Effectiveness of ICD therapy in real clinical practice. The Olomouc ICD Registry

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Background. Clinical parameters linked to a low benefit of ICD implantation and increased mortality risks are needed for an individualized assessment of potential benefits and risks of ICD implantation.
Methods. Analysis of a prospective registry of all patients hospitalized from 2009 to 2019 in a single centre for a first implantation of any type of ICD.
Results. A total of 2,681 patients were included in the registry. Until the end of follow-up (38.4 ± 29.1 months), 682 (25.4%) patients died. The one-year mortality in all patients, the one-year CV mortality, the three-year mortality in all patients, and the three-year CV mortality were 7.8%, 5.7%, 20.6%, and 14.8%, respectively. There was a statistically significant difference when the subgroups were compared according to the type of cardiomyopathy. No significant difference was found between primary and secondary prevention and between the types of devices. Male gender, age ≥ 75 years, diabetes mellitus, and atrial fibrillation were associated with a significantly increased mortality risk.
Conclusion. In an analysis of a long-term follow-up of 2,681 ICD patients, we found no mortality difference between patients with ischemic or non-ischemic cardiomyopathy and in the device type. A higher mortality risk was found in men, patients older than 75 years, diabetics, and those with atrial fibrillation.

Key words: implantable cardioverter-defibrillator, heart failure, primary prevention, time to shock, appropriate shock, mortality

Received: September 23, 2021; Revised: December 7, 2021; Accepted: December 8, 2021; Available online: December 17, 2021
https://doi.org/10.5507/bp.2021.071

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BACKGROUND

Implantable cardioverter-defibrillator (ICD) implantation has a mortality benefit when compared with guideline-directed medical therapy according to several randomized controlled trials in patients with heart failure (HF) (ref.[1-3]). However, these trials were finished a long time ago, and the current treatment of HF has led to a decrease in sudden cardiac death (SCD) rates since the early 2000s (ref.[4]). Thanks to the modern treatment of ischemic heart disease, HF, and other comorbidities, the SCD risk profile of patients indicated for ICD implantation has changed dramatically when compared with the situation at the time of the realization of legacy ICD studies. An analysis of 12 trials conducted between 1995 and 2014 demonstrated a 44% decline in the SCD rate within those twenty years[5]. This decrease in the SCD rate resulted in a very low rate of appropriate life-saving shocks in primary prevention patients[6]. Thus, the majority of patients with an ICD implanted for primary prevention do not experience a life-saving shock. A recent analysis of SCD survivors showed that, before the event, only a minority of these patients had been eligible for primary prevention ICD implantation[7]. ICD implantation is still not without risk as it may be associated with a significant increase in morbidity due to device infections, inappropriate shocks, as well as increased hospitalizations, healthcare costs, and reduced survival[8]. Left ventricular ejection fraction (LVEF) remains the main parameter for the selection of patients for primary prevention. However, not all patients with a low LVEF derive benefit from ICD implantation. Modern pharmacotherapy of HF with sacubitril-valsartan significantly decreases the occurrence of ventricular tachyarrhythmias[9]. A better selection of patients for primary prevention is required. A clear benefit can be demonstrated only in patients with a high risk of appropriate ICD intervention and low risk of non-arrhythmic mortality. Specific subgroups of patients, such as diabetics and those older than 75 years seem to derive a lower benefit from ICD implantation[10]. Clinical parameters linked to a low benefit of primary prevention ICD implantation and increased mortality risks are needed for an assessment of potential benefits and risks of this treatment. A personalized assessment of the individual risk of SCD, based not solely on LVEF, should be at the core of a modern approach to indication for ICD implantation. This would allow us to avoid the many unnecessary ICD implantations in patients with an ejection fraction below 35%, and

at the same time to protect those with an ejection fraction > 35% who carry a high individual risk from targeted CD implantation[11].

METHODS

Study population

The Olomouc registry is a prospective registry of all patients hospitalized in a single centre (University Hospital Olomouc, Czech Republic) for a first implantation of any type of ICD with or without cardiac resynchronization therapy (CRT) for primary or secondary prevention indication according to currently available guidelines. This registry was initiated in 2008 and was approved by the local institutional review board. Patients started to be enrolled in the registry on 1 November 2009. These data were part of the national ICD registry. An independent statistical analysis of this part of the national ICD registry was done by the Institute of Biostatistics and Analyses at the Faculty of Medicine of the Masaryk University (IBA FM MU) in Brno. Only patients with at least 12 months of follow-up were chosen to be included in the statistical analysis, so the last patient included was implanted in December 2019. From January 2009 to December 2019, we enrolled 2,681 patients. Patients with reimplantation and device upgrade were not included, and nor were those with a subcutaneous ICD. Patients were enrolled in the registry during the index hospitalization at the time of initial device implantation. Data were collected prospectively and included demographic and clinical characteristics including age, gender, BMI, NYHA class, comorbidities and pharmacotherapy, type of cardiomyopathy, type of device and electrode, and echocardiographic and ECG parameters.

Follow-up and study endpoints

All patients were followed up in the implanting centres' outpatient department every 3–6 months. Cardiovascular (CV) and non-CV deaths were documented. Their distinction was based on a review of the death certificate issued by the attending physician. If a patient missed two appointments for outpatient visits, his or her general practitioner or local cardiologist was contacted to ascertain if the patient was still alive. In patients lost to follow-up, these physicians and the Institute of Health Information and Statistics of the Czech Republic were consulted to find out if the patient was still alive and to specify the cause of death (CV or non-CV).

Study endpoints

The primary endpoint was death from any cause. The secondary endpoint was CV and non-CV death.

Statistical analysis

The statistical analysis focused on the differences in subgroups with different gender, age, presence of atrial fibrillation (AF) and diabetes mellitus (DM), as well as on primary and secondary endpoints. These subgroups were further analysed according to the type of implan-

Table 1. Baseline demographics of the whole patient group.

