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Original Article

Prospective evaluation of outcome of Indian patients who meet MADIT II (Multicenter Automatic Defibrillator Implantation Trial) criteria for implantable cardioverter defibrillator implantation: is it appropriate for Indian patients?

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ABSTRACT

Background: The MADIT II investigators had concluded that prophylactic use of an ICD improved survival in patients with prior myocardial infarction reduced left ventricular ejection fraction. Whether MADIT II criteria for ICD implantation are appropriate for Indian patients also is unclear and not studied.
Methods: A total of 144 patients, Mean age 56.23 ± 10.9 years who met MADIT II criteria were prospectively followed for 20.78 + 5.9 months.
Results: During the follow-up period, 26 (18.1%) patients died. 18 were sudden cardiac deaths and 8 were non SCD deaths. Total mortality did not correlate with Age, NYHA class, NSVT on Holter, PVC >10/hours, QRS width, or use of statins. Multivariate logistic regression model identified the following variables associated with increase all-cause mortality: No use of beta blocker (odd ratio:13.068, p = 0.021), No past revascularization (odd ratio:11.613,p = 0.007) and Increase serum creatinine level (odd ratio: 4.066, p = 0.035). The mortality rate in the present series was comparable with that in the MADIT II conventional therapy group though patient in present study are younger, less diabetic, hypertensive, smokers and better treated with beta-blockers, ACE/ARB and statin.
Conclusion: Indian patients with prior MI (more than one month back) and left ventricular ejection fraction of 30% or less had a cardiac mortality similar to western population who are not treated with prophylactic ICD. Patients of Indian origin should derive a similar benefit with prophylactic implantation of ICD as per MADIT II criteria as would a western population.
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1. Introduction

The benefit of implantable cardioverter defibrillator (ICD) in post myocardial infarction (MI) patient with low left ventricular ejection fraction (LVEF) is proven.[1,2,3,4] MADIT II study revealed that ICD improved the survival in post MI patients with LVEF less than 30%.[1] This trial used a simplified selection criterion of LVEF less than 30% after one month of myocardial infarction, obviating the need for any additional screening tests.

Due to high cost, widespread use of ICDs for primary prevention of sudden cardiac death (SCD) based solely on LVEF, has not been accepted, especially in developing counties.[5,6,7] It is well known that ethnical variations among populations may influence the long term outcome of coronary artery disease (CAD) patients and the mortality in these subset of patients may not be equal.[8,9] Study done in Japanese patients concluded that the SCD rate is much lower in MADIT II like patients in their population as compared to western populations and stated that it may be inappropriate to apply MADIT II criteria for ICD implantation to Japanese patients.[8] There is an obvious need for evaluation of other risk predictors of mortality in post MI patients in addition to LVEF for more rational utilization of this costly therapy in Indian population. Further risk

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stratification with additional risk markers may help in better assessment of the risk of mortality in Indian patients. This will help in planning national guidelines for ICD therapy in clinical practice. This may add in the selection of patients that will benefit most from ICD treatment and avoid unnecessary implantations of ICD. This study was done in patient who were advised ICD implantation but due to unaffordability or their personal choice continued to be on drug follow up without ICD. To the best of our knowledge till date no such study has been done in this context in an Indian population.

2. Material and methods

Total of 145 eligible patients were included in the study. Patients of either sex who were more than 21 years and had suffered a myocardial infarction in the past one month or beyond with LVEF of 30% or less were eligible for the study.

Patients were excluded if they were had an MI within a month, had undergone coronary revascularization within the preceding three months, had sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) or survived sudden cardiac death (SCD), NYHA class IV, childbearing age women not taking contraceptive measures, advanced cerebrovascular disease, autoimmune or inflammatory disease, hematologic disease, chronic renal failure or hepatic or malignant disease; or any conditions other than cardiac disease that was associated with a high likelihood of death during the trial. They were also excluded if they were not consenting for the study.

