



Mortality, sudden death and indication for cardioverter defibrillator implantation in a dialysis population



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ARTICLE INFO

Article history:

Received 24 October 2014

Received in revised form 9 February 2015

Accepted 16 March 2015

Available online 17 March 2015

Keywords:

Implantable cardioverter defibrillator

End stage renal disease

Mortality

Sudden death

Hemodialysis

ABSTRACT

Background: The incidence of sudden death among dialysis patients is high, but end stage renal disease was an exclusion criterion in the trials that demonstrated the benefit of implantable cardioverter defibrillator (ICD) for sudden death prevention.

Methods: Dialysis patients alive on January 2010 or starting dialysis between January 2010 and January 2013 were enrolled and retrospectively evaluated. Patients were divided into three groups: No-Indication, Indication-With ICD and Indication-Without ICD. Cox and Fine and Gray regression models were used to estimate the total and cause-specific (sudden or non-sudden) mortality hazard ratio (HR, HR_{cpRisk}), respectively. Survival was defined as the time from start of dialysis to the time of death.

Results: 154/2072 patients (7.4%) had indication for ICD implantation and 52 (33.8%) of them received the device; 688 (33.2%) deaths were recorded. Mortality was different among groups [Indication-With ICD vs No-Indication: HR 1.59 (95% CI 1.06–2.38) and Indication-Without ICD vs No-Indication: HR 2.67 (95% CI 2.09–3.39, $p < 0.001$)], 84/688 (12.2%) were sudden deaths. The cumulative incidence of sudden death was higher in patients with ICD indication [Indication-With ICD vs No-Indication HR_{cpRisk} 3.21 (95% CI 1.38–7.40) and Indication-Without ICD vs No-Indication: HR_{cpRisk} 4.19 (95% CI 2.38–7.39), $p < 0.001$], but also No-Indication patients showed a high rate of sudden death [8.5% (95% CI 6.5–10.9) at 8 years of follow-up].

Conclusions: Dialysis patients with ICD indication had a worse survival than No-Indication subjects and the prognosis was particularly poor for the Indication-Without ICD group. Sudden death incidence was much higher than in the general population, even among No-Indication subjects.

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1. Introduction

The incidence of sudden death among patients with end stage renal disease (ESRD) undergoing hemodialysis (HD) or peritoneal dialysis is high. In a European HD population about 19% of deaths were due to sudden death [1], while the 2013 US register reported that 27% of ESRD patients died suddenly [2]. In the USA 49/1000 HD patients/year and 36/1000 peritoneal dialysis patients/year die from sudden death,

but it is not known how many dialysis patients have an indication for implantable cardioverter defibrillator (ICD) according to the cardiologic guidelines. Only 5/1000 patients/year receive an ICD [2]. There are several reasons for the underuse of the device in the dialysis population. First, the presence of ESRD was an exclusion criterion in the major cardiologic trials that demonstrated that the ICD has a survival benefit in high risk populations [3–5] and for this reason the usefulness of ICD is not yet established in dialysis patients. However, the most recent ICD implantation guidelines do not exclude the possibility to receive the device for a dialysis patient presenting the indication, suggesting however to pay particular attention while making the decision [6]. Second, in the presence of chronic kidney disease or ESRD, the overall mortality of ICD

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Table 1
Demographic and clinical patient characteristics.

		Patient group		
		No-Indication (N = 1918)	Indication–Without ICD (N = 119)	Indication–With ICD (N = 52)
<i>Patient characteristics</i>				
Age (years) at the start of dialysis	N	1918	119	52
	Median	68.2	71.8	69.4
	Range	12.9–94.4	18.5–89.8	46.2–85.2
Gender				
Female	N (%)	739 (38.5)	30 (25.2)	11 (21.2)
Male		1179 (61.5)	89 (74.8)	41 (78.8)
NYHA class				
2		187 (9.8)	37 (31.1)	12 (23.1)
3		60 (3.2)	27 (22.7)	16 (30.8)
4		0 (0.0)	8 (6.7)	3 (5.8)
Left ventricular ejection fraction				
<35%	N (%)	0 (0.0)	84 (70.6)	37 (71.2)
≥35%		1918 (100.0)	35 (29.4)	15 (28.8)
<i>Type of dialysis</i>				
Hemodialysis	N (%)	1693 (88.3)	104 (87.4)	42 (80.8)
Peritoneal dialysis		225 (11.7)	15 (12.6)	10 (19.2)
<i>Comorbidities</i>				
Ischemic heart disease				
Yes	N (%)	610 (31.8)	87 (73.1)	37 (71.2)
Diabetes mellitus				
Yes	N (%)	499 (26.0)	47 (39.5)	19 (36.5)
Atrial fibrillation				
Yes	N (%)	473 (24.7)	56 (47.1)	26 (50.0)

