ESC European Society of Cardiology

European Heart Journal (2021) **42**, 3529–3537
doi:10.1093/eurheartj/ehab253

CLINICAL RESEARCH
Arrhythmias

Driving following defibrillator implantation: a nationwide register-linked survey study

Jenny Bjerre [1,2]*, Simone Hofman Rosenkranz[1], Morten Schou [1], Christian Jøns [3], Berit Thornvig Philbert [3], Charlotte Larroudé[1], Jens Cosedis Nielsen[4], Jens Brock Johansen[5], Sam Riahi [6], Thomas Maria Melchior[7], Christian Torp-Pedersen [8], Mark Hlatky [9], Gunnar Gislason [1,10], and Anne-Christine Ruwald [1,7]

[1]Department of Cardiology, Copenhagen University Hospital Herlev and Gentofte, Gentofte Hospitalsvej 6, 3rd Floor, Hellerup 2900, Denmark; [2]Department of Cardiology, Copenhagen University Hospital Bispebjerg and Frederiksberg, Bispebjerg Bakke 23, 2400 Copenhagen, Denmark; [3]Department of Cardiology, Copenhagen University Hospital Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen, Denmark; [4]Department of Clinical Medicine, Aarhus University Hospital, Palle Juul-Jensens Blvd. 82, 8200 Aarhus, Denmark; [5]Department of Cardiology, Odense University Hospital, J.B. Winsløws Vej 4, 5000 Odense C, Denmark; [6]Department of Cardiology, Aalborg University Hospital, Hobrovej 18-22, 9200 Aalborg, Denmark; [7]Department of Cardiology, Zealand University Hospital, Sygehusvej 10, 4000 Roskilde, Denmark; [8]Department of Cardiology and Clinical Research, Nordsjællands Hospital, Dyrehavevej 29, 3400 Hillerød, Denmark; [9]Department of Medicine, Stanford University School of Medicine, 615 Crothers Way Encina Commons, Stanford, CA 94305, USA; and [10]Department of Cardiovascular Epidemiology and Research, The Danish Heart Foundation, Vognmagergade 7, 1120 Copenhagen, Denmark

Received 26 November 2020; revised 4 March 2021; editorial decision 31 March 2021; accepted 13 April 2021; online publish-ahead-of-print 5 May 2021

See page 3538 for the editorial comment on this article (doi:10.1093/eurheartj/ehab490)

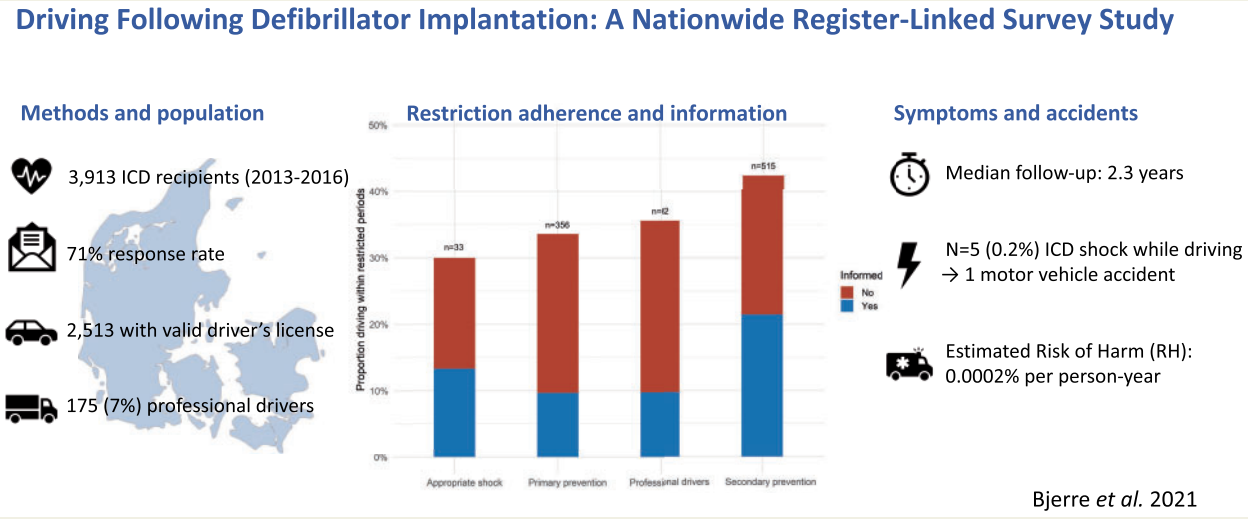
Aims Patients are restricted from driving following implantable cardioverter defibrillator (ICD) implantation or shock. We sought to investigate how many patients are aware of, and adhere to, the driving restrictions, and what proportion experience an ICD shock or other cardiac symptoms while driving.