Patients (n = 2 681)	
Age	66.3 ± 11.7
Age ≥ 75	633 (23.7%)
Gender	
Men	2071 (77.2%)
Women	610 (22.8%)
BMI	28.7 ± 5.2
Device type	
Single-chamber ICD	1466 (54.7%)
Dual-chamber ICD	144 (5.4%)
CRT	1069 (39.9%)
Type of indication	
Secondary prevention	462 (17.2%)
Primary prevention	2199 (82.8%)
Type of cardiomyopathy	
Ischemic cardiomyopathy	1494 (55.7%)
Non-ischemic cardiomyopathy	1187 (44.3%)
Comorbidities	
Diabetes mellitus	1049 (39.1%)
Hepatopathy	63 (2.3%)
COPD	255 (9.5%)
Chronic kidney disease	275 (10.3%)
Stroke	156 (5.8%)
Cancer	47 (1.8%)
AF	
AF paroxysmal	174 (6.5%)
AF persistent	431 (16.1%)
Pharmacotherapy	
Anticoagulation	979 (36.5%)
Antiaggregation	1164 (43.4%)
Digoxin	93 (3.5%)
Class I antiarrhythmics	30 (1.1%)
Class II antiarrhythmics	1825 (68.0%)
Class III antiarrhythmics	184 (6.8%)
Class IV antiarrhythmics	55 (2.1%)
Vasodilatation therapy	339 (12.6%)
Antihypertensives	1022 (38.1%)
Diuretics	2031 (75.8%)
ACE-inhibitors	1107 (41.3%)
Sacubitril-Valsartan	379 (14,1 %)
ARB	47 (1.8%)
Statins	1109 (41.4%)
Left ventricular ejection fraction	
EF >50%	126 (4.7%)
EF 40–49%	239 (8.9%)
EF 30–39%	1285 (47.9%)
EF <30%	938 (35.0%)
NYHA class	
NYHA I	163 (6.1%)
NYHA II	1378 (51.4%)
NYHA III	986 (36.8%)
NYHA IV	31 (1.2%)
ECG	
QRS (ms)	115.5 ± 36.2
LBBB	957 (35.7%)

BMI, body mass index; CRT, cardiac resynchronization therapy; COPD, chronic obstructive pulmonary disease; AF, atrial fibrillation; ARB, angiotensin receptor blockers; NYHA, New York Heart Association class.

Table 2. Differences in subgroups according to the type of implantation, type of device, and type of cardiomyopathy.

	Primary prevention (n = 2 199)	Secondary prevention (n = 462)	*P*	Ischemic cardiomyopathy (n = 1 494)	Non-ischemic cardiomyopathy (n = 830)	*P*	Single-chamber ICD (n = 1 446)	Dual-chamber ICD (n = 144)	CRT (n = 1 069)	*P*
Age	66.9 ± 10.9	63.1 ± 14.7	< 0.001	68.1 ± 10.0	64.7 ± 11.5	< 0.001	64.9 ± 12.4	65.0 ± 13.3	68.2 ± 10.0	< 0.001
Age ≥ 75	528 (24.0%)	100 (21.6%)	0.276	399 (26.7%)	156 (18.8%)	< 0.001	314 (21.4%)	27 (18.8%)	290 (27.1%)	0.001
Gender Men	1 719 (78.2%)	336 (72.7%)	0.011	1 190 (79.7%)	643 (77.5%)	0.217	1 110 (75.7%)	110 (76.4%)	849 (79.4%)	0.087
Women	480 (21.8%)	126 (27.3%)		304 (20.3%)	187 (22.5%)		356 (24.3%)	34 (23.6%)	220 (20.6%)	
BMI	28.9 ± 5.3	28.1 ± 4.3	0.079	28.7 ± 4.9	29.1 ± 5.7	0.421	28.7 ± 5.7	28.2 ± 4.7	28.9 ± 4.6	0.279
AF paroxysmal	142 (6.5%)	31 (6.7%)	0.841	93 (6.2%)	60 (7.2%)	0.35	81 (5.5%)	18 (12.5%)	75 (7.0%)	0.004
AF persistent	369 (16.8%)	57 (12.3%)	0.018	196 (13.1%)	180 (21.7%)	< 0.001	216 (14.7%)	15 (10.4%)	198 (18.5%)	0.006
EF >50%	51 (2.3%)	75 (16.2%)	< 0.001	33 (2.2%)	6 (0.7%)	< 0.001	98 (6.8%)	20 (13.9%)	8 (0.7%)	< 0.001
EF 40–49%	143 (6.5%)	95 (20.6%)		159 (10.6%)	37 (4.5%)		161 (11.1%)	25 (17.4%)	53 (5.0%)	
EF 30–39%	1 142 (51.9%)	137 (29.7%)		769 (51.5%)	380 (45.8%)		716 (49.5%)	50 (34.7%)	519 (48.6%)	
EF <30%	829 (37.7%)	96 (20.8%)		480 (32.1%)	401 (48.3%)		431 (29.8%)	31 (21.5%)	474 (44.3%)	
NYHA I	89 (4.0%)	72 (15.6%)	< 0.001	67 (4.5%)	20 (2.4%)	< 0.001	131 (9.1%)	17 (11.8%)	15 (1.4%)	< 0.001
NYHA II	1 140 (51.8%)	235 (50.9%)		843 (56.4%)	383 (46.1%)		954 (66.0%)	91 (63.2%)	333 (31.2%)	
NYHA III	853 (38.8%)	118 (25.5%)		530 (35.5%)	401 (48.3%)		299 (20.7%)	24 (16.7%)	661 (61.8%)	
NYHA IV	24 (1.1%)	7 (1.5%)		14 (0.9%)	14 (1.7%)		11 (0.8%)	3 (2.1%)	17 (1.6%)	
QRS (LBBB)	857 (32.8%)	100 (3.7%)	< 0.001	325 (21.8%)	360 (43.4%)	< 0.001	58 (4.0%)	10 (6.9%)	663 (62.0%)	< 0.001

BMI, body mass index; CRT, cardiac resynchronization therapy; AF, atrial fibrillation; NYHA, New York Heart Association class. Categorial variables are evaluated using Pearson's Chi-Squared test. Continuous variables are evaluated using Mann-Whitney or Kruskal-Wallis test.

Table 3. Mortality in the whole group and in subgroups according to of implantation, type of device and type of cardiomyopathy.

