


## ORIGINAL ARTICLE

# Prophylactic implantation of cardioverter-defibrillator in patients with advanced light-chain amyloidosis—A pilot study

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## Abstract

**Background:** Ventricular arrhythmias (VAs) and electromechanical dissociation have been observed as the most common causes of sudden cardiac death (SCD) in patients with light chain (AL) amyloidosis. However, an implantable cardioverter-defibrillator (ICD) has rarely been implanted in patients with advanced AL amyloidosis due to very poor prognosis.

**Methods:** Between July 2021 and December 2022, 10 patients with advanced cardiac AL amyloidosis referred to our institute who received prophylactic ICD implantation were prospectively recruited. The primary endpoint was the prevalence of VAs and appropriate ICD therapies determined by ICD interrogation. The secondary endpoint was all-cause mortality during the follow-up period.

**Results:** During a mean follow-up of  $12.1 \pm 4.4$  months, sustained ventricular tachycardia (VT)/ventricular fibrillation (VF) occurred in 4 of 10 (40%) patients. One patient had spontaneous termination of VT before the delivery of ICD therapy, and the remaining 3 patients had ICD therapies used, either ATP or shock. Inappropriate shock was not recorded in any patients. Patients with sustained VT/VF had wider QRS duration ( $143 \pm 41$  vs.  $99 \pm 10$  ms,  $p = 0.03$ ) and a higher incidence of bundle branch block (BBB)/interventricular conduction delay (IVCD) (75% vs. 0%,  $p = 0.01$ ) compared to those without.

**Conclusion:** VAs are commonly observed among patients with advanced AL amyloidosis, and ICD therapy can be effective in successfully treating sustained VA in these patients. On the basis of our preliminary data, prophylactic ICD implantation may be proposed to the advanced AL amyloidosis to improve the survival rate in selected patients with advanced AL amyloidosis, especially for the patients with wider QRS duration and BBB/IVCD.

## KEYWORDS

amyloidosis, implantable cardioverter-defibrillator, survival, ventricular arrhythmia

Hui-Qiang Wei and Jinghua Wang contributed equally to this work.

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## 1 | INTRODUCTION

Amyloidosis is an infiltrative multisystem disease of protein conformation and metabolism dysfunction that results in tissue deposition of insoluble fibrils. Light chain (AL) amyloidosis is a rare plasma cell dyscrasia characterized by overproduction of misfolded monoclonal light chains deposited in multiple organs, leading to progressive organ damage.<sup>1,2</sup> Cardiac involvement occurs in 60% of patients with AL amyloidosis and can result in progressive heart failure, arrhythmias, and conduction abnormalities.<sup>3</sup> Ventricular arrhythmias (VAs) and electromechanical dissociation have been observed as the most common cause of sudden cardiac death (SCD) in patients with AL amyloidosis.<sup>4–6</sup> Implantable cardioverter-defibrillator (ICD) is safe and effective in preventing SCD caused by fatal VAs. However, as consensus guidelines recommend against ICD placement for the prevention of SCD in patients with a life expectancy of less than 1 year, ICD has rarely been implanted in patients with advanced Mayo Stage III AL amyloidosis due to very poor prognosis.<sup>7,8</sup>

Over the past decade, concomitant with advances in disease-specific therapy for AL amyloidosis, the prognosis of this type of patient has improved.<sup>9–11</sup> In the meanwhile, there has been an increasingly recognized association between cardiac amyloidosis and VAs, including several studies of successful defibrillation in a significant proportion of cases with ICD.<sup>12,13</sup> This raises the possibility that ICD may have a role in the management of patients with AL amyloidosis, which previously was often not considered when the overall prognosis was more dismal.

In this study, we sought to investigate the impact of prophylactic ICD implantation on the value of the patients with newly diagnosed advanced AL amyloidosis and to predict the risk factors associated with VAs in this population.

