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Temporal trends and long term follow-up of implantable cardioverter defibrillator therapy for secondary prevention: A 15-year single-centre experience☆

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ABSTRACT

Background: The aim of this study was to determine overall and aetiology-related incidence of secondary prevention ICD implantation over the last 15 years in Canton Ticino and to assess clinical outcome according to time period of implantation.

Methods and results: Consecutive patients treated by implantation of an ICD for secondary prevention from 2000 to 2015 were included in the current study and compared between 5-year cohorts (2000/2004; 2005/2009; 2010/2015). Yearly implantation rate, changing in clinical presentation over years and events during follow-up were evaluated. One-hundred fifty six patients were included. ICD implantation rate increased from 2.1 in 2000–2005 to 5.1 in 2010–2015, respectively (p 0.001). There was an increase in the proportion of non-ischaemic patients and of ventricular tachycardia (VT) as presenting rhythm. No differences in appropriate ICD interventions were observed according to aetiology, presenting arrhythmia or type of device. Reverse remodelling was observed more often in non-ischaemic patients, without any influence on the occurrence of appropriate interventions. Previous myocardial infarction (MI), atrial fibrillation (AF), NYHA class 2–3 and left ventricular ejection fraction (LVEF) < 35% were predictors of appropriate therapies during follow-up.

Conclusions: Rate of implants for secondary prevention indication has almost doubled during the last 15 years. Importantly, there has been a progressive increase of non-ischaemic patients receiving an ICD, and of VT as presenting rhythm. Patients had an overall good survival and a relatively low incidence of appropriate therapies. Improvement of ejection fraction did not correlate with risk reduction of ventricular arrhythmias.

1. Introduction

Evidence from multiple randomized controlled trials supports the use of implantable cardioverter defibrillators (ICDs) in patients who survived a cardiac arrest or presented with haemodynamically not tolerated ventricular tachycardia (VT) or had recurrent VTs in the absence of reversible causes, receiving chronic optimal medical therapy [1–5]. It is now about 2 decades since the publication of landmark clinical trials on the use of ICD in secondary prevention of sudden cardiac death; during this long period of time, significant advances in the prevention and treatment of cardiovascular disease including heart failure and ventricular arrhythmias have been made. Little is known on how these major changes in diagnostic and management strategies have had an impact on the prevalence of out-of-hospital cardiac arrest (OHCA), on the presenting rhythm, clinical characteristics, and long-term outcome of patients undergoing ICD implantation in secondary prevention of SCD.

Recent registry data have indicated a gradual decrease in ventricular fibrillation (VF) as initial recorded rhythm during resuscitation for OHCA [6]; additionally, the significant increase in the performance of the survival chain in OHCA has resulted in a greater proportion of patients discharged from hospital with good neurological status, and 1-year outcome. However most of the OHCA registries do not report the underlying cardiac disease and the type of cardiac implantable electronic device (ICD or cardiac resynchronization therapy with ICD, CRT-D) used in these patients; thus it is unknown whether the observed changes are possibly related to a shift in the cardiomyopathy or type of device used.

The aim of this study was to determine overall and aetiology-related incidence of secondary prevention ICD implantation over the last

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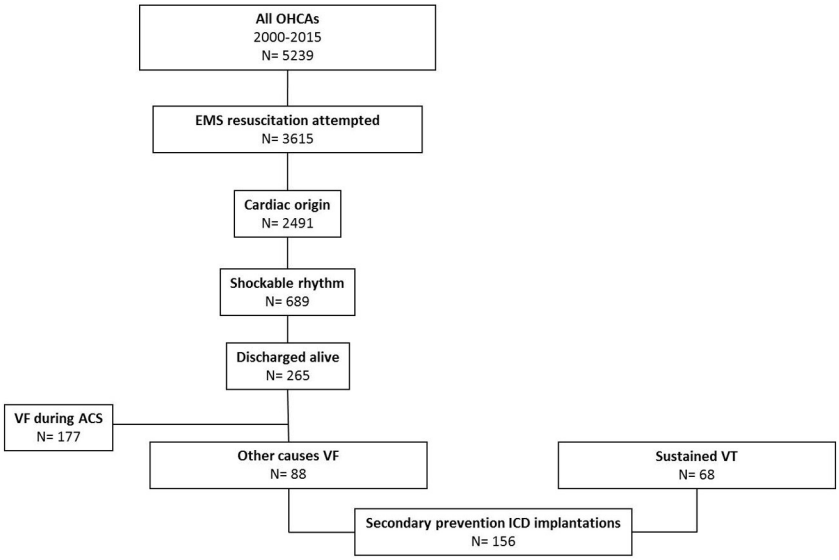

Fig. 1. Indication for secondary prevention ICD implantation in Canton Ticino.

15 years in Canton Ticino, and to assess the clinical profile of survivors of SCD and their clinical outcome according to time period of ICD implantation. Moreover, we aimed to determine whether the risk of subsequent arrhythmias was mitigated by reverse remodelling.

2. Methods

Since 2000, a web-based registry on out- of-hospital cardiac arrest (OHCA) in the region of Canton Ticino is available. [7] It contains a record of every individual who presented a cardiac arrest regardless of the aetiology, and includes patient's demographic data, comprehensive Emergency medical system (EMS)-related data, circumstances of OHCA and first documented rhythm at EMS arrival.

