modified therapeutics such as fluid restriction, anticoagulation, vasopressor use, and vasopressor choice may result in a better outcome. In the Indian population, to the best of our knowledge, there are no data regarding the true incidence of septic cardiomyopathy and its influence on the outcome of patients admitted to the ICU. In the present study, we intended to determine the burden of sepsis-induced cardiomyopathy in the Indian population and its effect on mortality and length of ICU stay in admitted patients.

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Materials and Methods

Study Design

This was a prospective observational study conducted on patients admitted with sepsis to the ICU of a tertiary care teaching hospital in North India from March 2020 to December 2020.

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Sample Size Calculation

The study of Narvaez et al.[3] observed that the incidence of sepsis-induced cardiomyopathy was 22.8%. Taking this as the reference value, with 10% margin of error and 5% level of significance, the minimum required sample size was 68 patients. To reduce the margin of error, the total sample size was 100.

Formula used was—$N \geq (i(1-i))/(ME/z_{\alpha})^2$

where Z_{α} is the value of Z at two-sided alpha error of 5%, *ME* is the margin of error, and *i* is the incidence rate.

Inclusion Criteria

- Patients aged 18 years and above.
- Patients having sepsis are defined as per 2016 sepsis-3 guidelines.[1]
- Patients with normal ECHO at the time of admission.

Exclusion Criteria

Patients were excluded if they had any of the following criteria:

- Patients with preexisting LV dysfunction based on clinical history and previous ECHO findings.
- Patients without known LV dysfunction but clinical and baseline investigations suggestive of preexisting cardiac disease.
- Patients with abnormal echocardiogram at the time of admission.
- Patients admitted with primary cardiac illness.
- History of uncontrolled hypertension.
- Absence of sinus rhythm such as atrial fibrillation, atrial flutter, any type of atrial-ventricular block, and presence of pacemaker.
- Pregnant patients.
- Patients with poor transthoracic ECHO window.
- Patients who left the hospital or died before the second ECHO, that is, 48–72 hours of window.
- Patients who developed acute coronary syndrome at any point of ICU or hospital stay.

Methodology

After obtaining written informed consent, in patients with sepsis, baseline characteristics like age, sex, and personal history such as smoking, obstructive airway disease, diabetes mellitus, hypertension, alcoholism, opioid abuse, and site of infection were compared. Prognostic markers like sequential organ failure assessment (SOFA) score, acute physiological and chronic health evaluation II (APACHE II) score, and lactate levels were compared with the worst documented value in the first 24 hours of admission. Index ECHO was done within the first 24 hours of admission to ICU and another ECHO was performed after 48–72 hours to establish LV dysfunction (systolic or diastolic). Mortality and duration of ICU stay were compared in both groups of patients, that is, patients without LV dysfunction (group I) or with LV dysfunction (group II). Infection site documentation was done after reporting any sign of infection on imaging like chest X-ray, CT scans, and ultrasonography or confirmation of growth of organism on blood, fluid, or tissue culture.

Statistical Analysis

The presentation of the categorical variables was done in number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The normality of data was analyzed by using Kolmogorov–Smirnov test. Nonparametric tests were used in the cases in which the data were not normal. The following statistical tests were applied for the results:

- The quantitative variables which were not normally distributed were compared using Mann–Whitney test (for two groups) and Kruskal–Wallis test (for more than two groups). The independent *t* test was used for comparison of quantitative variables that were normally distributed between two groups.
- The comparison of the qualitative variables was performed using Chi-square test. If an expected value was less than 5 in any cell, then Fisher's exact test was used.

A *p*-value of less than 0.05 was considered statistically significant.

Results

The mean age in group I was 57.02 ± 14.47 years, while in group II, it was 58.64 ± 16.69. There were 27 females (31.40%) and 59 males (68.60%) in group I and 7 females (50%) and 7 males (50%) in group II. The demographic characteristics of the study subjects are listed in Table 1. Both the groups were comparable in terms of past medical

Table 1: Comparison of baseline characteristics between patients without and with cardiac dysfunction