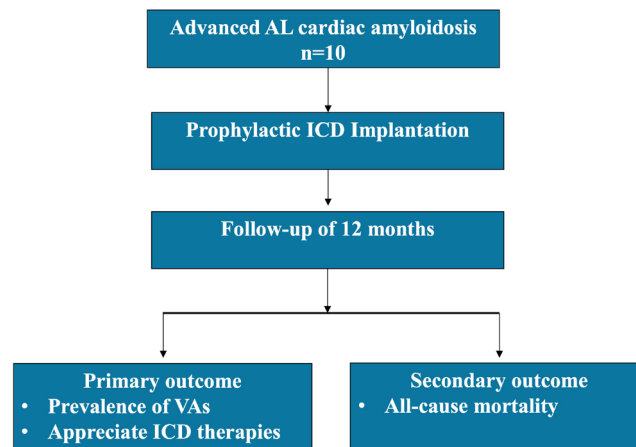
## 2 | METHODS

### 2.1 | Study population

Between July 2021 and December 2022, consecutive patients with advanced cardiac AL amyloidosis referred to our institute who received prophylactic ICD implantation were prospectively recruited for analysis (Figure 1). All patients provided written informed consent prior to the insertion of the ICD. This study was approved by the Ethics Committee of the Guangdong Provincial People's Hospital (approval no. KY-Q-2022-063-02).

### 2.2 | Baseline clinical assessments

A comprehensive clinical consultation was performed in each case. All patients underwent electrocardiogram (ECG), transthoracic echocardiography including tissue Doppler imaging, Holter monitoring, and laboratory testing including N-terminal pro-brain



**FIGURE 1** Flowchart of consecutive patients with advanced light chain cardiac amyloidosis enrolled in this study. AL, light chain; ICD, implantable cardioverter-defibrillator; VA, ventricular arrhythmia. ICD treatment was successful in the majority of patients. Patients with wider QRS duration and RBBB/IVCD were more likely to experience sustained VAs. A higher level of hs-cTnT and wider QRS duration were significantly associated with mortality in patients with advanced AL amyloidosis. Hs-cTnT, high-sensitivity cardiac Troponin T; ICD, implantable cardioverter-defibrillator; IVCD, interventricular conduction delay; RBBB, right bundle branch block; VA, ventricular arrhythmia.

natriuretic peptide (NT-ProBNP) and high-sensitivity cardiac Troponin T (hs-cTnT). Serological investigations included the identification and quantitation of any circulating paraprotein and the measurement of serum free light chains differential (dFLC). Stage was classified according to the widely used Mayo 2012 staging system.<sup>14</sup> Diastolic dysfunction on echocardiography was graded as mild, moderate, or severe, and left ventricular (LV) strain was assessed by tissue Doppler imaging.

### 2.3 | Laboratory markers

The updated Mayo prognostic scoring model for AL-type amyloidosis includes hs-cTnT, NT-ProBNP, and dFLC. The following criteria were used for staging: hs-cTnT  $\geq 0.04$  ng/mL, NT-ProBNP  $\geq 1800$  pg/mL, and dFLC  $\geq 180$  mg/L. Each variable was assigned a score of 1, and patients with AL-type amyloidosis were categorized into four stages (I, II, III, IV for scores of 0, 1, 2, 3, respectively).

### 2.4 | ICD programming

All patients had a standard ICD programming with a ventricular tachycardia (VT) zone starting at 170 bpm, usually with a long detection time (e.g., number of intervals to detect = 30/40) and a ventricular fibrillation (VF) zone starting at 220 bpm. Antitachycardia pacing (ATP), including three bursts and three ramps followed by shocks, was set for the VT zone (i.e., 170–220 bpm.), whereas high energy shocks only (with one antitachycardia pacing attempt during charge)

were programmed for the VF zone (i.e., VF or VT > 220bpm). Pacing was programmed for activation at a minimum of 40bpm (single chamber) or 60bpm (dual chamber).

## 2.5 | Outcome variables

The primary endpoint was the prevalence of VAs and appropriate ICD therapies determined by ICD interrogation. The secondary endpoint was all-cause mortality during the follow-up period. Patients after device implantation were followed at 1 month, 3 months, and then every 6 months or sooner if clinically indicated.