Methods and results We performed a nationwide survey of all living Danish residents 18 years or older who received a first-time ICD between 2013 and 2016 ($n = 3913$) and linked their responses with nationwide registers. Of 2741 respondents (47% primary prevention, 83% male, median age 67 years), 2513 (92%) held a valid driver's license at ICD implantation, 175 (7%) of whom had a license for professional driving. Many drivers were unaware of driving restrictions: primary prevention 58%; secondary prevention 36%; post-appropriate shock 28%; professional drivers 55%. Almost all (94%) resumed non-professional driving after ICD implantation, more than one-third during the restricted period; 35% resumed professional driving. During a median follow-up of 2.3 years, 5 (0.2%) reported receiving an ICD shock while driving, one of which resulted in a traffic accident. The estimated risk of harm was 0.0002% per person-year.

Conclusion In this nationwide study, many ICD patients were unaware of driving restrictions, and more than one third resumed driving during a driving restriction period. However, the rate of reported ICD shocks while driving was very low.

* Corresponding author. Tel: +45 31957313, Fax: +45 39777642, Email: jennybjerre@gmail.com

Graphical Abstract



In a nationwide study of >2500 implantable cardioverter defibrillator recipients, the reported rate of shocks while driving was very low despite widespread non-adherence to driving restrictions.

Keywords Implantable cardioverter defibrillator • Driving restriction • Motor vehicle accident • Defibrillator shock

Introduction

Implantable cardioverter defibrillators (ICDs) significantly reduce the risk of sudden cardiac death, both in survivors of malignant ventricular arrhythmias (secondary prevention) and in patients at increased risk of sudden cardiac arrest (primary prevention).[1–3]

Concern about the risk of sudden incapacitation while driving led to driving restrictions in patients following ICD implantation or ICD therapy. Current guidelines from the European Society of Cardiology (ESC) recommend a 3-month restriction following secondary prevention ICD implantation or appropriate ICD shock, and a 1-month restriction following primary prevention ICD implantation.[4] American Heart Association guidelines are more restrictive, recommending a 6-month driving ban following ICD implantation for secondary prevention or appropriate ICD therapy.[5] Both groups recommend permanent restriction of professional driving and driving of vehicles above 3500 kg.[4,5]

Driving is considered a basic necessity by many people, and inability to drive may severely limit individuals and adversely affect their quality of life.[6] Whether driving restrictions for contemporary ICD patients are needed to ensure safety has been much discussed.[7,8] Recent advances in device programming, pharmacological management, and catheter ablation for ventricular tachycardia underline the need for updated data to guide policy about driving for ICD patients.[9–12]

Although implantation rates are increasing worldwide,[13] there are few data describing driving behaviour of unselected contemporary ICD recipients. Despite guideline recommendations,[4] previous studies suggest that patient education regarding driving restrictions is often not given or recalled by ICD recipients, and that adherence to restrictions is poor.[14–17]

Therefore, we studied a nationwide ICD population to investigate patient awareness of driving restrictions and their adherence to them, as well as the proportion who experienced an ICD shock, syncope, or other cardiac symptoms while driving.

Methods

Study design and population

We surveyed a nationwide ICD cohort, identified by comprehensive national Danish registers. At the time of birth or immigration, all residents in Denmark are provided with a unique and permanent civil registration number, which enables individual-level linkage of nationwide administrative registers as well as patient-reported data.

We included all patients ≥18 years of age who had a first-time ICD implantation performed in Denmark between January 1, 2013 and December 31, 2016 ($n = 4514$). Following exclusions due to pre-test or pilot test participation ($n = 64$), death ($n = 415$), emigration, or invalid addresses ($n = 122$), we distributed the final questionnaire to 3913 ICD patients (Supplementary material online, *Figure S1*).

During the study period, primary prevention ICD implantation was recommended for patients with symptomatic ischaemic cardiomyopathy with an LVEF ≤ 35% despite optimal medical therapy. However, non-ischaemic cardiomyopathy patients receiving an ICD through the DANISH

trial are also included in our cohort.[18] Secondary prevention ICD recipients were cardiac arrest survivors or patients with documented hemodynamically unstable ventricular tachycardia or fibrillation.[19]

Danish recommendations restricted ICD patients from private driving (motorcycle, car, and tractor; Group 1 license) for 1 week or 1 month following primary prevention ICD implantation, depending on whether home monitoring was established. After secondary prevention ICD implantation or delivery of an appropriate ICD shock, patients were restricted from driving for 3 months. In contrast to ESC guidelines,[4] there were no restrictions following appropriate anti-tachycardia pacing therapy. Professional driving and driving of vehicles >3500 kg (Group 2 license) was permanently restricted.[20] Danish ICD recipients keep their license card, and the police is not routinely informed about driving restrictions for medical reasons.