Baseline characteristics	*Without LV dysfunction (n = 86) group I*	*With LV dysfunction (n = 14) group II*	*Total*	*p-value*
Age (years)				
Mean ± SD	57.02 ± 14.47	58.64 ± 16.69	57.25 ± 14.72	0.637[†]
Median (25th–75th percentile)	60 (47–67)	62.5 (40–73)	60 (46–68)	
Range	20–81	35–78	20–81	
Gender				
Female	27 (31.40%)	7 (50%)	34 (34%)	0.173[§]
Male	59 (68.60%)	7 (50%)	66 (66%)	
Body mass index (kg/m²)				
<18.5	1 (1.16%)	1 (7.14%)	2 (2%)	0.426[‡]
18.5–24.99	39 (45.35%)	5 (35.71%)	44 (44%)	
25–29.99	29 (33.72%)	5 (35.71%)	34 (34%)	
≥30	17 (19.77%)	3 (21.43%)	20 (20%)	
Mean ± SD	25.7 ± 3.54	25.73 ± 4.03	25.7 ± 3.59	0.975[*]
Median (25th–75th percentile)	25.35 (23.45–28.1)	25.9 (24.2–28.3)	25.4 (23.55–28.1)	
Range	18.2–32.8	18.2–32	18.2–32.8	

[*]Independent *t* test, [†]Mann–Whitney test, [‡]Fisher's exact test, [§]Chi-square test

Table 2: Comparison of past medical history between patients without and with cardiac dysfunction

Past medical history	*Group I*	*Group II*	*Total*	*p-value*
No significant history	21 (24.42%)	2 (14.29%)	23 (23%)	0.127‡
Alcoholic	6 (6.98%)	2 (14.29%)	8 (8%)	
Chronic kidney disease	8 (9.30%)	1 (7.14%)	9 (9%)	
Chronic liver disease	10 (11.63%)	0 (0%)	10 (10%)	
Chronic obstructive airway disease	3 (3.49%)	0 (0%)	3 (3%)	
Stroke	3 (3.49%)	0 (0%)	3 (3%)	
Diabetes mellitus	27 (31.40%)	5 (35.71%)	32 (32%)	
Hypertension	1 (1.16%)	1 (7.14%)	2 (2%)	
Hypothyroid	1 (1.16%)	0 (0%)	1 (1%)	
Opium addiction	4 (4.65%)	1 (7.14%)	5 (5%)	
Psychiatry	0 (0%)	2 (14.29%)	2 (2%)	
Other thyroid illness	2 (2.33%)	0 (0%)	2 (2%)	
Total	86 (100%)	14 (100%)	100 (100%)	

‡Fisher's exact test

Table 3: Comparison of infection site between patients without and with cardiac dysfunction

Infection site	*Group I*	*Group II*	*Total*	*p-value*
Abdomen	11 (12.79%)	0 (0%)	11 (11%)	0.573‡
Blood	9 (10.47%)	2 (14.29%)	11 (11%)	
Bone	2 (2.33%)	0 (0%)	2 (2%)	
Brain	14 (16.28%)	0 (0%)	10 (14%)	
Lung	25 (29.07%)	7 (50%)	32 (32%)	
Pancreas	3 (3.49%)	0 (0%)	3 (3%)	
Skin	1 (1.16%)	0 (0%)	1 (1%)	
Spine	1 (1.16%)	1 (7.14%)	2 (2%)	
Soft tissue	6 (6.98%)	1 (7.14%)	7 (7%)	
Renal infections except urinary tract infection	2 (2.33%)	0 (0%)	2 (2%)	
Urinary tract infection	12 (13.95%)	3 (21.43%)	15 (15%)	
Total	86 (100%)	14 (100%)	100 (100%)	

‡Fisher's exact test

history (Table 2) and infection site (Table 3). Diabetes mellitus was the most common comorbid condition in both the groups. Lung was the most common site of infection in 29.07% of the patients followed by genito-urinary tract (13.95%) and abdomen (12.79%) in group I. In group II, the most common site of infection was lung (50%) followed by urinary tract (21.43%) and blood (14.29%). The mean SOFA score in group I was 6.55 ± 3.5 and 9.14 ± 3.06 in group II, which was statistically significant ($p = 0.013$). The mean APACHE II score was 13.73 ± 5.74 in group I and 18.86 ± 6.02 in group II ($p = 0.007$). Figure 1 shows the comparison of SOFA and APACHE II score between the groups. Mean lactate was 2.69 ± 1.4 mmol/L in group I and 3.46 ± 2.08 mmol/L in group II ($p = 0.174$). The average days of mechanical ventilation in group I were 2.41 ± 3.82 and 4.43 ± 4.27 in group II ($p = 0.034$). The number of patients without septic shock during study period was 38 (44.19%) in group I and 4 (28.57%) in group II ($p = 0.384$). Incidence of all-cause ICU mortality was 11 (12.79%) in group I and 3 (21.43%) in group II ($p = 0.409$). Mean duration of ICU stay was 8.26 ± 4.41 days in group I and 13.21 ± 6.83 days in group II.