VA was classified as VF if a rate was <240bpm; VT was defined as a rate between 120bpm and 240bpm and was further classified as sustained if it required ATP or a shock for termination. Stored electrograms of the first ICD therapy after implantation were reviewed if available, in order to determine the type of arrhythmia and appropriateness of therapy. If the therapy was delivered for sustained VT or VF, it was deemed appropriate. Inappropriate therapy was defined as that delivered for supraventricular tachycardia or due to device malfunction. If electrograms were not available, the classification was contingent upon clinical documentation during clinic visits. Nonsustained VT (NSVT) was defined as the presence of >3 beats at a rate >120bpm.

## 2.6 | Statistical analysis

All continuous variables are presented as mean  $\pm$  standard deviations. The categorical variables are expressed as numbers and percentages. Categorical variables were compared using chi-squared analysis. Continuous variables were compared using the Student *t* test or Mann-Whitney *U* test, depending on data distribution. A two-tailed value of  $p < 0.05$  was considered statistically significant. All statistical analyses were performed using SPSS 21.0 (SPSS, Inc., Chicago, IL, USA).

## 3 | RESULTS

### 3.1 | Patient characteristics

From July 2021 to December 2022, a total of 10 patients with advanced cardiac AL amyloidosis who received prophylactic ICD implantation at our institute were enrolled. Baseline clinical characteristics are summarized in Table 1. Study patients had a mean age of  $60.7 \pm 11.3$  years. The mean hs-cTnT, mean NT-ProBNP concentration, and dFLC were  $0.13 \pm 0.09$  ng/mL,  $7257 \pm 4582$  pg/mL, and  $2903 \pm 5276$  mg/L, respectively. Two patients were classified as stage III, and 8 patients as stage IV with the updated Mayo 2012 staging system. On 12-lead ECG, the mean PR interval and QRS duration were  $211 \pm 64$  and  $117 \pm 33$  ms.

TABLE 1 Baseline clinical characteristics.

| Patients                          | n = 10          |
|-----------------------------------|-----------------|
| Age (years)                       | $60.7 \pm 11.3$ |
| Male gender (%)                   | 7 (70)          |
| NYHA class                        | $3.0 \pm 0.8$   |
| 24-h Holter recording             |                 |
| NSVT                              | 5 (50%)         |
| Atrial arrhythmias                | 6 (60%)         |
| Heart rate mean (bpm)             | $73.7 \pm 9.0$  |
| Medication                        |                 |
| Renin-angiotensin system blockade | 2 (20%)         |
| Beta-blockers                     | 0               |
| Amiodarone                        | 2 (20%)         |
| Anticoagulant therapy             | 6 (60%)         |
| NT-ProBNP (pg/mL)                 | $7257 \pm 4582$ |
| Cardiac troponin T (ng/ml)        | $0.13 \pm 0.09$ |
| dFLC (mg/L)                       | $2903 \pm 5276$ |
| Updated Mayo Clinic disease stage |                 |
| III                               | 2 (20%)         |
| IV                                | 8 (80%)         |
| Echocardiography                  |                 |
| LVEF (%)                          | $60.2 \pm 8.0$  |
| GLS                               | $-10.0 \pm 2.9$ |
| Septal wall thickness (mm)        | $12.9 \pm 1.8$  |
| E/e'                              | $22.2 \pm 15.0$ |
| LA (mm)                           | $39.7 \pm 4.1$  |
| Electrocardiogram                 |                 |
| PR interval (ms)                  | $211 \pm 64$    |
| Bundle branch block (%)           | 3 (30%)         |
| QRS duration (ms)                 | $117 \pm 33$    |
| ICD type                          |                 |
| Single chamber                    | 4 (40%)         |
| Dual chamber                      | 6 (60%)         |

Note: Values are expressed as mean  $\pm$  SD or as n (%).

Abbreviations: dFLC, free light chains differential; GLS, global longitudinal strain; ICD, implantable cardioverter defibrillator; LA, left atrial; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-brain natriuretic peptide; NSVT, nonsustained ventricular tachycardia; NYHA, New York Heart Association.

First-degree atrioventricular block was observed in 4 patients. Two patients had right bundle branch block (RBBB) and 1 patient with interventricular conduction delay (IVCD). On echocardiography, the mean interventricular septal thickness was  $12.9 \pm 1.8$  mm and the mean left ventricular ejection fraction (LVEF) was  $60.2 \pm 8.0\%$ . Only two patients were tolerant of neurohormonal blockade due to renal impairment, hypotension, or a combination of the two. Six patients received anticoagulant therapy due to atrial fibrillation. All patients underwent chemotherapy.