Questionnaire development and distribution

Development of the questionnaire has been described elsewhere.[21] Briefly, we constructed the questionnaire based on a systematic review of the literature and findings of semi-structured focus group interviews ($n = 10$). Overall, pre-testing by cognitive interviewing ($n = 28$), pilot testing ($n = 50$), and test-retesting ($n = 25$) demonstrated good content validity, feasible data collection methods, a robust response rate, and good reliability of the questionnaire items.[21] We applied branching methods to guide the individual respondents through the questionnaire. Consequently, the denominator for the different questionnaire items may vary.

ICD recipients who reported not holding a valid driver's licence at time of ICD implantation were excluded from further questions. In line with European and Danish guidelines, we defined private driving as driving of regular cars, motorcycles or tractors, and large vehicle and professional driving as driving of vehicles >3500 kg or any driving for professional purposes, including passenger transportation.[4,22]

We mailed study invitations on May 16, 2017 urging participants to complete an anonymous, web-based questionnaire using a patient-specific code (they could request a paper version). After 3 weeks, we mailed non-responders a reminder along with a paper version of the questionnaire (Supplementary material online). All paper-based responses were entered into the web-based questionnaire software (SurveyXact, Ramboll A/S[23]) by double manual entry.

Data sources

We identified patients and retrieved data from the Danish Pacemaker and ICD register[24] on indication for implantation (primary or secondary prevention), New York Heart Association functional class, and left ventricular ejection fraction. We identified comorbidities and hospital contacts following motor vehicle accidents from discharge diagnosis codes registered in the Danish National Patient Register[25–27] and pharmacotherapy through Anatomic Therapeutical Chemical codes in the Danish Register for Medicinal Product Statistics.[28] We utilized the Danish Register of Causes of Death to identify ICD recipients who had died due to a motor vehicle accident prior to questionnaire distribution[29] (Supplementary material online, *Table S1*).

We retrieved each patient's updated address, vital status, sex, date of birth, and emigration history from the Danish Civil Registration System and obtained data on educational attainment and personal income from Statistics Denmark. Lastly, we used the patient's residence municipality code to characterize the degree of urbanization, according to Eurostat classifications.[30]

Statistical analyses

The questionnaire response rate was calculated using the American Association for Public Opinion Research's Response Rate Calculator, version 9.[31] We defined all returned questionnaires, partial or complete, as responders and performed all analyses on an available case basis without imputation for item non-response. We did not apply any weighting methods to adjust for non-response bias. Thus, estimates of population parameters are not reported.

We compared continuous variables using Wilcoxon rank-sum test and dichotomous variables using chi-square or Fisher's exact test, as appropriate. We assessed statistical significance as a two-sided *P*-value of <0.05.

Non-adherence to driving restrictions was defined as resumption of driving within the guideline-recommended restricted periods and we applied multivariable logistic regression models to estimate the odds ratios (ORs) with 95% confidence intervals (CIs) for risk factors associated with non-adherence (Supplementary material online). We estimated the incidence rates and their 95% CIs of cardiac symptoms while driving per 10 000 person-hour spent driving from reported driving habits (Supplementary material online).

Based on patient-reported data on ICD shocks while driving, we calculated a modified risk of harm (RH), as has been done previously.[32] The RH formula, developed by the Canadian Cardiology Society in 1992[33] and adopted by guidelines worldwide,[4,20,34] attempts to quantify the risk of death or injury to other road users posed by a patient with heart disease as:

$RH = TD \times SCI \times V \times Ac$. Here, TD represents proportion of time spent driving (normally set at 0.04/1 h per day for private drivers, and 0.25/6 h per day for professional drivers); SCI is the time-dependent risk of sudden cardiac incapacitation, for ICD patients equalling the risk of ICD shock multiplied by the probability that an ICD shock will lead to syncope (the latter typically set to 0.14 or 0.32[35,36]); V is the risk depending on type of vehicle (0.28 for standard passenger cars or 1.0 for commercial heavy trucks); and Ac is the probability that an event while driving will result in death or injury to others (normally set at 0.02 per event).[33,37] We defined $TD \times SCI$ as the percent of respondents reporting ICD shock while driving per patient-year $\times$ the estimated risk of syncope with ICD shock (0.32). In additional scenario analyses, we assumed the rate of ICD shocks while driving was 2, 5 and 20$\times$ higher than reported by the respondents to account for potential underreporting.

We performed statistical analyses using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and R (version 3.5, R Foundation for Statistical Computing).