Patients enrolled underwent regular follow up by either outpatient visits or telephonic consults at 6 months (±1 month), 1 year (±1 month) and at end of study (18–24 months).

A standard clinical history, physical examination including relevant blood tests and 12 lead electrocardiogram (ECG) was done at baseline and each out-patient follow-up visits. The detail record of patient's medication, use of ICD and antiarrhythmic drugs were recorded. All patients had undergone treadmill teat (TMT) or 6 min' walk test at baseline, holter and echocardiography at baseline, and at 12 months follow up. Coronary angiography and revascularization was performed as per need.

The primary end point of the study was all cause mortality. Secondary end points were composite of all-cause mortality, resuscitated sudden cardiac death, documented VT/VF, hospitalization due to heart failure and in patients with ICD occurrence of first appropriate shock. All-cause mortality was further classified as death due to[10]

a) Sudden cardiac death – Cardiac death within 1 h of onset of acute symptoms. Unwitnessed death, that is unexpected & without other apparent cause including death during sleep, was included in the category of sudden cardiac death.
b) Non sudden cardiac death - All cardiac death which are not classified as sudden cardiac death, including cardiac death of hospitalized patients on inotropic support.
c) Non cardiac death- These included deaths due to causes other than cardiac such as malignancy, pneumonia, trauma, etc.
d) Unknown- When there was no discernible apparent cause, it was classified as an unknown death. We confirmed the information of patients' death by the death certificates or information feedback from family members of the patients.

Mode of death was adjudicated based on the above classification.

2.1. Statistical analysis

Assuming estimated mortality of around 10% over 2 years (as against 19.8% in MADIT II) in Indian population we calculated that the sample size of 144 patients would be required to detect this event rate with precision of ±5% with 95% confidence. Presuming drop rate of 10% in the study around 160 patients were planned to be included in the study.

Recruitment was stopped after 145 patients were enrolled. On interim analysis, as the target sample size of 144 was reached, only 1 patient was lost to follow-up and event rate was more than expected, further recruitment was stopped at 145 patients.

Microsoft excel was used to store the data from the patients and analysis were made with SPSS statistical software version 17 for Windows. Continuous variables were presented as mean ± standard deviation. Dichotomous variables were presented as count and percentage. Categorical variables were compared using Chi square and Fisher's exact test. Univariate and multivariate logistic regression models were used to determine the relationship between clinical characteristic and all-cause mortality. A p value < 0.05 was considered significant. Cumulative probabilities of survival were estimated by Kaplan–Meier methods and compare with Log-rank test.

3. Results

Out of 145 patients enrolled one patient lost follow up; therefor 144 patients were taken for analysis. Mean follow up of the patients was 20.78 ± 5.9 months (range 1–30 months). The baseline clinical characteristics are provided in Table 1. Time duration from MI to enrolment ranged from 1 to 192 months (44.37 ± 45.38 months). At the time of enrolment 47 patients (32.6%) had an MI within a year while 26 patients (18.1%) had an MI within the last 6 months.

Baseline angiography was available in 99 patients (68.7%). Of these, 55 (38.2%) had single vessel disease, 27 (18.8%) had double vessel disease and 17 (11.8%) had triple vessel disease. A history of prior angioplasty was there in 37 patients (25.7%) while 8 patients (5.6%) had undergone bypass surgery.

Mean left ventricular ejection fraction (LVEF) was 25.49 ± 4.13% at enrollment. In 48 patients (40.28%) LVEF was ≤25%. Follow-up echo at 12 months was available in 110 patients with mean ejection fraction of 25.94 ± 4.88%.

Mean QRS duration was 113.65 ± 26.91 msec. Of these QRS duration >120 ms was observed in 42 patients (29.17%) while 21 patients (14.58%) had QRS duration > 150 msec. Five patients had atrial fibrillation.