TABLE 2 Patient characteristics and the results of ICD therapy.

| Patient no. | Age (years) | Gender | NYHA class | Updated Mayo Clinic disease stage | LVEF (%) | QRSd (ms) | Bundle branch block | Presence of NSVT | Sustained VT/VF | ICD therapy                                    | Survival |
|-------------|-------------|--------|------------|-----------------------------------|----------|-----------|---------------------|------------------|-----------------|--|----------|
| 1           | 44          | M      | II         | III                               | 53       | 102       | N                   | N                | N               | N  | Alive    |
| 2           | 48          | F      | III        | III                               | 66       | 86        | N                   | Y                | N               | N  | Alive    |
| 3           | 54          | F      | IV         | IV                                | 68       | 94        | N                   | N                | VT              | Shock aborted owing to spontaneous termination | Alive    |
| 4           | 59          | F      | III        | IV                                | 55       | 114       | N                   | N                | N               | N  | Alive    |
| 5           | 58          | M      | II         | IV                                | 53       | 182       | RBBB                | N                | VT              | ATP  | Death    |
| 6           | 58          | M      | IV         | IV                                | 64       | 126       | IVCD                | Y                | VF              | Shock  | Alive    |
| 7           | 83          | M      | IV         | IV                                | 45       | 98        | N                   | Y                | N               | N  | Alive    |
| 8           | 65          | M      | III        | IV                                | 68       | 103       | N                   | Y                | N               | N  | Death    |
| 9           | 69          | M      | II         | IV                                | 64       | 96        | N                   | Y                | N               | N  | Alive    |
| 10          | 69          | M      | III        | IV                                | 66       | 172       | RBBB                | N                | VF              | Shock  | Death    |

Abbreviations: ICD, implantable cardioverter defibrillator; IVCD, interventricular conduction delay; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; NSVT, nonsustained ventricular tachycardia; RBBB, right bundle branch block; VF, ventricular fibrillation; VT, ventricular tachycardia.

TABLE 3 Comparison of clinical data in patients with and without sustained VAs.

|                            | Sustained VAs (n = 4) | No sustained VAs (n = 6) | p value |
|----------------------------|-----------------------|--------------------------|---------|
| NT-ProBNP (pg/mL)          | 9239 ± 5268           | 5937 ± 3989              | 0.09    |
| Cardiac troponin T (ng/mL) | 0.19 ± 0.12           | 0.06 ± 0.02              | 0.08    |
| dFLC (mg/L)                | 5193 ± 7920           | 1376 ± 2339              | 0.06    |
| LVEF (%)                   | 62.8 ± 6.7            | 58.5 ± 9.0               | 0.44    |
| GLS                        | -9.7 ± 2.6            | -10.4 ± 3.1              | 0.75    |
| E/e'                       | 31.2 ± 20.1           | 17.8 ± 5.8               | 0.28    |
| Septal wall thickness (mm) | 13.5 ± 2.6            | 12.5 ± 1.2               | 0.45    |
| LA (mm)                    | 41.5 ± 3.0            | 38.5 ± 0.45              | 0.28    |
| PR interval (ms)           | 248 ± 82              | 191 ± 42                 | 0.15    |
| Bundle branch block (%)    | 3 (75%)               | 0 (0%)                   | 0.01    |
| QRS duration (ms)          | 143 ± 41              | 99 ± 10                  | 0.03    |
| Presence of NSVT           | 2 (50%)               | 3 (50%)                  | 0.33    |

Note: Values are expressed as mean ± SD or as n (%).

Abbreviations: dFLC, free light chains differential; GLS, global longitudinal strain; LA, left atrial; LVEF, left ventricular ejection fraction; NSVT, nonsustained ventricular tachycardia; NT-proBNP, N-terminal pro-brain natriuretic peptide; VA, ventricular arrhythmia.