Ethical considerations

The study complies with the Declaration of Helsinki and was reported to the regional Ethical Committee which concluded no ethical approval was needed (reference number H-17002489). However, the study was registered and approved by the data responsible institute (Capital Region of Denmark, P-2019-051). Approval to obtain current addresses on the study participants was granted by the Danish Health Data Authority (FSEID-2420). Participants were informed that responding to the questionnaire was considered providing informed consent. Neither questionnaire nor cover letter included specific information about the guideline-recommended driving restrictions. Danish data protection legislation prohibits detailed reporting of register-based observations with counts <3, but not from data solely generated from questionnaire responses.

Table 1 Characteristics of questionnaire responders at implantable cardioverter defibrillator implantation

Characteristic	All patients	Primary prevention ICD	Secondary prevention ICD
N	2741	1274	1467
Male sex (%)	2276 (83.0)	1058 (83.0)	1218 (83.0)
Age at ICD implant (median, IQR), years	67 (59, 73)	68 (61, 74)	66 (58, 72)
Months since ICD implantation, median (IQR)	28 (16, 40)	29 (16, 41)	27 (15, 39)
NYHA class > II (%)[a]	310 (12.9)	222 (19.6)	88 (6.9)
LVEF, median (IQR), %[b]	30 (25, 45)	30 (25, 30)	40 (30, 50)
CRT-D (%)	617 (22.5)	437 (34.3)	180 (12.3)
Congestive heart failure (%)	1888 (68.9)	1178 (92.5)	710 (48.4)
Ischaemic heart disease (%)	2130 (77.7)	1101 (86.4)	1029 (70.1)
Previous MI (%)	1493 (54.5)	793 (62.2)	700 (47.7)
Previous CABG (%)	654 (23.9)	374 (29.4)	280 (19.1)
Previous PCI (%)	1286 (46.9)	663 (52.0)	623 (42.5)
Cerebrovascular disease (%)	363 (13.2)	186 (14.6)	177 (12.1)
Atrial fibrillation (%)	623 (22.7)	298 (23.4)	325 (22.2)
Syncope (%)	299 (10.9)	132 (10.4)	167 (11.4)
Diabetes (%)	578 (21.1)	334 (26.2)	244 (16.6)
Chronic obstructive pulmonary disease (%)	431 (15.7)	219 (17.2)	212 (14.5)
Chronic kidney disease (%)	82 (3.0)	47 (3.7)	35 (2.4)
Alcohol abuse (%)	45 (1.6)	15 (1.2)	30 (2.0)
Beta-blockers (%)	2302 (84.0)	1138 (89.3)	1164 (79.3)
ACE inhibitor/ARB (%)	2169 (79.1)	1154 (90.6)	1015 (69.2)
Diuretics (%)	1668 (60.9)	991 (77.8)	677 (46.1)
Digoxin (%)	207 (7.6)	113 (8.9)	94 (6.4)
Antiarrhythmics (%)	305 (11.1)	65 (5.1)	240 (16.4)
Income quartiles (%)			
First quartile	602 (22.0)	325 (25.5)	277 (18.9)
Second quartile	678 (24.7)	323 (25.4)	355 (24.2)
Third quartile	695 (25.4)	323 (25.4)	372 (25.4)
Fourth quartile	766 (27.9)	303 (23.8)	463 (31.6)
Education level (%)			
Basic school	796 (29.0)	386 (30.3)	410 (27.9)
High school	89 (3.2)	33 (2.6)	56 (3.8)
Vocational	1191 (43.5)	555 (43.6)	636 (43.4)
Short/medium	440 (16.1)	199 (15.6)	241 (16.4)
Long/higher education	166 (6.1)	63 (4.9)	103 (7.0)
Unknown	59 (2.2)	38 (3.0)	21 (1.4)
Geographic residence at ICD implantation (%)[c]			
Densely populated area	665 (24.3)	309 (24.3)	356 (24.3)
Intermediate density area	1060 (38.7)	496 (38.9)	564 (38.4)
Thinly populated area	1007 (36.7)	461 (36.2)	546 (37.2)

ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; CABG, coronary artery bypass grafting; CRT-D, cardiac resynchronization therapy with defibrillation; ICD, implantable cardioverter defibrillator; IQR, interquartile range; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
[a]Missing *n* = 329.
[b]Missing *n* = 5.
[c]Missing *n* = 18.

Results

Among the 415 ICD recipients who died prior to questionnaire distribution, less than 3 had died due to a motor vehicle accident.