	All patients (n = 2 681)	Primary prevention (n = 2 199)	Secondary prevention (n = 462)	*P*	Ischemic cardiomyopathy (n = 1 494)	Non-ischemic cardiomyopathy (n = 830)	*P*	Single-chamber ICD (n = 1 446)	Dual-chamber ICD (n = 144)	CRT (n = 1 069)	*P*
Deaths	682 (25.4%)	535 (24.3%)	134 (29.0%)	0.673	421 (28.2%)	198 (23.9%)	<0.001	338 (23.1%)	36 (25.0%)	308 (28.8%)	0.193
CV cause of death	479 (17.9%)	376 (17.1%)	93 (20.1%)	0.795	290 (19.4%)	146 (17.6%)	0.010	223 (15.2%)	28 (19.4%)	228 (21.3%)	0.052
non-CV cause of death	203 (7.6%)	159 (7.2%)	41 (8.9%)	0.709	131 (8.8%)	52 (6.3%)	0.002	115 (7.8%)	8 (5.6%)	80 (7.5%)	0.174

Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2023 Sep; 167(3):225-235.

tation, type of device, and type of cardiomyopathy. Standard descriptive statistics was used in the analysis; mean supplemented by standard deviation or median supplemented by interquartile range for continuous variables, and absolute and relative frequencies for categorical variables. Statistical significance of differences among patient groups was evaluated using the Pearson Chi-Square test for categorical variables and the Mann-Whitney or Kruskal-Wallis tests for continuous variables. Survival probability was calculated and visualized by the Kaplan-Meier method. Statistical significance of outcome differences in survival was assessed with the log-rank test. The analysis was computed using SPSS 25.0.0.1.

RESULTS

Demographics

A total of 2,681 patients were included in the registry. The follow-up period was 38.4 ± 29.1 months on average. A single-chamber ICD was implanted in 1,466 cases, dual-chamber ICD in 144 cases, and ICD with CRT (CRT-D) in 1,069 cases. Baseline demographics of the whole patient group can be seen in Table 1. Differences in subgroups according to the type of implantation, type of device, and type of cardiomyopathy are depicted in Table 2.

Categorial variables are evaluated using the Pearson's Chi-Squared test. Continuous variables are evaluated using the Mann-Whitney or Kruskal-Wallis tests.

Mortality

Mortality in the whole group and in subgroups according to the type of implantation, type of device, and type of cardiomyopathy is shown in Table 3. Until the end of follow-up, of the 2,681 patients, 682 (25.4%) died. There was a statistically significant difference when the subgroups were compared according to the type of cardiomyopathy. No significant difference was found between primary and secondary prevention and between the types of devices.

Basic demographic characteristics of patients with death from all causes according to indication for ICD implantation are shown in Fig. 1.

The survival probability according to the type of death (total, CV, and non-CV) in the whole patient group is shown in Fig. 2.

The one-year mortality in all patients was 7.8%; the one-year CV mortality 5.7%; the three-year mortality in all patients 20.6%; and the three-year CV mortality was 14.8%. The survival probability (all-cause death) according to the type of implantation, type of device, and type of cardiomyopathy is shown in Fig. 2. There was a statistically significant difference in the survival probability when ischemic (n = 1,494) and non-ischemic (n = 830) cardiomyopathies were compared (421 /28.2%/ vs. 198 /23.9%/; $P<0.001$). There was no statistically significant difference in the survival probability when the secondary (n = 462) and primary (n = 2,199) prevention indications for implantation (134 /29.0%/ vs. 535 /24.3%/; $P=0.673$) and single-chamber (n = 1,466) vs. dual-chamber (n = 144) vs. CRT (n = 1,069) were compared (338 /23.1%/ vs. 36 /25.0%/ vs. 308 /28.8%/; $P=0.193$). Survival probability classified according to gender, age, AF, and DM is shown in Fig. 3.

Mortality in subgroups

Gender

Survival probability of women (n = 610) and men (n = 2,071) according to the type of implantation, type of device, type of cardiomyopathy is shown in Fig. 4. Women in general had lower mortality than men (126 /20.7%/ vs. 556 /26.9%/; $P=0.018$). This mortality difference was driven by a significantly better survival of women than men with non-ischemic cardiomyopathy (29 /15.5%/ vs.

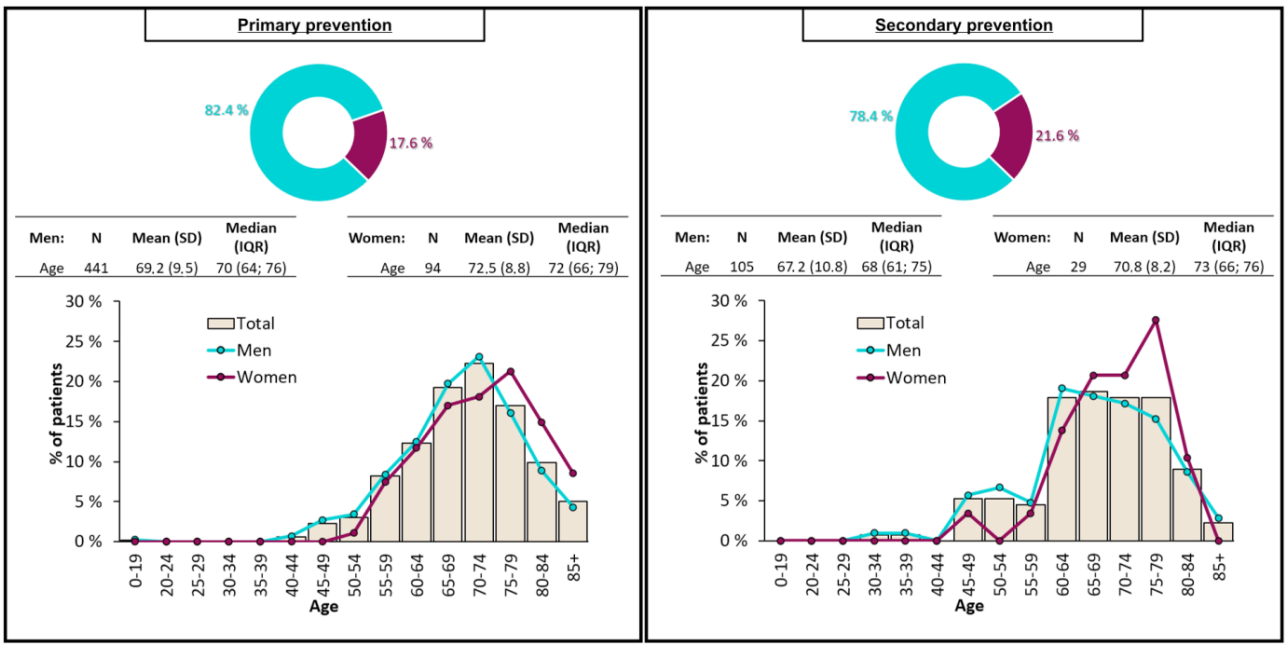

Fig. 1. Basic demographic characteristics of patients with death from all causes according to indication for ICD implantation.