Holter was repeated in 108 patients after 1 year. On follow-up holter, non-sustain ventricular tachycardia (NSVT) was present in 26 patients (24.1%). Frequent PVCs (PVC >10/hour) were seen in 23 patients (21.3%). Sixteen patients who has NSVT on 1 year follow-up holter did not have NSVT in the baseline holter. Eleven patients who had NSVT at baseline holter did not have NSVT on follow-up holter at 1 year. The detail of medications at the time of enrollment and medication at last contact is shown in Table 2.

3.1. Outcomes at follow-up

During the follow-up of period of 20.77 ± 5.9 months, the primary outcome of all-cause mortality was observed 26 patients (18.1%). Sudden cardiac death accounted for 18 of these deaths while non SCD were seen in 8 patients. There were no deaths attributable due to non-cardiac causes. There were a total of 25 hospitalizations in 24 patients (16.66%) during the course of follow up. 12 patients (8.3%) were admitted for worsening of heart failure during the course of follow up. During follow-up only one patient

Table 1
Baseline Characteristics of the patients (n = 144).

	Mean ± SD	Range
Age (years)	56.23 ± 10.88	31–89
Male:Female	132:12	
Height (cm)	165.22 ± 7.90	125–180
Weight (kg)	66.88 ± 12.66	39–102
Body mass index	24.47 + 4.2	14.7–35.9
Interval of most recent MI and the enrolment (months)	44.37 ± 45.38	1–192
NYHA Class		
I	20 (13.9%)	
II	83 (57.6%)	
III	41 (28.5%)	
Diabetes	34 (23.6%)	
Duration of Diabetes	97.0 ± 78.0	1–360
Hypertension	55(38.2%)	
Smokers	20 (13.9%)	
Duration of smoking	28.35 ± 12.2	7–60
Past History of transient ischemic attach, Cerebrovascular accident	2 (1.4%)	
Pulse/minute	81.10 ± 12.98	54–121
Systolic Blood Pressure mm Hg	120.58 ± 17.79	84–191
Diastolic Blood Pressure mm Hg	74.38 ± 9.84	54–107
Left ventricular ejection fraction %	25.49 ± 4.14	11–30
Left ventricular end diastolic dimension (cm)	6.13 ± 0.85	3.0–8.0
Left ventricular end systolic dimension (cm)	5.06 ± 0.85	2.7–7.2
Presence of Mitral regurgitation	30 (21%)	
QRS Duration (ms)	113.65 ± 26.91	78–196
Presence of Bundle Branch Block	23 (16%)	
Presence of Non sustain ventricular tachycardia on Holter	29 (20.1%)	
Presence of PVC >10/hours on Holter	31 (21.5%)	
Haemoglobin g%	12.58 ± 1.62	6.2–17.1
Urea mg%	37.76 ± 16.59	18–105
Creatinine mg%	1.186 ± 0.46	0.5–4.9
Potassium mEq/L	4.55 ± 0.43	3.5–5.7
Serum Total cholesterol mg/dl	157.97 ± 46.41	66–345
Serum LDL cholesterol mg/dl	94.25 ± 38.47	30–265
Serum HDL cholesterol mg/dl	38.10 ± 6.210	18–60
Serum Triglyceride mg/dl	123.49 ± 51.92	48–381

NYHA – New York heart association.

received an ICD. During the follow one patient had an ST elevation myocardial infarction and one patient had a transient ischemic attack.

The mean time of death from index MI was 58.78 ± 48.10 months (Range 5–177). When patients with SCD vs no SCD were compared, there was no significant differences between mean duration since MI (64.04 ± 43.31 vs 46.94 ± 58.96 months) though there was a trend toward longer duration since MI in patients who had SCD.