Cardiocentro Ticino is the only cardiologic tertiary centre receiving all patients who suffered from an acute coronary syndrome or from an OHCA. It covers all of ICD implanting activity in the region. All consecutive patients treated with an ICD were prospectively included in an internal web-based registry. It contains patient demographics, medication at implant, diagnostic examinations including resting ECG, echocardiography, cardiac magnetic resonance imaging (if performed), and coronary angiography before implant. Moreover, the registry contains follow-up clinical status data, ICD programming, and echocardiographic findings.

Given the long follow-up period of some patients, the ICD programming was adjusted based on the individual clinical history and availability of new clinical evidence for device programming in secondary prevention patients [8–10]. More commonly, a monitor zone (>150 bpm), fast VT zone (180–200 bpm) with anti-tachycardia pacing (ATP) as well as shocks, and ventricular fibrillation (VF) detection zone (>200 bpm) with shocks were programmed in all cases. Supraventricular tachycardia discrimination was always on.

Clinical follow-up of patients consisted of physical examination and ECG performed at least every 6 months. Follow-up of the device was performed at 1 and 3 months after ICD implantation and every 6 months thereafter. Since 2010, remote monitoring (RM) has been systematically implemented. During follow-up, hospitalization for heart failure, acute coronary syndrome, coronary revascularization and stroke were systematically collected. Reverse remodelling was assessed with echocardiogram at 6 month follow-up and was defined as a recovery of LVEF and a reduction of end systolic volume (ESV) of more than 10% [11]. Appropriate therapies were defined as shocks or ATP delivered for VT or VF.

Continuous data are presented as median and 25th–75th percentiles (IQR) and categorical data as counts and percentages; they were compared between 5-year cohorts (2000/2004; 2005/2009; 2010/2015) with the Kruskall Wallis test and the Fisher exact test, respectively. Yearly implantation rates are computed on the census estimate provided by the Swiss Federal Statistics Office [12]. Rates in the 5-year cohorts were compared by means of Poisson regression. They were plotted as Forrest plots, together with their cohort and overall metaanalytic estimates. Median follow-up (IQR) was computed with the inverse Kaplan Meier method. Event rates per 100 person year and 95% confidence intervals (95%CI) were computed. [Event-free] survival was estimated by Kaplan–Meier method. [Event-free] survival was compared between categories of a series of candidate predictors with the logrank test. Hazard ratios (HR) and 95%CI were calculated. Time-dependent Cox regression was used to assess the role of 6-month remodelling on event-free survival. Endpoints for these analyses were appropriate ICD therapies, a combined clinical endpoint of ICD therapies, all-cause hospitalization, and death, and overall mortality. Statistical analyses were conducted using the Stata 14 software (Stata Corporation, College Station, TX, USA). A 2-sided p-value less than 0.05 was considered statistically significant.

Table 1
Demographic characteristics of patients according to implantation period.

	2000–2004 (n = 25)	2005–2009 (n = 47)	2010–2015 (n = 84)	p value
Ischaemic aetiology, n (%)	15 (60)	33 (70)	45 (53)	0.13
DCM, n (%)	8 (32)	9 (19)	27 (32)	0.22
Other diagnosis, n (%)	2 (8)	5 (11)	12 (15)	0.08
Male gender, n (%)	19 (90)	38 (84)	65 (83)	0.75
Age, median [IQR]	65 [57–69]	65 [57–71]	66 [55–74]	0.34
Presenting arrhythmia, n (%)				0.65
Sustained VT	9 (36)	22 (47)	37 (44)	
VF	16 (64)	25 (53)	47 (56)	
Beta-blocker therapy, n (%)	17 (70)	38 (80)	60 (71)	0.46
ACEs/ARBs therapy, n (%)	18 (72)	37 (78)	57 (68)	0.34
Amiodarone, n (%)	7 (30)	13 (27)	23 (27)	0.36
EF, median [IQR]	49 [32–60]	39 [30–50]	39 [30–53]	0.10
Type of device, n (%)				
Single-chamber	9 (36)	13 (27)	23 (27)	0.23
Dual-chamber	15 (60)	30 (64)	40 (48)	0.06
S-ICD	0	0	5 (6)	0.01
CRT-D	1 (4)	4 (9)	16 (19)	0.03

DCM: idiopathic dilated cardiomyopathy, VT: ventricular tachycardia, VF: ventricular fibrillation, EF: left ventricular ejection fraction, S-ICD: subcutaneous-implantable cardioverter defibrillator, CRT-D: cardiac resynchronization therapy-defibrillator.

3. Results

From January 2000 to December 2015, 5239 OHCAs has occurred; 689 patients presented with a shockable heart rhythm. Two hundred sixty five of them survived. 177 patients had a VF during an acute coronary syndrome, while the remaining 88 patients received an ICD in secondary prevention before discharge from hospital. During the same period, additional 68 patients received an ICD due to sustained VT (Fig. 1). Demographic characteristics are summarized in Table 1. Patients were prevalently male, with ischaemic heart disease, and moderately impaired left ventricular ejection fraction. No significant differences were observed in age, sex and medications at implant. Implantations due to sustained VT as presenting arrhythmia rose from 36% in 2000–2004 to 44% in the last 5-years. There was little difference in the proportion of single versus dual-chamber ICDs over the years, whereas a significant increase in CRT-D devices was observed (p 0.03).

The overall incidence of ICD implantations was 3.9 units per 100,000 inhabitants/year, and the yearly implantation rate of ICD is shown in Fig. 2. There was a significant increase in implantation rate from 2.3