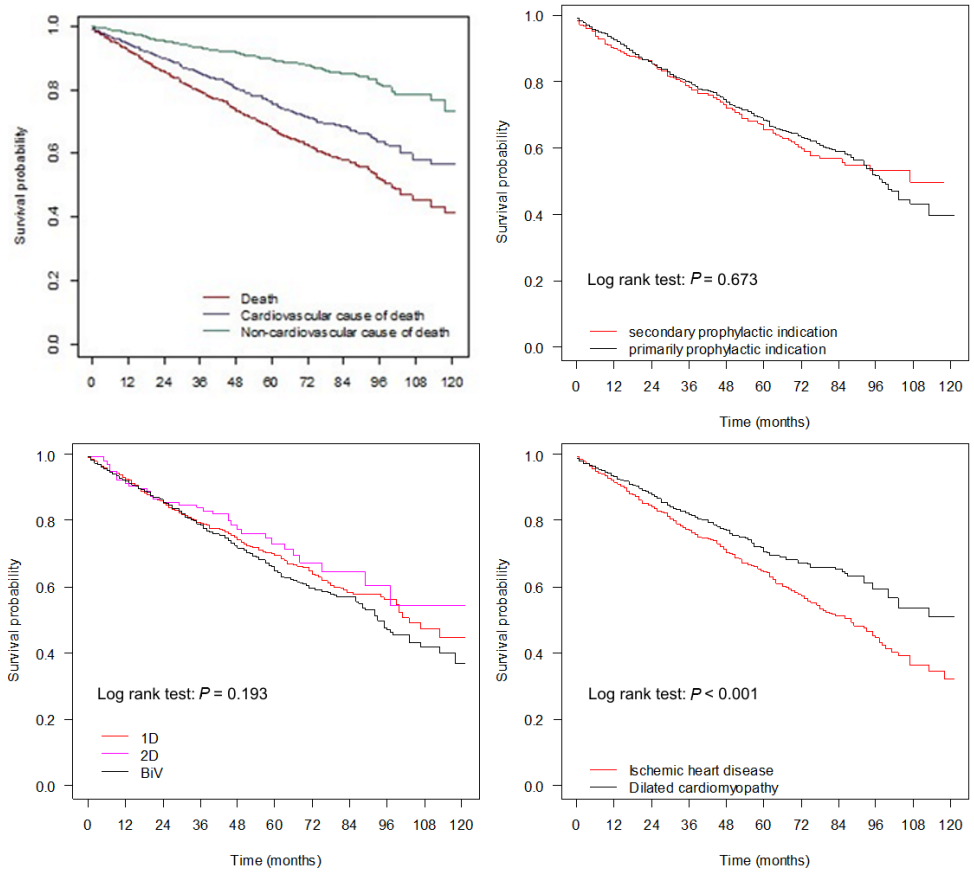

Fig. 2. Survival probability according to the type of implantation, type of device, type of cardiomyopathy, and type of death (total, cardiovascular, and non-cardiovascular).

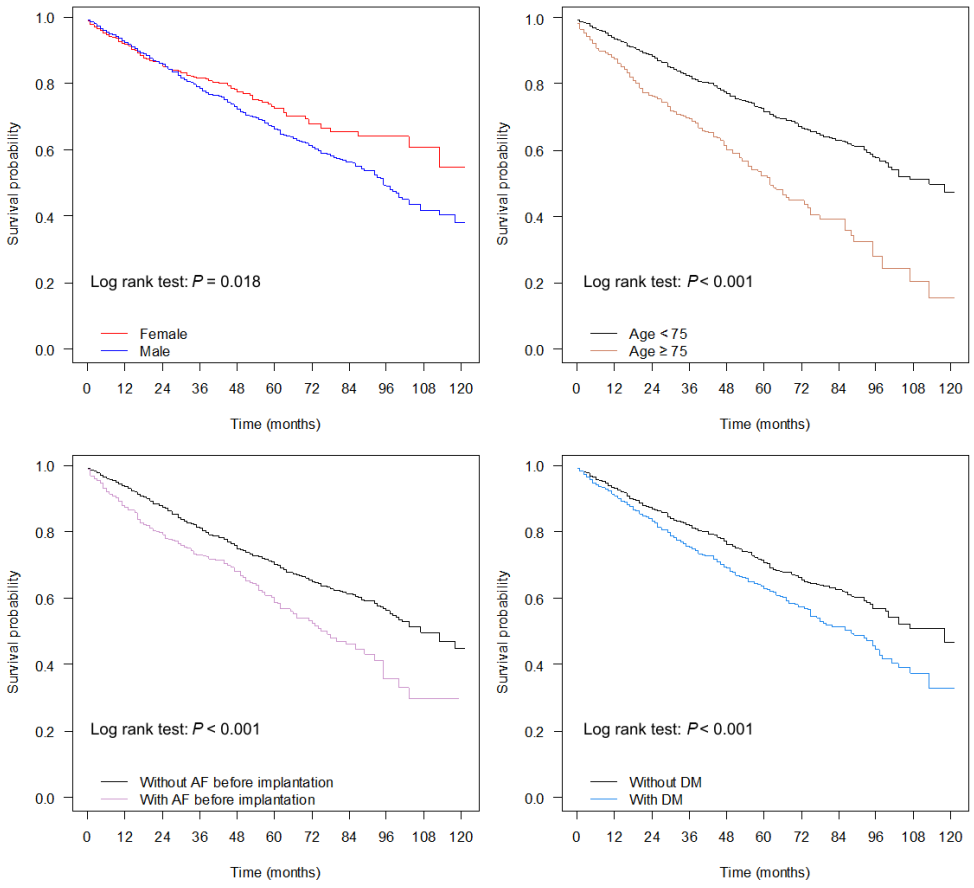

Fig. 3. Survival probability classified according to gender, age, atrial fibrillation, and diabetes mellitus.