Clinical characteristics of survivors versus non-survivors is shown in Table 3. Survivors were younger than non-survivors and were more likely to have undergone coronary bypass surgery or coronary angioplasty than non-survivors. Non-survivors had a worse NYHA heart failure class, a lower LVEF, and were less likely to be on beta blockers than survivors. There were no differences in the prevalence of hypertension, atrial fibrillation, or hyperlipidaemia between the two groups. Time between enrolment to most recent MI was also not different between survivors and non survivors (43.64 ± 45.24 vs 47.70 ± 46.78, p = ns).

When QRS duration was compared between survivors and non survivors, no significant difference was observed. When a cut off of 120 ms was taken still no significant difference was seen. This finding was different from the MADIT II trial in which QRS of >120 ms was associated with worse outcome. Even presence of NSVT or PVC >10/hours did not predict death. Poorer LVEF was associated with significant higher mortality, though in, multivariate analysis it was not found to be significant. There was statistically significant difference in the use of beta blockers and statins in survivors versus non survivors. Serum creatinine levels were worse in non survivors than in survivors.

Relationship between the patient's clinical characteristics and all-cause mortality was analyzed according to the follow up outcome. Univariate analysis showed that patient with age >65 years, NYHA class > II, lower LVEF, presence of diabetes, no history of revascularization, no use of beta blocker and statins along with higher serum creatinine levels correlated with all-cause mortality. Multivariate analysis (Table 4) adjusting for these factors showed a constant decrease in risk for all-cause mortality with use of beta blockers and revascularization. Higher risk for all-cause mortality with increase serum creatinine level was also observed. Kaplan–Meier estimates of the effect of these factors on cumulative probability of all-cause mortality are shown in Fig. 1.

No patients had resuscitated sudden cardiac death, documented VT/VF and first appropriate shock. During follow up 30 patients reached the secondary outcome of all-cause mortality and hospitalization of heart failure.

When relationship between the patient's clinical factors and SCD were analyzed, using bivariate logistic analysis we found age >65yrs (odd ratio 0.181, CI 0.048–0.690, p = 0.012) and past history of revascularization (odds ratio 0.096, CI 0.011–0.845, p = 0.035) had significant protective effect on SCD. An increased risk of SCD associated with increase in serum creatinine levels (odds ratio 3.399, CI 1.154–10.013, p = 0.026).

3.2. Comparison of present study with MADIT II (Table 5)

When our data is compared with the MADIT II[1] population, we observed a similar mortality of our patients when compared with the conventional treatment arm of MADIT II (18.1% vs 19.8%). There were some important differences between our study population versus the MADIT II study population. Our patient cohort included more males and were younger than those in the MADIT II study. While more patients in MADIT II were asymptomatic (NYHA Class I), the number of patients in NYHA class III were similar in both series. Diabetes, hypertension and history of smoking were less frequently seen in our patients as compared to MADIT II. When compared to MADIT II conventional group, far fewer patients received revascularization (percutaneous coronary intervention and/or coronary artery bypass surgery) in our cohort. Our patients also had less atrial fibrillation and had narrower QRS. Prolonged QRS (QRS width of >120 ms) was observed more frequently in the MADIT II study. However, use of guideline directed medical therapy (GDMT) such as use of beta blockers, ACE/ARBs, statins was much higher in our population as compared to MADIT II. Our study population was also less likely to be prescribed digoxin and amiodarone as compared to MADIT II population.

Table 2
Medication at baseline and at last contact.

	Medication at baseline	Medication at last contact
Aspirin	140 (97.2%)	139 (96.5%)
Clopidogril	111 (77.1%)	111 (77.1%)
Beta blocker	131 (91%)	135 (93.8%)
Angiotensin converting enzyme inhibitor/ angiotensin receptor blockers	124 (86.1%)	126 (87.5%)
Statin	134 (93.1%)	136 (94.4%)
Digoxin	7 (4.9%)	7 (4.9%)
K+ sparing diuretic	71 (49.3%)	72 (50%)

Table 3
Clinical characteristics of survivors and non-survivors.