The incidence of LV dysfunction was 14%. Mean left ventricular ejection fraction (LVEF) after 48–72 hours of ICU admission was 58.26 ± 2.4% in group I and 35.71 ± 9.58% in group II. There were 86 (100%) patients without diastolic dysfunction in group I and 6 (42.86%) in group II. There were three (21.43%) and five (35.71%) patients with grade II and grade III diastolic dysfunction,

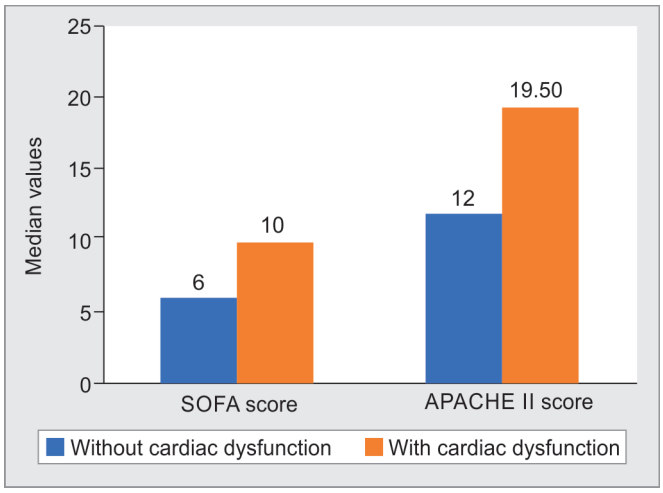

Fig. 1: Graphical presentation showing a comparison of SOFA and APACHE II score between the patients without and with cardiac dysfunction

Table 4: Comparison of ECHO parameters after 48 hours between patients without and with left ventricular dysfunction

ECHO parameters after 48 hours	*Without LV dysfunction (n = 86) group I*	*With LV dysfunction (n = 14) group II*	*Total*	*p-value*
Diastolic grade				
No diastolic dysfunction	86 (100%)	6 (42.86%)	92 (92%)	<0.0001‡
Grade I	0 (0%)	0 (0%)	0 (0%)	
Grade II	0 (0%)	3 (21.43%)	3 (3%)	
Grade III	0 (0%)	5 (35.71%)	5 (5%)	
LVEF (%)				
Mean ± SD	58.26 ± 2.4	35.71 ± 9.58	55.1 ± 8.88	<0.0001†
Median (25th–75th percentile)	60 (55–60)	35 (30–40)	60 (55–60)	
Range	55–60	25–60	25–60	

†Mann–Whitney test, ‡Fisher's exact test

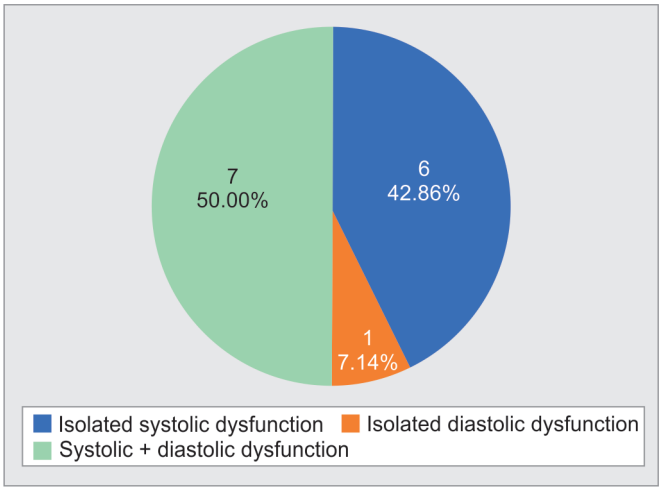

Fig. 2: Graphical presentation showing distribution of LV dysfunction among patients of group II

respectively, in group II patients. No patient in either group had grade I diastolic dysfunction. Table 4 shows the comparison of ECHO parameters after 48 hours between patients without and with cardiac dysfunction. Distribution of LV dysfunction is shown graphically in Figure 2. There were six (42.86%) patients with isolated systolic dysfunction, one (7.14%) patient with isolated LV diastolic dysfunction, and seven (50.00%) patients with combined LV systolic and diastolic dysfunctions. There were 13 patients who developed systolic dysfunction at 48 hours of admission. Out of these, two (15.38%) died during follow-up. Out of the remaining 11 patients, 9 (69.38%) had complete recovery of systolic dysfunction and 2 (15.38%) had persistent systolic dysfunction. There were eight patients who developed diastolic dysfunction at 48 hours of ICU admission. Out of these, three (37.50%) died during follow-up. Out of the remaining five patients, four (50.0%) had a complete reversal and one (12.50%) had persistent diastolic dysfunction at the time of discharge. There was no ICU mortality in isolated systolic dysfunction patients, 100% ($n = 1$) mortality in isolated diastolic dysfunction, and 28.57% ($n = 2$) mortality in combined dysfunction ($p = 0.154$). There was no hospital mortality in isolated systolic dysfunction patients, 100% ($n = 1$) mortality in isolated diastolic dysfunction, and 28.57% ($n = 2$) mortality in combined dysfunction. The mean duration of ICU stay was 13 ± 7.27 in isolated systolic dysfunction, 18 days in isolated diastolic dysfunction, and 12.71 ± 7.27 days in combined dysfunction. The mean duration of hospital stay was 16.67 ± 8.16 days in isolated systolic dysfunction, 18 days in isolated diastolic dysfunction, and 17.57 ± 10.53 days in combined dysfunction. Table 5 shows the association of outcome with LV dysfunction.