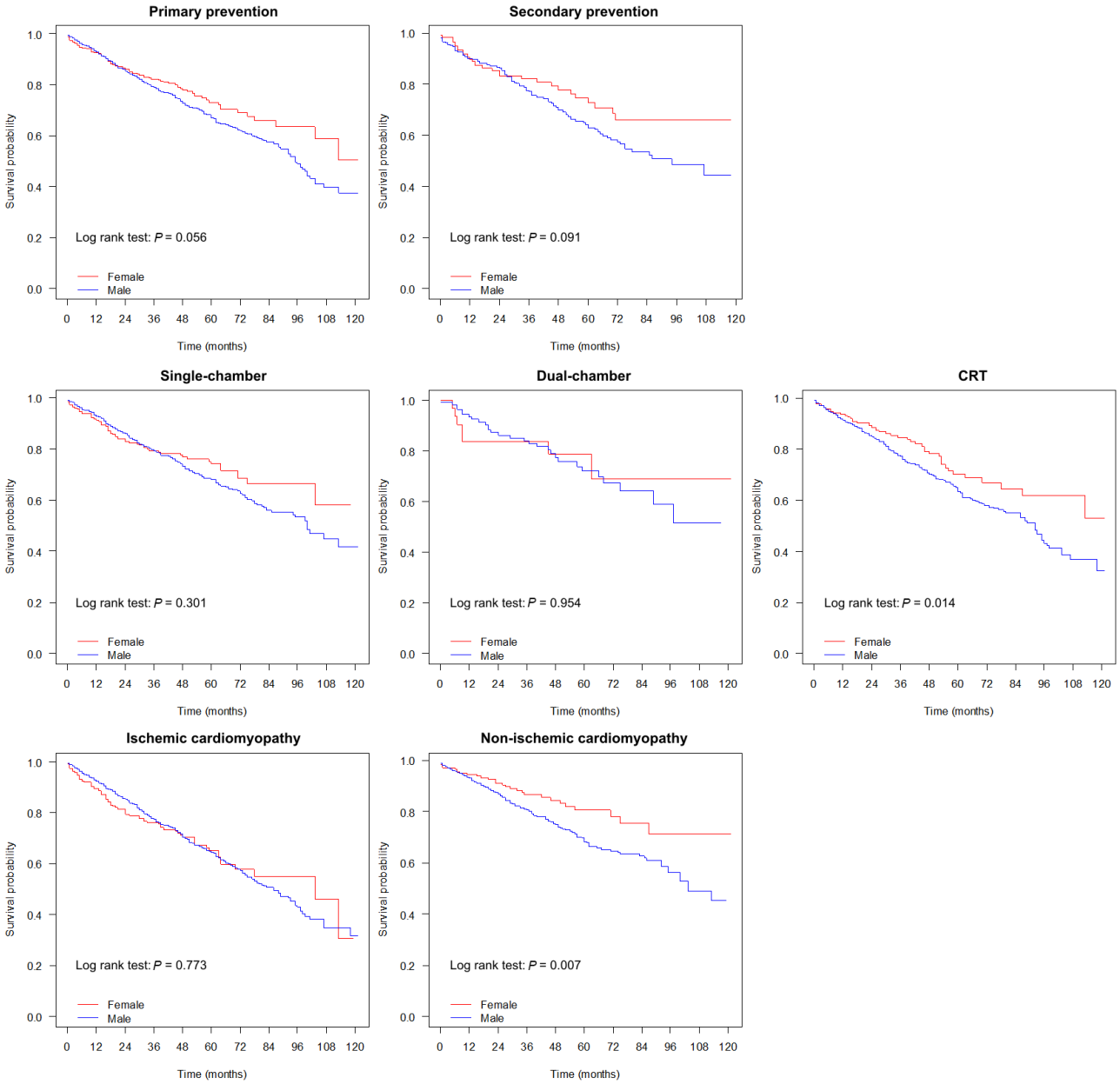

Fig. 4. Survival probability of women and men according to the type of implantation, type of device, and type of cardiomyopathy.

169 /26.3%/; *P*=0.007) and with CRT (47 /21.4%/ vs. 261 /30.7%/; *P*=0.014). No statistically significant difference was found in all types of implantation (94 /19.6%/ vs. 441 /25.7%/; *P*=0.056 in primary prevention; 29 /23.0%/ vs. 105 /31.3%/; *P*=0.091 in secondary prevention); in single-chamber ICDs (72 /20.2%/ vs. 266 /24.0%/; *P*=0.301); dual-chamber ICDs (7 /20.6%/ vs. 29 /26.4%/; *P*=0.954); and in ischemic cardiomyopathy (81 /26.6%/ vs. 340 /28.6%/; *P*=0.773).

Age

Survival probability of all patients younger (n = 2,048) or older (n = 633) than 75 years according to the type of implantation, type of device, and type of cardiomyopathy is shown in Fig. 5. The difference in mortality was significant in general (467 /22.8%/ vs. 215 /34.0%/; *P*<0.001); in all types of implantation (364 /21.8%/ vs. 171 /32.4%/; *P*<0.001 in primary prevention; 95 /26.2%/ vs. 39 /39%/; *P*=0.001 in secondary prevention); all types of devices (225 /19.5%/ vs. 113 /36.0%/; *P*<0.001 in single-chamber; 25 /21.4%/ vs. 11 /40.7%/; *P*=0.029 in dual-chamber; 217 /27.8%/ vs. 91 /31.4%/; *P*<0.001 in CRT) as well as in all types of cardiomyopathies (246 /25.0%/ vs. 137 /36.8%/; *P*<0.001 in ischemic cardiomyopathy; 145 /21.5%/ vs. 53 /34.0%/; *P*<0.001 in non-ischemic cardiomyopathy).