	Survivors N = 118	Non survivors N = 26	P VALUE	OR (95%- CI)
Age (years)	55.53 ± 10.27	59.42 ± 13.09	0.098	
Age ≥65 years (n = 30)	20 (16.9%)	10 (38.4%)	0.014	3.063 (1.214–7.723)
Male	110(93%)	22 (84.6%)	0.151	2.5(.692–9.033)
Female	8 (7%)	4 (15.4%)		
NYHA class			0.027	2.631 (1.094–6.327)
I&II	89 (75.4%)	14(53.8%)		
III	29(24.6%)	12(46.2%)		
Interval of <12 months between most recent MI and the enrolment (months)	38 (32.2%)	9 (34.6%)	0.812	1.115 (.455–2.729)
Hypertension	41(34.7%)	14 (53.8%)	0.070	2.191 (.928–5.173)
Diabetes	24 (20.3%)	10 (38.5%)	0.049	2.448 (.987–6.072)
History of cigarette smoker	17 (14.4%)	3 (11.5%)	0.753	0.810(.218–3.006)
History of Revascularization	43 (36.4%)	2 (7.7%)	0.004	6.88(1.55–30.54)
Pulse/min	80.38 ± 12.7	84.38 ± 13.95	0.155	
QRS Duration ms	112.69 ± 26.48	118.04 ± 28.89	0.360	
QRS interval >120 ms	33 (28%)	9 (34.6%)	0.500	1.364(.553–3.362)
≤120 ms	85 (72%)	17 (65.4%)		
LVEF %	25.98 ± 3.81	23.46 ± 4.88	0.004	
NSVT	24 (20.3%)	5 (19.2%)	0.923	0.948 (.332–2.786)
PVC >10/hours	27 (22.9%)	4 (15.4%)	0.414	0.621 (.196–1.966)
Aspirin	113(95.7%)	26 (100%)	0.285	0.813(.751–.880)
ACEIs & ARBs	106 (89.8%)	20 (76.9%)	0.072	2.650 (.891–7.884)
Beta-blockers	115 (97.5%)	20 (76.9%)	0.000	11.500(2.657–49.766)
Statins	114 (96.6%)	22 (84.6%)	0.016	5.182(1.204–22.293)
spironolactone	55 (38.2%)	17 (11.8%)	0.083	0.462(.191–1.12)
Hemoglobin g%	12.59 ± 1.70	12.50 ± 1.20	0.805	
Serum urea mg/dl	35.20 ± 12.99	49.35 ± 24.769	0.000	
Serum Creatinine mg/dl	1.13 ± 0.31	1.45 ± 0.84	0.001	
Serum Potassium mEq/L	4.53 ± 0.43	4.62 ± 0.45	0.111	

MI- Myocardial infarction, LVEF – Left ventricular ejection fraction, NSVT – Non sustain ventricular tachycardia, PVC- premature ventricular complex, ACEIs & ARBs- Angiotensin converting enzyme inhibitors/angiotensin receptor blockers.

Hospitalization due to heart failure was less frequent in our patients and while SCD was more frequent in our population when compared to conventional therapy group of MADIT II (61% vs 69.2%)

4. Discussion

The present study evaluated an Indian population who met the MADIT II criteria for ICD implantation for primary prevention of SCD. All these patients were offered an ICD but did not get the procedure done either due to economic or personal reasons. These patients were followed up and risk factors for all-cause mortality were assessed. Use of beta blocker and previous revascularization was associated with a favorable impact on total mortality. Previous studies have demonstrated that use of beta blockers and statins as well as revascularization with either PCI or CABG has been associated with lower mortality in post MI patients.[11,12,13] In our study deranged renal function was also associated with increased mortality. Renal insufficiency has been shown in previous studies to be independently associated with an increased risk for all-cause mortality in patients with heart failure.[14]

Table 4
Variable affecting the rate of all-cause mortality.