### 3.2 | Primary outcome

During a mean follow-up of  $12.1 \pm 4.4$  months, sustained VT/VF occurred in 4 of 10 (40%) patients (Table 2). Of the 4 patients with VT/VF, one patient had spontaneous termination of VT before the delivery of ICD therapy. The remaining three patients had ICD therapies used, either ATP or shock. ICD therapy was successful in two of three patients, resulting in the termination of the arrhythmia. One patient who received ICD therapy had sustained VT treated successfully with ATP. One patient with sustained VT was successfully terminated with shock therapy. One patient had a VF arrest with the delivery of ICD shock but was unable to terminate the arrhythmia. Eventually, this patient died after treatment failure owing to pulseless electrical activity (PEA). Inappropriate shock was not recorded in all patients.

### 3.3 | Predictors of sustained VT/VF

Patients with sustained VT/VF had wider QRS duration ( $143 \pm 41$  vs.  $99 \pm 10$  ms,  $p = 0.03$ ) and higher incidence of RBBB/IVCD (75% vs. 0%,  $p = 0.01$ ) compared to those without. The levels of hs-cTnT ( $0.19 \pm 0.12$  vs.  $0.06 \pm 0.02$  ng/mL,  $p = 0.08$ ), NT-proBNP ( $9239 \pm 5268$  vs.  $5937 \pm 3989$  pg/mL,  $p = 0.09$ ), and dFLC ( $5193 \pm 7920$  vs.  $1176 \pm 2339$  mg/L,  $p = 0.06$ ) trended higher in

patients with sustained VT/VF (Table 3). In multivariate analysis, no variables were independently associated with the risk of sustained VT/VF.

### 3.4 | Secondary outcome

Death occurred in 3 of 10 (30%) patients over the follow-up period. One patient (No. 5) died due to respiratory failure following coronavirus infection. The causes of death in the other two patients were terminal heart failure (No. 8) and PEA (No. 10). The level of hs-cTnT was significantly higher ( $0.23 \pm 0.1$  vs.  $0.09 \pm 0.06$  ng/mL,  $p = 0.03$ ), and QRS duration was wider ( $171 \pm 11$  vs.  $102 \pm 13$  ms,  $p < 0.001$ ) in nonsurvivors than in survivors.

## 4 | DISCUSSION

### 4.1 | Major findings

The average survival time of patients suffering from AL amyloidosis with Mayo stage IV is less than 6 months, and SCD is usually an important cause of early death. The current study evaluated the impact of prophylactic implantation of ICD in patients with advanced AL amyloidosis. The main findings of our study are (1) sustained VAs were commonly observed in patients with advanced AL amyloidosis, and ICD treatment was successful in the majority of patients; (2) patients with wider QRS duration and RBBB/IVCD were more likely to experience sustained VAs; and (3) higher levels of hs-cTnT and wider QRS duration were significantly associated with mortality in patients with advanced AL amyloidosis.

### 4.2 | Efficacy of primary prevention with ICD

Several studies have reported the high incidence of ICD therapy in primary prevention patients with cardiac amyloidosis.<sup>4,12,15,16</sup> Kristen et al.<sup>4</sup> reported 19 AL amyloidosis patients with high risk for SCD who received primary prevention ICD therapies. The results described that two patients with sustained VT were successfully treated by ICD. Lin et al.<sup>15</sup> presented 33 patients with AL amyloidosis, 25 with primary prevention indications. Their results showed that 6 of 25 patients experienced at least one appropriate shock therapy during a median follow-up of 23 months. Varr et al.<sup>12</sup> found that 80% of patients with cardiac amyloidosis had successful ICD therapy for life-threatening VAs. Kim et al.<sup>16</sup> studied 23 AL amyloidosis patients with primary ICD prevention. In their study, 6 patients received appropriate ICD therapies. However, ICD has rarely been implanted in patients with advanced AL amyloidosis in previous studies. In our pilot study, 10 patients with advanced AL amyloidosis received primary ICD prevention, and ICD therapy was successful in 67% of patients. Inappropriate shock was not observed in any patients. Our study indicated that successful ICD therapy was relatively high in

patients with advanced AL amyloidosis, and these patients might benefit from the primary ICD prevention.