The questionnaire was returned by 2772 individuals (*n* = 1274 primary prevention), an overall response rate of 71% (Supplementary material online, *Table S2*). We excluded 31 responders without data on ICD indication yielding a final analysable population of 2741 ICD patients (Supplementary material online, *Figure S1*). The responders

Table 2 Driving characteristics of questionnaire responders

Characteristic, *n* (%)	All patients	Primary prevention ICD	Secondary prevention ICD	Missing, *n*[b]
Private license at ICD implant (%) (*n* = 2741)[a]	2513 (92.3)	1156 (91.4)	1357 (93.0)	17
Professional/large vehicle license at ICD implant (%) (*n* = 2513)	684 (27.9)	316 (28.2)	368 (27.7)	64
Use of professional/large vehicle license 6 months prior to ICD implant (%) (*n* = 684)	175 (27.0)	68 (23.2)	107 (30.2)	37
Purpose of professional/large vehicle license, users (%) (*n* = 175)				0
Truck driver	73 (41.7)	26 (38.2)	47 (43.9)	
Bus driver	45 (25.7)	16 (23.5)	29 (27.1)	
Taxi driver	22 (12.6)	7 (10.3)	15 (14.0)	
Private use	54 (30.9)	23 (33.8)	31 (29.0)	
Other purposes[c]	32 (18.3)	12 (17.6)	20 (18.7)	
Only driver in household (%) (*n* = 2513)	713 (28.7)	363 (31.8)	350 (26.1)	31
Employed at ICD implant (%) (*n* = 2741)	990 (36.4)	408 (32.3)	582 (40.0)	23
Has resumed driving following ICD implantation (*n* = 2513)	2344 (94.2)	1085 (94.9)	1259 (93.5)	24

ICD, implantable cardioverter defibrillator.
[a]The number of eligible patients for each questionnaire item may vary.
[b]Analyses were performed on an available case basis.
[c]Including, among others, military personnel, car dealers, professional movers, ambulance drivers, driving instructors, and auto mechanics.

were predominantly male (83%) and had a median age of 67 [interquartile range (IQR): 59–73] years (*Table 1*).

Compared with responders, the 1130 non-responders were significantly younger, more likely to be female, primary prevention ICD recipients, have more comorbidities, receive less guideline-recommended pharmacotherapy, and have a lower socioeconomic status. Non-responders and responders had similar rates of motor vehicle accidents requiring medical evaluation following ICD implantation (0.6% vs. 0.3%, $P = 0.135$) (Supplementary material online, *Table S3*). None of these accidents occurred within 6 months following ICD implantation.

Almost all patients ($n = 2513$, 92%) held a valid driver's license at ICD implantation, 175 (7%) of whom were also using a license for professional driving or driving of large vehicles within the 6 months prior to ICD implantation (*Table 2*).

Information on driving restrictions

Among those with a valid private driver's license ($n = 2513$), 58% ($n = 652$) of primary prevention and 36% ($n = 474$) of secondary prevention patients reported that they were unaware of driving restrictions following ICD implantation (*Table 3*). Of the 54% ($n = 1339$), who reported being informed of any restrictions, 54% ($n = 717$) reported being informed of the guideline-recommended restricted periods following ICD implantation. Fewer primary prevention patients (29%) than secondary prevention patients (67%) recalled being informed about the correct restrictions. Only 45% ($n = 79$) of active professional drivers reported having been informed about specific restrictions for professional or large vehicle driving. Following appropriate ICD shock ($n = 131$), 72% ($n = 94$) reported they had been informed about driving restrictions (*Table 3*). Recall of receipt of information was slightly better in responders with more recent ICD implantations (Supplementary material online, *Figure S2*).

Resumption of driving

Following ICD implantation, 2344 (94%) patients resumed driving, with no significant difference between primary and secondary prevention patients ($P = 0.14$) (Supplementary material online, *Table S4*). The median time to resumption of driving following implantation was 8 days (IQR: 3–21) for primary prevention patients and 90 days (IQR: 21–90) for secondary prevention patients. Of the 131 patients who had experienced an appropriate ICD shock, 120 also provided information about driving resumption and 94% of them resumed driving following the shock at a median time of 90 days (IQR: 30–90) (*Figure 1*). Lastly, 35% ($n = 62$) of the active professional drivers had resumed professional or large vehicle driving with a median time to resumption of 29 days (IQR: 10–90): 66% of these reported they were truck, bus, or taxi drivers.

Non-adherence

2290 ICD recipients reported when they had resumed private driving following ICD implantation or appropriate ICD shock. Among these, 34% of primary prevention patients, 43% of secondary prevention patients, and 30% of those who experienced an appropriate ICD shock had resumed driving during the recommended restricted periods (*Figure 1*). The proportion of patients driving within the restricted periods was significantly higher among those unaware of driving restrictions, as compared with patients who reported being informed ($P < 0.001$). However, for secondary prevention patients and after appropriate shock, resumption of driving within the restricted period was almost equally distributed between patients who were informed and those who were not (*Figure 2*).