Variables	Odd ratio	95% CI	P Value
Beta blockers	13.068	1.463–116.709	0.021
revascularization	11.613	1.956–68.944	0.007
Creatinine mg/dl	4.066	1.103–14.984	0.035
Age >65 years	2.719	0.785–9.412	0.114
NYHA class > II	2.248	0.711–7.114	0.168
Diabetes	1.996	0.592–6.713	0.265
Left ventricular ejection fraction %	0.940	0.830–1.065	0.330
Statins	2.559	0.390–16.784	0.328

NYHA – New York heart association.

While the MADIT II study[1] demonstrated a survival benefit with use of an implantable cardioverter defibrillator in patients with prior MI and LVEF ≤30%, non-randomized studies conducted in MADIT II other ethnically varied populations such as among Japanese and Chinese patients failed to demonstrate a mortality benefit of ICD therapy[8,9]

In a retrospective analysis of MADIT II eligible patients from Japan, Tanno et al evaluated outcomes in 90 patients (M/F: 75/15; mean age: 65 ± 9 years) who met MADIT II criteria. During the 37 ± 12-month follow-up period, fifteen patients died; of these deaths, nine were attributed to congestive heart failure, only two were sudden cardiac deaths, one secondary to acute MI and three patients died due to non-cardiac causes. The authors reported a survival rate in their series which was comparable with that in the MADIT II defibrillator group, but higher than that in the MADIT II conventional therapy group. A significantly greater percentage of patients in their study were asymptomatic (NYHA class I) and had undergone percutaneous coronary intervention than in the MADIT II study. Thus the authors concluded that using prophylactic ICD using the MADIT II criteria may be inappropriate in Japanese patients.[8]

One of the major differences of our study from the study of Tannoo et al[8] is that our study population was enrolled prospectively (though it is still a non-randomized population). These patients were enrolled consecutively from the outpatient department of a large tertiary hospital. Also, compared with Tanno et al[8] our patients were younger (56.2 ± 10.9 vs 64 ± 10) and significantly smaller percentage of the patients were in NYHA functional class I (13.9% vs. 79%). Fewer patients in our series underwent revascularization (31.3% vs. 87%). As our patients were younger, comorbidities such as diabetes (23.6% vs. 37%) and hypertension (38.3% vs. 73%) were expectedly lower. The proportion of patients who had a remote MI (>6 months duration at the time of enrolment) was similar in both series (78.5% vs. 81.9%). Prevalence of