Atrial fibrillation

Survival probability of all patients with (n = 602) or without (n = 2,079) atrial fibrillation prior to implantation according to the type of implantation, type of device, and type of cardiomyopathy is shown in Fig. 6. The difference in mortality was significant in general (194 /32.3%/ vs. 488 /23.5%/; *P*<0.001); in all types of implantation (155 /30.4%/ vs. 380 /22.5%/; *P*<0.001 in primary prevention;

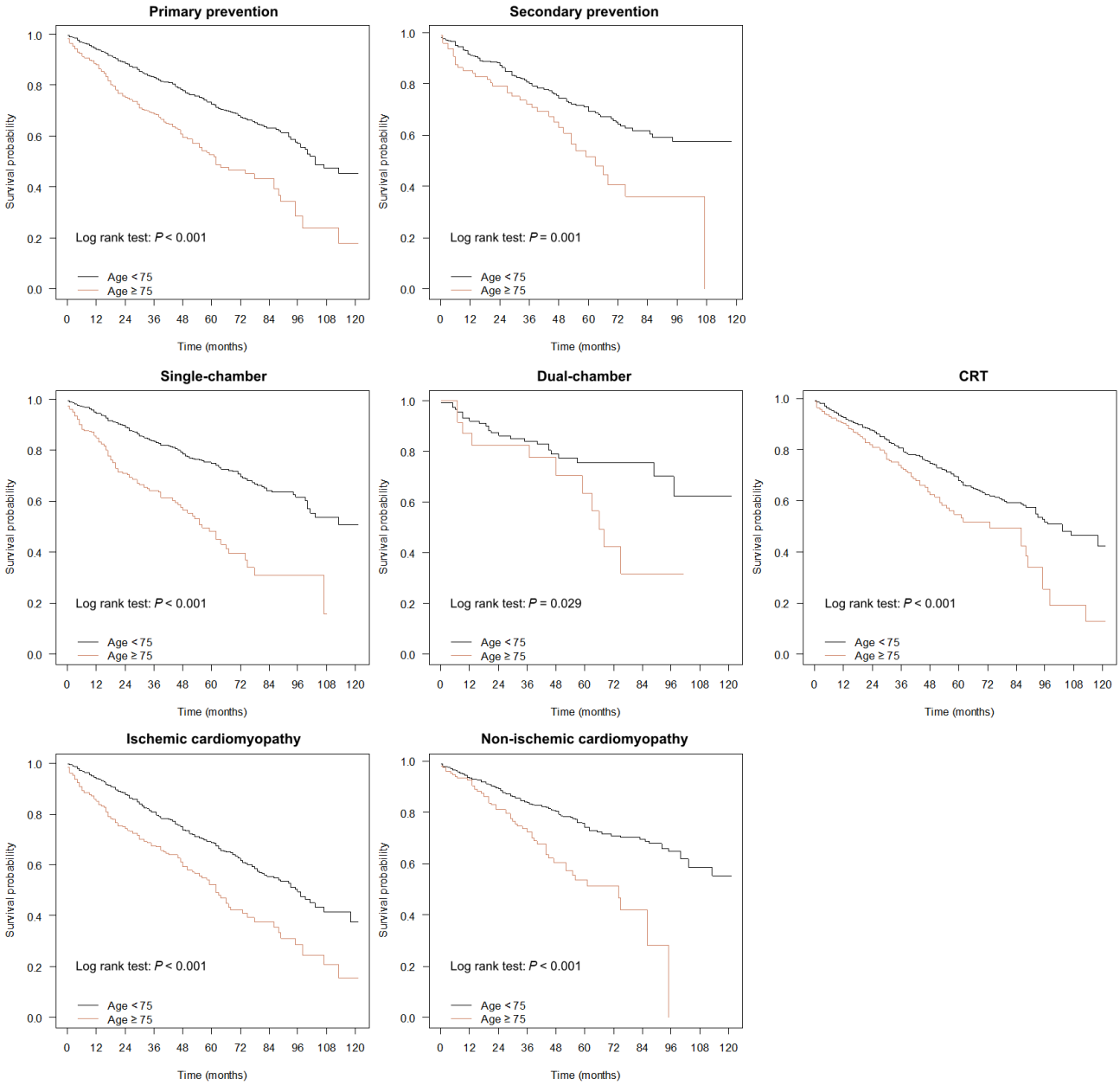

Fig. 5. Survival probability of all patients younger or older than 75 years according to the type of implantation, type of device, and type of cardiomyopathy.

33 /38.4%/ vs. 101 /26.9%/; *P*=0.002 in secondary prevention); in single-chamber ICDs (105 /35.4%/ vs. 233 /19.9%/; *P*<0.001); CRTs (83 /30.5%/ vs. 225 /28.2%/; *P*=0.042) as well as in all types of cardiomyopathy (88 /35.3%/ vs. 295 /26.6%/; *P*<0.001 in ischemic cardiomyopathy; 77 /32.3%/ vs. 121 /20.4%/; *P*<0.001 in non-ischemic cardiomyopathy). The difference was not significant in dual-chamber devices (6 /19.4%/ vs. 30 /26.5%/; *P*=0.593).

Diabetes mellitus

Survival probability of all patients with (n = 1,049) or without (n = 1,632) diabetes mellitus prior to implantation according to the type of implantation, type of device, and type of cardiomyopathy is shown in Fig. 7. The difference in mortality was significant in general (311 /29.6%/ vs. 371 /22.7%/; *P*<0.001); in all types of implantation (256 /28.8%/ vs. 279 /21.3%/; *P*<0.001 in primary prevention; 48 /32.2%/ vs. 86 /27.5%/; *P*=0.110 in secondary prevention); in single-chamber ICDs (159 /30.0%/ vs. 179 /19.9%/; *P*<0.001) as well as in all types of cardiomyopathies (188 /30.0%/ vs. 195 /26.7%/; *P*=0.029 in ischemic cardiomyopathy; 86 /29.4%/ vs. 112 /20.9%/; *P*=0.010 in non-ischemic cardiomyopathy). The difference was not significant in dual-chamber devices (17 /29.3%/ vs. 19 /22.1%/; *P*=0.220) and CRTs (135 /32.1%/ vs. 173 /26.7%/; *P*=0.104).