In a multivariable logistic regression model, significant predictors of non-adherence to private driving restrictions were non-receipt of information, secondary prevention ICD indication, male sex, age above 60 years, and being the only driver in the household (Supplementary material online, *Figure S3*). In a model of knowingly driving in

Table 3 Information received about driving restrictions, as recalled by patients

	Primary prevention ICD ($n = 1156$)	Secondary prevention ICD ($n = 1357$)	Appropriate ICD shock ($n = 131$)	Professional drivers ($n = 175$)
Informed about driving restrictions				
n (%)[a]	1135 (98.2)	1330 (98.0)	131 (100)	174 (99.4)
Yes	483 (42.6)	856 (64.4)	94 (71.8)	79 (45.4)
No	339 (29.9)	246 (18.5)	28 (21.4)	61 (35.1)
Cannot remember	313 (27.6)	228 (17.1)	9 (6.9)	34 (19.5)
Information received				
n (%)[a]	483 (100)	855 (99.9)	94 (100)	79 (100)
Information recalled corresponds to guidelines	141 (29.2)	576 (67.4)	84 (89.4)	56 (70.9)
Resume driving immediately or when I felt ready	142 (29.4)	77 (9.0)	5 (5.3)	3 (3.8)
Resume driving after 1 week	141 (29.2)	46 (5.4)	0	0
Resume driving after 1 month	83 (17.2)	79 (9.2)	3 (3.2)	1 (1.3)
Resume driving after 3 months	66 (13.7)	576 (67.4)	84 (89.4)	12 (15.2)
Never resume driving again	1 (0.2)	2 (0.2)	0	56 (70.9)
Others[b]	50 (10.4)	75 (8.8)	2 (2.1)	7 (8.9)

ICD, implantable cardioverter defibrillator.
[a]*n* (%) represents the number and percentage of eligible patients who had replied to the specific question.
[b]Including, among others, following general practitioner's check-up, defibrillator testing, 2 weeks, and 6 months.