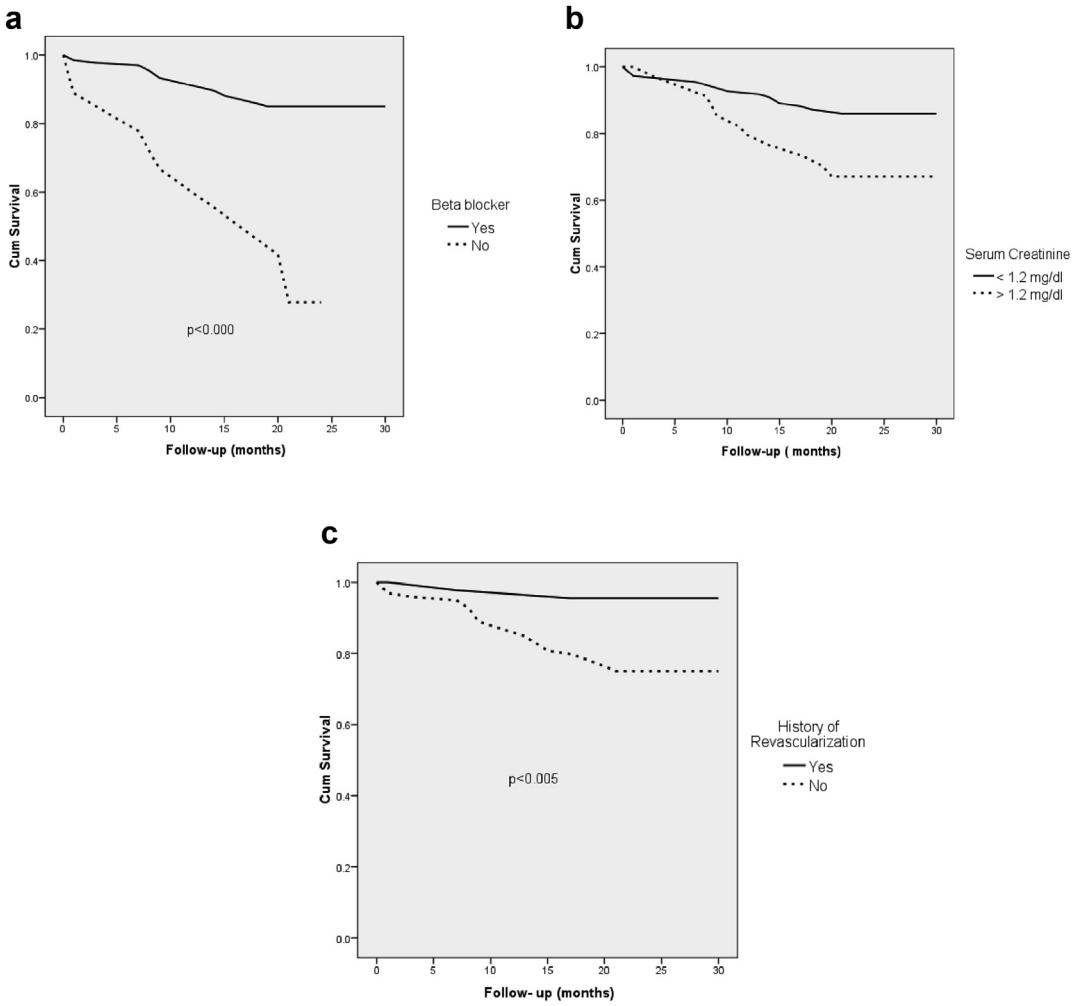

Fig. 1. Kaplan–Meier estimate of the probability of survival between a-patients with or without beta blockers, b-serum creatinine levels >1.2 mg/dl vs ≤ 1.2 mg/dl, c-b patients who had history of revascularization (angioplasty or CABG) prior to enrolment.

QRS width of more than 120 ms was observed in 29.2% in our series as compare to 21% in the study by Tanno et al.[8] There was a significantly greater proportion of patients on GDMT including β-blockers, ACE or ARB and statins in our series. In spite of a more favourable age and risk factor profile, total mortality was still higher (18.1% vs 16.7%) and the proportion of SCD significantly higher in our study (69.2% vs 13.3%). The better outcomes in the Japanese patients may have been attributable to a better NYHA class, and greater use of primary PCI and revascularization than in our population.

Dai SM et al[9] studied 417 post MI patients with low EF ≤ 35% in a Chinese population. Of the 55 patients (13.1%) who died during the 32 ± 24 months of follow-up, 37 (67%) died suddenly. Worse NYHA class (NYHA class ≥ III, hazard ratio (HR) 2.361), poorer LV function (LVEF ≤ 20%, HR 2.514), presence of sustained ventricular tachycardia (HR 6.453), and older age ≥ 70 years (HR 3.116) were associated with all-cause death. Presence of sustained ventricular tachycardia (HR 6.491) and age ≥ 70 years (HR 2.694) were specifically associated with SCD. As compared to our study, LV function was lower in our study (25.46 ± 4.1% vs. 29.09 ± 6.49%) and revascularization was performed less often in our study than in the study by Dai et al (31.3% vs. 49%). Use of guideline directed medical therapy including beta blockers, ACE/ARB and statins was better in our study.