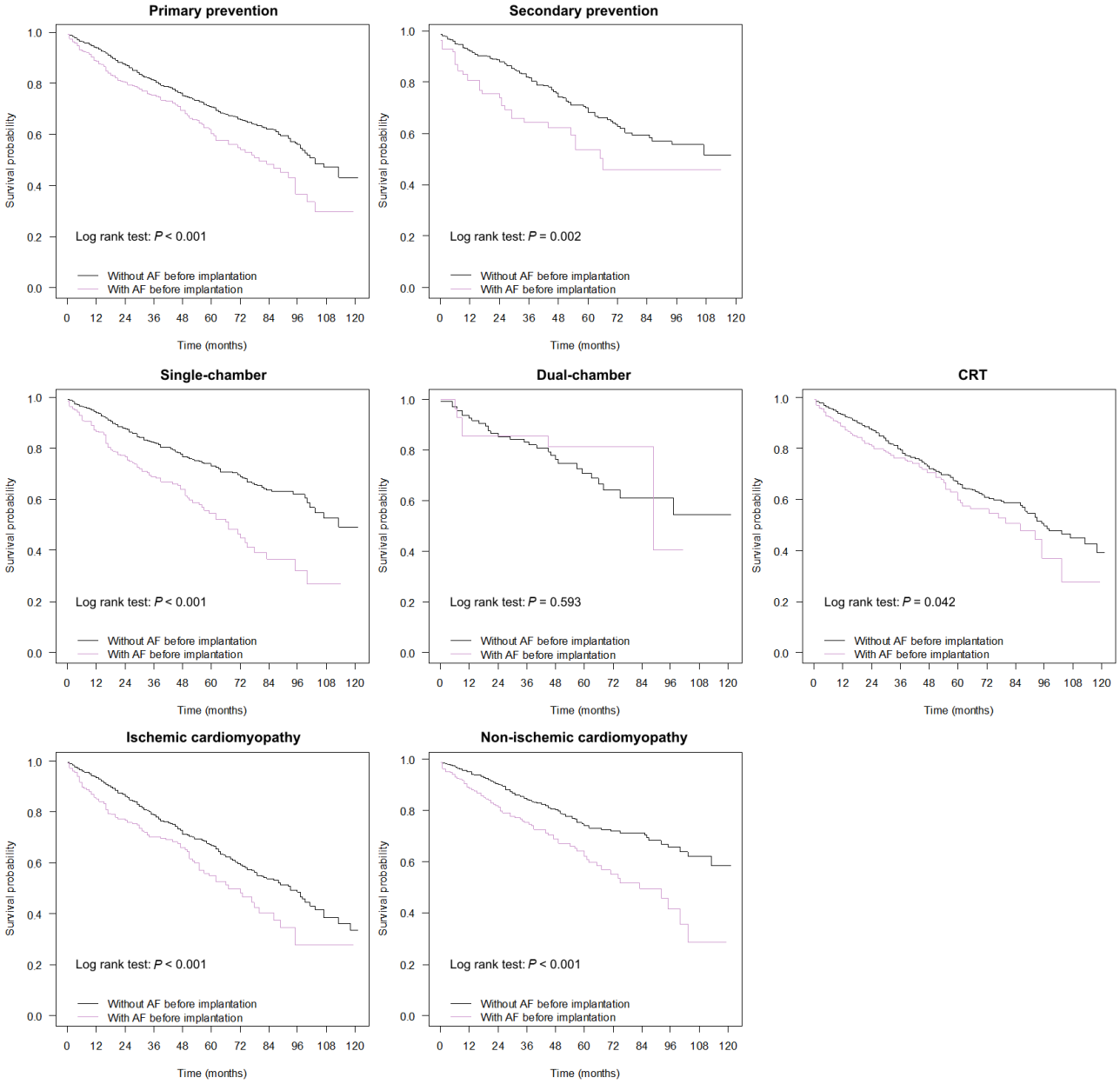

Fig. 6. Survival probability of all patients with or without atrial fibrillation prior to implantation according to the type of implantation, type of device, and type of cardiomyopathy.

DISCUSSION

Since the early 2000s, there has been an apparent gradual decrease in the mortality of HF patients in both observational and randomized studies[4,12]. This can be attributed to improvements in HF pharmacotherapy, a higher prevalence of CRT, and an optimized ICD programming[13]. Simultaneously, the rates of SCD have decreased, as have the numbers of appropriate life-saving ICD therapies. The average annual shock rate in the MADIT-II trial was 17%, whereas the percentages of patients who had a life-saving shock were 3% and 4% in the Israeli ICD registry during a 30-month follow-up and in the MADIT-RIT during an average follow-up of 1.6 years, respectively[6,14]. An estimation based on the results of the Israeli ICD registry indicates that 95% of ICD recipients in the primary prevention indication category do not receive a life-saving ICD therapy[6]. ICDs cannot be implanted in all patients. This strategy is not viable due to limited healthcare resources, and implantation of ICD and CRT devices is not without risk as it is still associated with significant morbidity, increased hospitalizations, and reduced survival[15]. ICD implantation may have a significant impact on mortality only in patients with a low risk of non-arrhythmic mortality and a high risk of appropriate ICD intervention. Our analysis of a 10-year follow-up (a mean follow-up of 38.4 ± 29.1 months) of 2,681 consecutive patients with an implanted ICD in a contemporary real-world setting focused on finding subgroups of patients with significant differences in mortality, which could enable us to identify patients with a better outcome after ICD implantation.