Discussion

There has been a significant advancement in the treatment of sepsis and septic shock, but it continues to be a major burden on healthcare system owing to high morbidity and mortality. Sepsis-induced cardiomyopathy (SICM) is an increasingly recognized entity and no gold standard diagnostic criteria exist for the diagnosis of SICM. A recent review article by L'Heureux et al. in 2020–2021 laid down a few fundamental features of SICM.[4] They suggested the following:

- Left ventricular (LV) dysfunction in SICM is acute and usually reverts within 7–10 days.
- LV dysfunction in sepsis is global, i.e., systolic and diastolic, involving both right and left ventricles.
- Left ventricle gets dilated.
- Patients may show decreasing responsiveness to volume and catecholamine resuscitation.
- Acute coronary syndrome is excluded as a cause for ventricular dysfunction.

As per this definition, the patient must survive the event to document the reversibility of dysfunction. The incidence of SICM in our study was 14%. Narvaez et al.[3] studied the incidence of SICM in 57 consecutive patients and reported a higher incidence of 22.8%. The mean LVEF was 34 ± 10.6% within the first 24 hours of admission, with complete recovery in survivors. The mean LVEF in our study was similar (35.71 ± 9.58%). The study by Narvaez et al. considered the first ECHO as the basis of the diagnosis of SICM so the preexistent LV dysfunction could not be ruled out. Further, they did not include diastolic dysfunction as the inclusion criteria for the diagnosis of SICM. Another recent study by Hanumanthu et al. studied 168 patients with septic shock.[5] They followed the findings of index ECHO within 72 hours of admission and were considered as SICM if they had a reversible decline in the ejection fraction of more or equal to 10%. Incidence of SICM in their study was 9.5% with the mean LVEF of 25%. The same study characteristically considered reversibility as the inclusion criteria for 42 SICM patients. They included a large sample size; however, as it was a retrospective data

Table 5: Association of clinical outcome with left ventricular dysfunction

Outcome	*Isolated systolic dysfunction (n = 6)*	*Isolated diastolic dysfunction (n = 1)*	*Systolic + diastolic dysfunction (n = 7)*	*Total*	*p-value*
ICU mortality					
No	6 (100%)	0 (0%)	5 (71.43%)	11 (78.57%)	0.154‡
Yes	0 (0%)	1 (100%)	2 (28.57%)	3 (21.43%)	
Hospital mortality					
No	6 (100%)	0 (0%)	5 (71.43%)	11 (78.57%)	0.154‡
Yes	0 (0%)	1 (100%)	2 (28.57%)	3 (21.43%)	
Duration of ICU stay (days)					
Mean ± SD	13 ± 7.27	18 ± 0	12.71 ± 7.27	13.21 ± 6.83	
Median (25th–75th percentile)	12.5 (7.25–17)	18 (18–18)	10 (7.5–16)	12.5 (6.75–18)	0.681¶
Range	5–24	18–18	6–26	5–26	
Duration of hospital stay (days)					
Mean ± SD	16.67 ± 8.16	18 ± 0	17.57 ± 10.53	17.21 ± 8.78	
Median (25th–75th percentile)	16 (10.5–20)	18 (18–18)	14 (10–22.5)	15 (10–20.25)	0.823¶
Range	8–30	18–18	9–35	8–35	

‡Fisher's exact test, ¶Kruskal–Wallis test

analysis, they could not firmly exclude preexisting LV dysfunction on the basis of previous history and ECHO findings. They did not include isolated diastolic dysfunction as criteria for diagnosing SICM either. This study included patients with septic shock only. However, this was not the case in our study as we included all patients with sepsis irrespective of the presence or absence of shock. Many other studies, including a study by Li et al.,[6] conducted a retrospective analysis and reported an incidence of 18.8%. A wide range of incidence rates can be attributed to the lack of any consensus definition of SICM. Another explanation could be the varied timing of ECHO done for the diagnosis, as examination findings may vary at different points of time either because of the reversibility of infective process or the use of vasopressors like norepinephrine. The baseline characteristics like age, sex, and body mass index were comparable in patients with or without LV dysfunction. The study subjects in both the groups of our study were having lung infection in the majority and the result was not statistically significant. We could not establish any linear relationship of site of infection with SICM with present data.