patients is significantly higher than that reported in patients with ICD and normal kidney function and the risk of death after ICD implantation for primary prevention is proportional to chronic kidney disease severity [7–14]. Third, the infective and implant-procedure-related complications in chronic kidney disease patients are higher than in the non-chronic kidney disease population [15]. There are very few mortality studies in dialysis patients with ICD indication comparing ICD patients with no-ICD patients and the results are controversial [16]. Moreover there are no studies comparing total mortality and sudden death incidence in dialysis patients with and without ICD indication.

The aim of this study was to estimate, in a dialysis population, the prevalence of patients with ICD indication and to compare total and sudden mortality occurring in this subgroup with those of subjects without ICD indication. In addition the prognosis of patients with ICD indication, according to ICD presence, has been investigated.

2. Methods

This is an Italian multicenter retrospective study.

All dialysis patients (undergoing HD or peritoneal dialysis), alive on the 1st of January 2010 or starting dialysis between the 1st January 2010 and the 31st of January 2013 (recruitment time), were enrolled and their clinical charts revised. For all patients the ICD indication was evaluated; on the 31st of January 2013 for alive subjects and at the time of death if deceased.

Primary prevention indication was defined by MADIT I and II and/or SCDHeFT criteria [3–5], while secondary prevention was considered in patients who had a history of cardiac-arrest.

Patients were considered eligible for the study only if an echocardiogram with a measured value of left ventricular ejection fraction, made within 6 months before recruitment if alive, or 6 months before death if deceased, was available. Patients were divided into three groups: without ICD indication (No-Indication), with ICD indication and with implanted ICD (Indication–With ICD), and with ICD indication but without implanted ICD (Indication–Without ICD). Because the exact time of ICD indication starting was not available, patients having ICD implantation after the start of dialysis were analyzed in a double manner: classifying them as Indication–Without ICD (scenario A) or as No-Indication

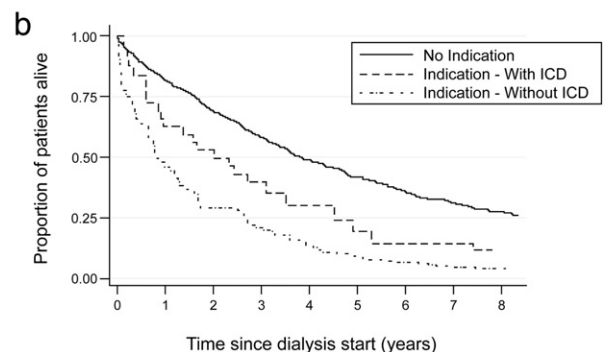
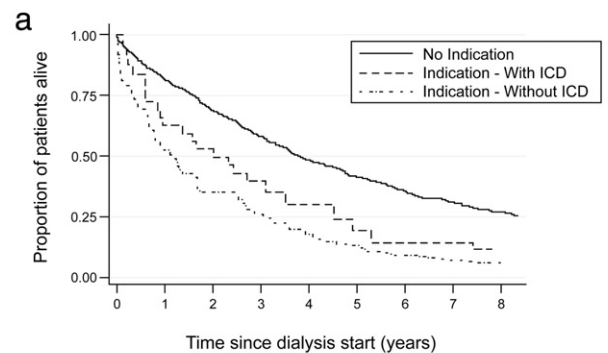


Fig. 1. Survival curves of the three study groups. Scenario A: Patients with implanted ICD after the start of dialysis are classified as 'Indication–Without ICD' before ICD implantation. Scenario B: Patients with implanted ICD after the start of dialysis are classified as 'No-Indication' before ICD implantation.

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