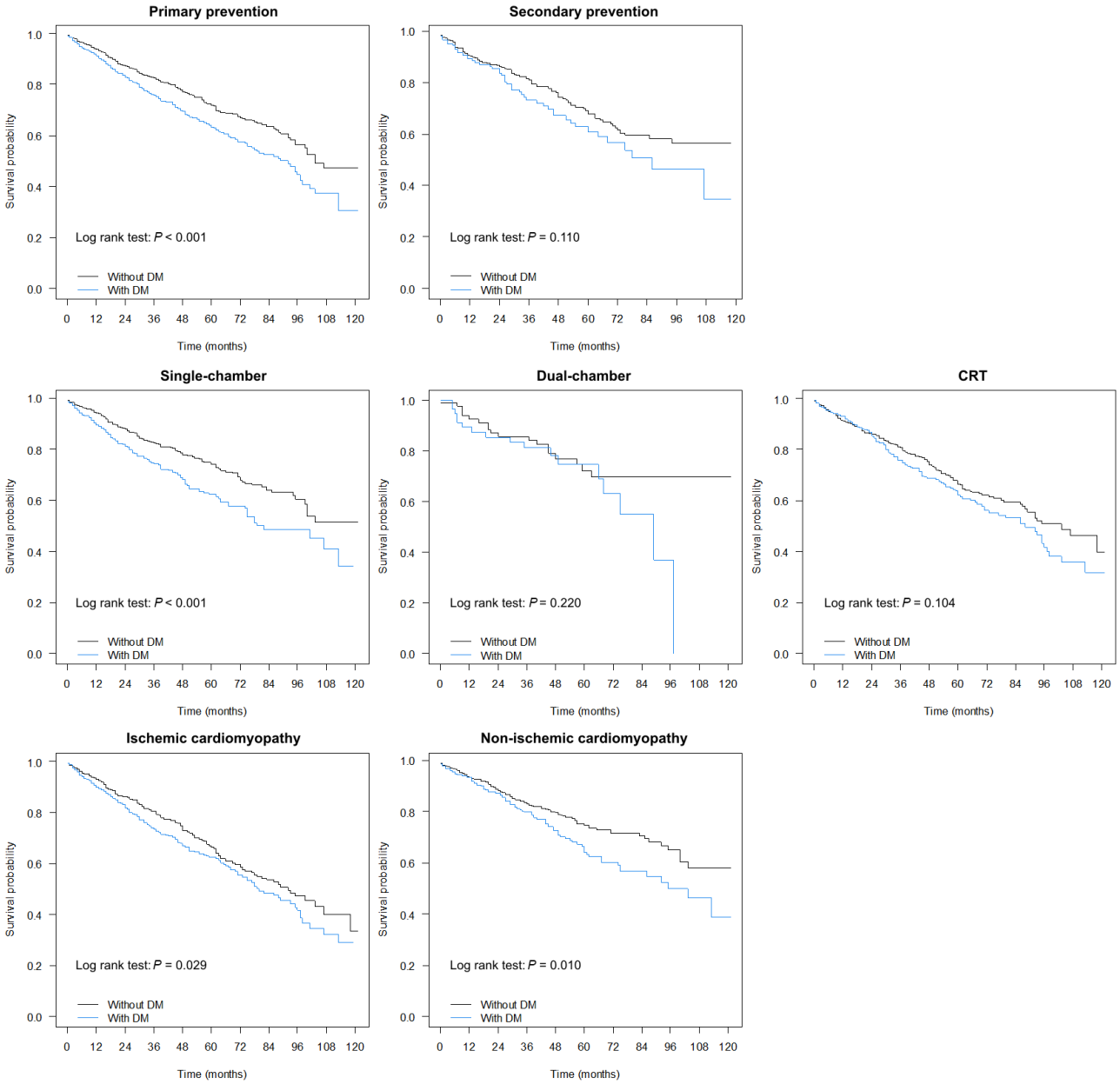

Fig. 7. Survival probability of all patients with or without diabetes mellitus prior to implantation according to the type of implantation, type of device, and type of cardiomyopathy.

In our patient group, the one-year mortality in all patients was 7.8%, CV mortality 5.7%; the three-year mortality in all patients 20.6%, and CV mortality 14.8%. The mortality in our patient group was higher when compared with the Israeli ICD registry which reported a mortality of 14% at 30 months of follow-up[6]. Moreover, data from the EU-CERT-ICD Multicentre Cohort Study showed a slightly lower mortality (5.6% annual mortality in the ICD group) (ref.[10]). The somewhat higher mortality in our patient group could be explained by a high proportion of patients with severe comorbidities. Diabetes mellitus was present in almost 40% of patients, chronic renal insufficiency in 10%, and AF in more than 22% of patients. The analysis of data from our registry focused on several parameters that were found most usable by previous studies. Barra et al. found that patients with ICM (ischemic cardiomyopathy) were more prone to die from arrhythmia than those with NICM (non-ischemic cardiomyopathy) (ref.[16]). Similar rates of appropriate ICD therapy in primary prevention ICD indication were documented in ICM and NICM by Amara et al.[17]. We documented a statistically significant difference in mortality when the subgroups were compared according to the type of cardiomyopathy. Patients with ICM had higher all-cause, CV, and non-CV mortality rates in comparison with NICM patients. In our study, 39.9% of all ICDs were CRT-Ds. This is a far higher number in comparison with studies from the early 2000s, and this proportion of CRT is comparable with that in the Israeli ICD registry where 45% of ICDs were CRT-D[6]. No significant difference was found between patients implanted for primary and secondary prevention indication and between the types of devices (1-D, 2-D ICD, and CRT-D). This is in accordance with the Danish ICD Register which demonstrated no differ-

ence in the risk of all-cause mortality associated with the device type[18].

A lower survival advantage in ICD patients was demonstrated in diabetics and patients older than 75 years in the EU-CERT-ICD controlled multicentre cohort study[10]. This finding is consistent with our data. In our study, there was a significantly higher mortality in all patients older than 75 years, irrespective of the device type or type of cardiomyopathy. When comparing diabetics with non-diabetics, there was no difference in mortality in patients with a dual-chamber ICD and CRT-D. In single-chamber ICDs, the difference in mortality was significant. Also, when patients were compared according to the type of cardiomyopathy, diabetes was associated with a significantly higher mortality risk in ICM as well as in NICM. Atrial fibrillation was found to be associated with an increased risk for mortality and HF progression in patients with asymptomatic and symptomatic left ventricular systolic dysfunction[19]. In our patient group, AF was associated with an increased mortality risk in all subgroups of patients except those with a dual-chamber ICD. This might be explained by a more frequent paroxysmal AF diagnosis in dual-chamber ICDs. Patients with more comorbidities and persistent or permanent AF are generally more often implanted a 1-D ICD or CRT-D with a subsequent AV node ablation. Women are generally less often present in clinical trials evaluating the benefit of ICD in HF patients[20]. In our registry, women were a minority as well (22.8%). Women in general had a lower mortality than men. This mortality difference was driven by a significantly better survival of women than men with non-ischemic cardiomyopathy and with CRT. Our data confirm the significant differences in the mortality of individual subgroups of patients and further support the need for a new approach to risk stratification for SCD. A personalized assessment of the individual risk is the goal of the upcoming PROFID project[11].

Several study limitations need to be recognized. The main limitation is the observational nature of the study. There is no control group to be compared with the ICD group. Data on appropriate and inappropriate shocks were not included in the registry and are thus not available for analysis. Some information bias cannot be ruled out since the registry data were not checked externally.

CONCLUSION

In an analysis of a long-term follow-up of 2,681 ICD patients, we found no mortality difference between patients with ischemic or non-ischemic cardiomyopathy and in the device type. A higher mortality risk was found in men, patients older than 75 years, diabetics, and those with atrial fibrillation.

Author contributions: MT, TS: literature search, manuscript writing, data analysis, final approval; MF, VD, IS: follow-up of the patients; JJ, KB, MB, MV, JD: data analysis; JK: data analysis, final approval.

Conflict of interest statement: The authors state that there are no conflicts of interest regarding the publication of this article.

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