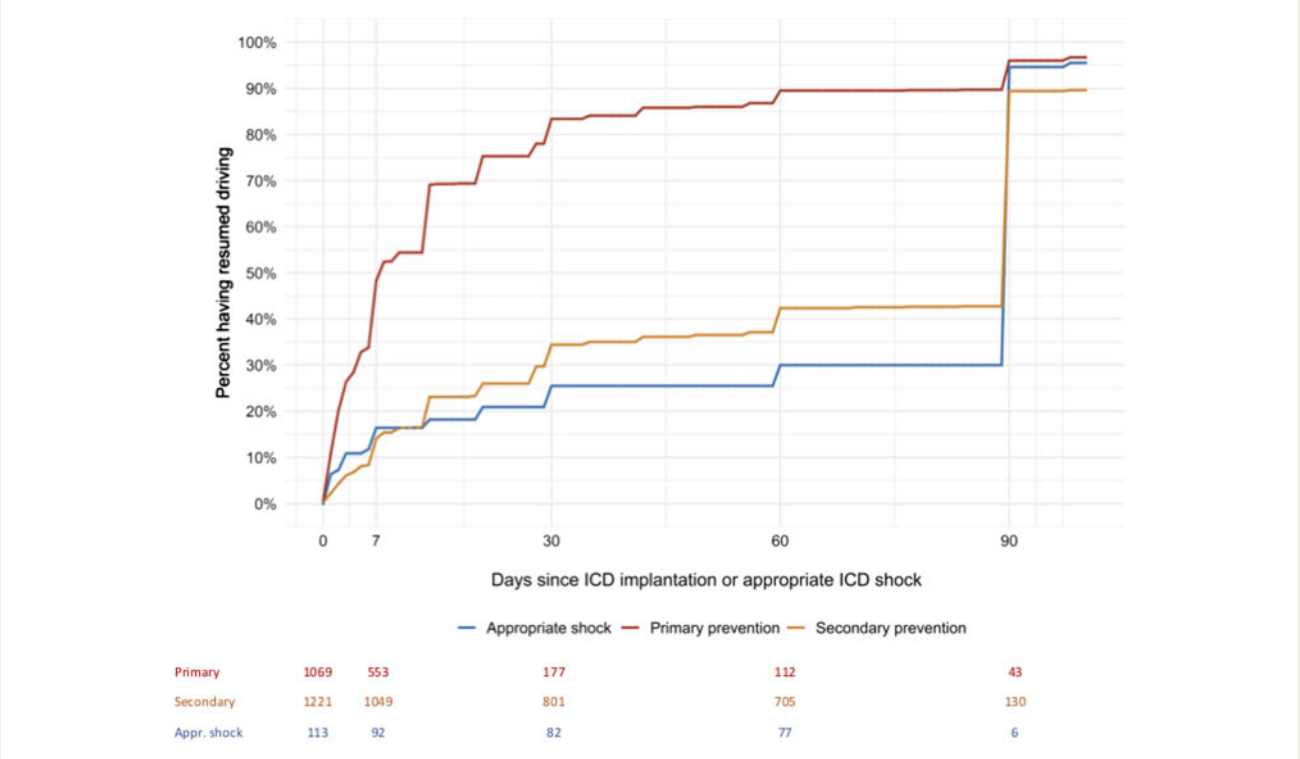


Figure 1 Resumption of driving following implantable cardioverter defibrillator implantation or appropriate implantable cardioverter defibrillator shock. **Time to resumption of driving following implantable cardioverter defibrillator implantation for primary prevention, secondary prevention and following appropriate implantable cardioverter defibrillator shock with days and percent having resumed driving. Among those who reported time to resumption of private driving ($n = 2290$), 34% of primary prevention patients reported having resumed driving within the recommended 7-day restriction period and 43% of secondary prevention patients resumed driving within 3 months. Among patients having experienced an appropriate implantable cardioverter defibrillator shock and provided response on driving resumption ($n = 120$), 94% ($n = 113$) reported the resumption of driving, whereof 30% occurred before the 3-month period had passed.**