A study by Sato et al.[7] showed a higher SOFA (median 10 vs 7) and APACHE II scores (median 27 vs 21) in patients with SICM vs without SICM. The high APACHE II and SOFA scores at the time of admission were associated with a higher chance of developing SICM. Havaldar et al.[8] concluded that mitral annular plane systolic excursion (MAPSE) APACHE II score combined is a good predictor of mortality. Another similar study by Bergenzaun et al.[9] studied 50 patients prospectively and concluded that MAPSE and SOFA scores are good predictors of outcome in shock patients. The results of our study were comparable to previous studies. The mean lactate was higher in SICM group; however, it was not statistically significant. This is comparable to other studies. Li et al.[6] concluded lactate levels >4 mmol/L at the time of admission as an independent risk factor for SICM.

Average days of mechanical ventilation were 4.43 ± 4.27 in SICM patients. Incidence of septic shock was 71.43% in patients with LV dysfunction. However, the difference was not statistically significant. All-cause ICU mortality was 21.43% in patients with SICM and average duration of ICU stay was 12.5 days (6.75–18). Length of hospitalization was longer and statistically significant ($p = 0.007$) as compared to the patients with normal LV function. Sato et al.[7] reported an average length of ICU stay of 8 days (6–20) and in-hospital mortality of 24.1% in SICM patients which is comparable to our study. Length of stay in the ICU is influenced by multiple factors such as varied hospital policies, facilities of monitoring in wards, primary disease, complications, and monitoring of therapy. There is a lack of data available on the duration of ICU stay in SICM patients, especially from India.

In our study, we had six (42.8%) patients with isolated systolic dysfunction, one (7.14%) patient with isolated LV diastolic dysfunction, and seven (50%) patients with combined LV systolic and diastolic dysfunctions. Out of the total 14 patients, 2 patients died were having combined LV systolic and diastolic dysfunctions, 1 patient with isolated LV diastolic dysfunction as depicted in Table 5. There was 100% recovery in isolated LV systolic dysfunction. Earlier studies by Parker et al.[10] suggested that the occurrence of septic cardiomyopathy as protective as 10 out of the 13 survivors had LVEF of 40%. Other recent studies have shown worse outcomes. The relationship between systolic dysfunction and outcome is still not clearly defined. Landesberg et al.[11] reported an incidence of isolated diastolic dysfunction at 38%, combined systolic and diastolic dysfunctions at 14.1%, and isolated systolic dysfunction at 9.1%. This study reported worse outcomes in patients with SICM. Another study by Sturgess et al.[12] concluded diastolic dysfunction as an independent predictor of mortality better than cardiac biomarkers.

We have shown the incidence of SICM, and its presence leads to worse outcomes in our study. All patients were studied by transthoracic ECHO. As echocardiogram is considered as "point-of-care" test for ICU patients and with a modest learning curve, it can provide valuable information regarding myocardium status and treatment modifications need to be done by intensivists.

Prognostic scores in the ICU like SOFA and APACHE II already exist and provide valuable information regarding predictive outcomes of patients. ECHO, which is available bedside, can provide

valuable information about the myocardium status. More research is needed to consider it as an independent predictor of mortality and include it in various ICU prognostic scores. These imaging techniques and derived parameters may prove fruitful as dynamic variables for therapy modification.

Limitations of Study

As this study was a single-center study and the sample[4] size was small, findings cannot be applied to the general population. All observations were collected by a single observer. Any patient who developed LV dysfunction after 72 hours of admission was not included in the study. We could not study the impact of different therapeutic interventions on ECHO findings over a period of time. During the hospitalization period in patients with global LV dysfunction, we could not definitely be ruled out the evidence of acute coronary syndrome (type II MI)[13] as coronary angiography was not performed. However, best efforts were done on the basis of clinical, ECG, and ECHO findings to rule out myocardial infarction.

Conclusion

After going through various aspects of the study, we may conclude the following:

- Sepsis-induced cardiomyopathy in ICU is quite prevalent and clinically significant.
- Sepsis-induced cardiomyopathy (SICM) patients have higher SOFA and APACHE II scores at the time of admission.
- All-cause ICU mortality and length of stay in ICU are prolonged in patients with SICM.

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