Our study population was relatively younger, had a better risk factor profile (fewer diabetics, hypertensives and smokers) and received better GDMT (beta blockers, ACEI/ARB and statins) as compared to MADIT II population. However all-cause mortality in this population was similar to the mortality in the MADIT II conventional therapy arm. Mortality in our patients was higher when compared with Japanese population[8] and Chinese population.[9]

5. Conclusion

Despite a favourable clinical profile, all-cause mortality in Indian patients who have a low LVEF (≤30%) at least a month following myocardial infarction was high and comparable to the conventionally treated arm without an ICD in a western population. Even better treatment with GDMT could not improve clinical outcomes in this group of patients. Our study population had more SCD (69.2%) than the conventionally treated arm of MADIT II. Numerous clinical factors including age, NYHA class, presence of NSVT or PVCs >10/hour and increased QRS width were not useful to identify patients at risk for all-cause mortality and SCD. Thus Indian patients who have had a previous MI (at least one month earlier) and have a LVEF ≤ 30% should benefit from prophylactic ICD implantation. Other clinical markers (besides LVEF) used in this study were not useful in discriminating patients at risk for all-cause mortality and SCD. There is a need to identify additional risk markers for SCD in these patients.

Table 5
Comparison of patients characteristic and outcome with MADIT II population.

	MADIT Defibrillator group	MADIT Conventional therapy group	Present series
Age (year)	64 ± 10	65 ± 10	56.23 ± 10.88
Male sex %	84	85	91.7
NYHA Class %			
I	35	39	13.9
II	35	34	57.6
III	25	23	28.5
Hypertension %	53	53	38.2
Diabetes %	33	38	23.6
Smoker %	80	82	13.9
History of Angioplasty %	45	42	25.7
History % CABG	58	56	5.6
Interval of >6 months between Recent MI and enrolment %	88	87	78.5
Atrial fibrillation %	9	8	3.5
QRS > 120 ms %	50	51	29.17
LVEF %	23 ± 5	23 ± 6	25.46 ± 4.1
Beta blocker %	70	70	93.8
ACEI/ARB%	68	72	87.5
Statin%	67	64	94.4
Digoxin%	57	57	4.9
Amiodarone %	13	10	2.8
Diuretics %	72	81	87.5
Hospitalization for HF %	19.9	14.9	8.3
Deaths %	14.2	19.8	18.1
SCD %	35	61	69.2

CABG-coronary artery bypass surgery, LVEF- left ventricular ejection fraction, ACEI/ARB- Angiotensin converting enzyme inhibitors/angiotensin receptor blockers, HF- heart failure, SCD-sudden cardiac death.

5.1. Limitations

Limitation of the study are that we do not have comparative arm and patients are not consecutive patients. Patient who were advised ICD implantation but due to unaffordability or their personal choice continued to be on drug follow up without ICD. This may create selection bias in analysis of the data. The cause of death was determined only by verbal autopsy.

Key messages

What is already known on this subject?

Patients who survive a myocardial infarction with LVEF <30%, are a high-risk for sudden death. LVEF is found to be only consistent predictor of SCD. Only 1/3 patients of ICD receive shock during their life time. In developing counties, to ovoid unnecessary implantation of this costly device, there is need to find additional risk marker, which beside LVEF can stratify risk more accurately.

What does this study add?

This study provides data on Post MI patients with LVEF <30%, in the Indian population and analyzed various other risk factor and their predictive value. The study found that other clinical markers (besides LVEF) were not useful in discriminating patients at risk for all-cause mortality and SCD in MADIT II population.

How might this impact on clinical practice?

Our study suggests that the incidence of SCD in Indian patients with a previous MI and LVEF <30% is as high as that in the MADIT II population which represent western world. Therefore, ICD implantation for primary prevention should be considered in all patients who meets MADIT II indication and at present, no other risk factor beside LVEF, can be taken as a marker for predicting Death in these patients.

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Declaration of Competing Interest

None declared.

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