### 4.3 | Incidence and predictors of sustained ventricular arrhythmias

Previous studies have reported that the incidence of sustained VAs was high within the cardiac amyloidosis population. Varr et al.<sup>12</sup> reported that sustained VT/VF occurred in 19% of patients. Hamon et al.<sup>17</sup> demonstrated that 27% of patients experienced monomorphic VT and VF. In the present study, sustained VT or VF occurred in 40% of patients with advanced AL amyloidosis. Patients with wider QRS duration and RBBB/IVCD had a higher incidence of VT/VF, suggesting widespread involvement of the myocardium and the conduction system. This may provide an anatomical substrate responsible for reentrant VA. These patients may need close monitoring for the development of conduction system diseases that require ICD implantation during follow-up.

### 4.4 | Mortality outcome in advanced AL amyloidosis

Advanced AL amyloidosis is a severe disease with a high mortality rate. The leading cause of death in this population involves cardiac disease, such as PEA or terminal heart failure.<sup>17,18</sup> ICD indication in this specific population remains unclear. Currently, the mortality rate of these patients is decreasing due to a better understanding of the disease and more appropriate specific therapy. Kim et al. studied 91 patients with cardiac amyloidosis to assess survival with and without primary ICD prevention. In their study, there was no significant survival benefit in cardiac amyloidosis patients with primary ICD. However, the authors still considered that there was potential for ICD benefit in specific patients with cardiac amyloidosis. In our study, sustained VT occurred in four patients, and successful ICD therapy was achieved in three patients. These three patients were still alive during our follow-up visit. If ICD had not been placed in these patients, the outcome might have been different. According to our preliminary data, ICD implantation may be proposed to the selected population to improve the survival rate, especially for the patients with wider QRS duration and RBBB/IVCD. Cardiac resynchronization therapy with a defibrillator (CRT-D) may bring benefits in advanced heart failure patients with LV systolic dysfunction and wide QRS duration. However, LVEF is frequently preserved in patients with cardiac amyloidosis. CRT-D implantation may not be suitable for these patients.

### 4.5 | Clinical implications

Currently, as consensus guidelines recommend against ICD placement for the primary prevention of SCD in patients with a life expectancy of less than 1 year, ICD should not be implanted in patients

with advanced AL amyloidosis due to very poor prognosis. However, our data indicated that ICD implantation may make sense, at least safe, and no negative impacts in some patients with advanced AL amyloidosis. A life expectancy of less than 1 year might not be the contradiction for ICD implantation. Novel criteria are required to better select patients amenable to prophylactic ICD implantation. Furthermore, the importance of ICD implantation and shared decision-making with these patients should also be underscored.

#### 4.6 | Future prospects

VAs are commonly observed among patients with advanced AL amyloidosis. ICD placement combined with disease-specific therapy for AL amyloidosis, including anti-amyloid fibril therapy, cardiac transplantation, and mesenchymal stem cell therapy, may play important roles in different stages of disease and maximally improve the survival rate. ICD implantation can reduce SCD, which may improve life quality, provide psychological support, and create more time for chemotherapy effect. Therefore, the indication for ICD implantation in patients with advanced AL amyloidosis may be expanded in the future. However, when deciding whether to place ICD implantation in the selected AL amyloidosis population is still unclear, and future investigation with large sample sizes is urgently needed to help answer this question.

#### 4.7 | Study limitations

This study has several limitations. Our study is limited by the small number of patients. It should also be noted that only patients with advanced Mayo Stage III were included, whether the findings are applicable to patients with less severe cardiac AL amyloidosis remains unknown and should be further investigated.

### 5 | CONCLUSION

VAs are common among patients with advanced AL amyloidosis, and ICD therapy can be effective in successfully treating sustained VA in these patients. On the basis of our preliminary data, prophylactic ICD implantation may be proposed to patients with advanced AL amyloidosis to improve the survival rate in selected patients with advanced AL amyloidosis, especially for patients with wider QRS duration and RBBB/IVCD.

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#### CONFLICT OF INTEREST STATEMENT

Authors declare no conflict of interests for this article.

#### DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article are available upon reasonable request.

#### ETHICS STATEMENT

The study protocol was approved by the institutional ethics committee.

#### INFORMED CONSENT

All patients provided written informed consent.

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