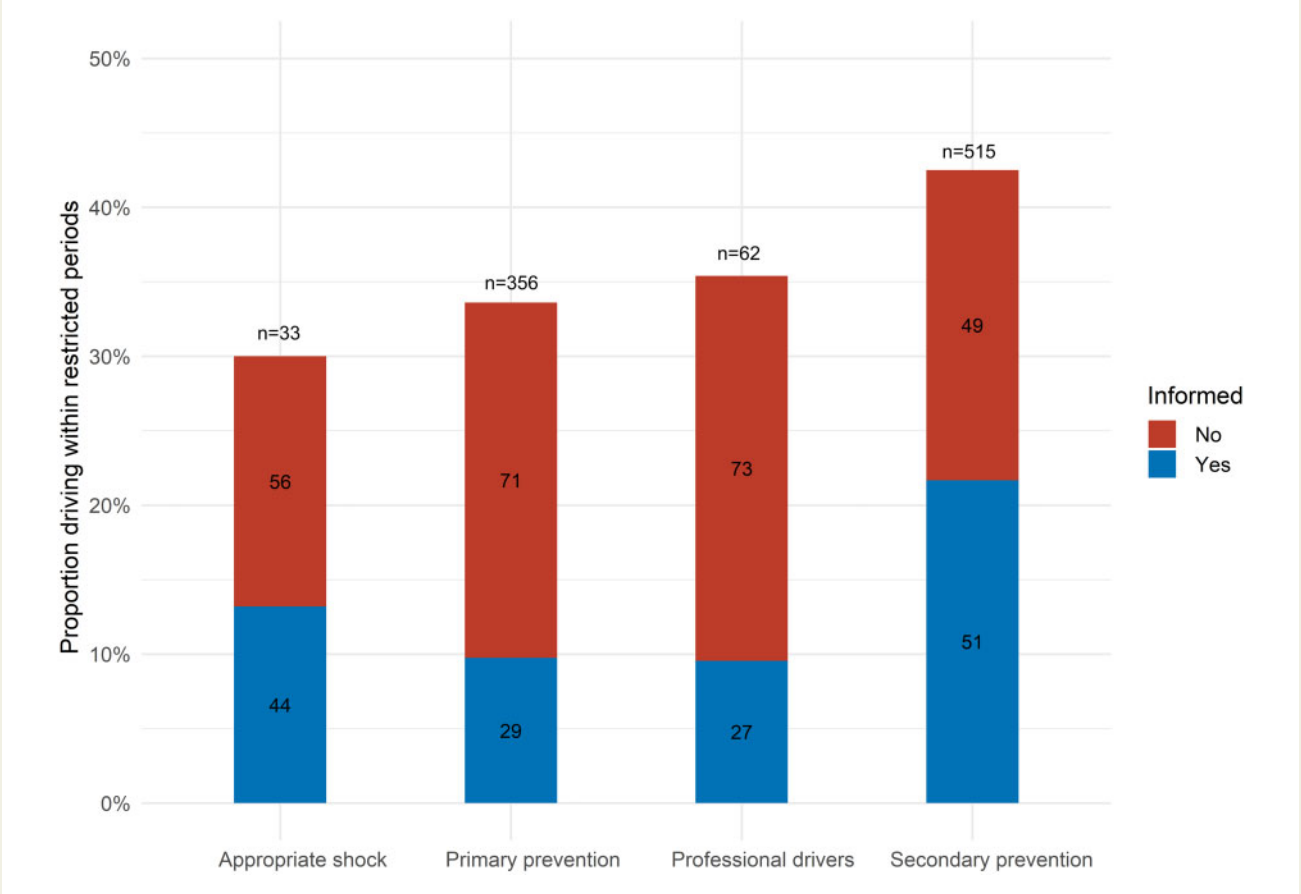


Figure 2 Proportion of patients driving within restricted period by information status. **The proportion of patients with implantable cardioverter defibrillators driving within the restricted periods (1 week following primary prevention implantable cardioverter defibrillator implantation, 3 months following secondary prevention implantable cardioverter defibrillator implantation and appropriate implantable cardioverter defibrillator shock, and permanent restriction of professional and large vehicle driving). The bar height represents the overall percentage of patients resuming driving within the restricted periods. Among these, the blue stacks represent the percentage of patients reporting receipt of specific driving restrictions following implantable cardioverter defibrillator implantation or implantable cardioverter defibrillator shock, and the red stacks represent the percentage of patients who reported they had not received information or could not recall having received information about any driving restrictions.**

restricted periods ($n = 831$), only male sex (OR: 1.89, 95% CI: 1.00–3.58) and age >60 years (OR: 0.44, 95% CI: 0.27–0.72) were significant predictors (Supplementary material online, *Figure S4*).

Cardiac symptoms while driving

During a median period of 2.3 years (IQR: 1.3–3.4), 316 (13%) reported experiencing an ICD shock (primary prevention: 9%; secondary prevention: 16%, $P = 0.023$), the majority reporting the shock was appropriate (primary prevention: 38%; secondary prevention: 46%). Inappropriate shocks constituted 13% and 22% of shocks for primary and secondary prevention patients, respectively. The remaining shocks were reported as of unknown aetiology.

Only 5 (0.2%) of the patients who had resumed driving after ICD implantation reported receiving an ICD shock while driving, and another 5 (0.2%) patients reported syncope (unrelated to ICD shock therapy) while driving (Supplementary material online, *Table S5*). This corresponded to a risk of 0.10% per patient-year. One episode of ICD shock and one episode of syncope while driving resulted in a motor vehicle accident. Calculating a theoretical RH, the risk to other road users posed by the ICD patients in our cohort would be: 0.01 × 0.32 (TD × SCI: percent experiencing ICD shock while driving per patient-year and the risk of syncope in relation with ICD shock) × 0.28 (V: private vehicle) × 0.02 (Ac: incapacitation causing injuring accident) = 0.0002% per person-year. Assuming the responders' rate of ICD shocks while driving was 20 times higher than reported by the patients over the same follow-up time resulted in an RH of 0.003% (Supplementary material online, *Table S6*).

All patients experiencing an ICD shock while driving were male with a median age of 64 years and none were professional drivers. Three of five patients had adhered to driving guidelines. We are unaware whether the remaining two ICD shocks occurred within a restricted period.

Dizziness, palpitations, and chest pain while driving were more common events (Supplementary material online, *Table S5*), but none resulted in a motor vehicle accident.

Discussion

This nationwide survey study of >2700 contemporary ICD patients demonstrates that many ICD patients were unaware of recommended driving restrictions following implantation and appropriate ICD shock. Furthermore, up to 43% of private drivers and 35% of professional and large vehicle drivers had resumed driving during restricted periods. Nevertheless, only 5 (0.2%) individuals reported receiving an ICD shock while driving (*Graphical Abstract*).

Our results are consistent with previous studies of selected patients showing that physician-recommended driving restrictions are often not given or not recalled by patients,[14,15,38] that almost all patients resume driving following ICD implantation,[15,16] and that many patients resume driving before restricted periods have ended.[14–16,38] Secondary prevention patients, subject to a 3-month restricted period following ICD implantation, were more likely to resume driving prematurely than primary prevention patients only subject to a 1-week restriction. There is considerable heterogeneity in driving restrictions worldwide,[39] and adherence might be poorer in countries recommending a driving ban of 6 months or more following ICD implantation or ICD therapy.

Not surprisingly, we found that patients who said they were not informed about driving restrictions were less likely to follow them. Recall and comprehension of discharge instructions can be problematic, especially in older patients, and our results are within the ranges following other medical admissions.[40–42] Clearly, a stronger focus on communicating driving restrictions to patients is warranted, which might improve adherence.[21] Discharge discussions should include patients' next of kin and simple communication tools, for example 'teach-back methods', could prove helpful.[40,43] Information should be given in writing, and special patient discharge programs could also be valuable.[40,44]

However, almost half of secondary prevention and appropriate shock patients who resumed driving too early reported they had in fact been informed about driving restrictions. That many consider driving to be almost a basic human right, and that driving restrictions can significantly interfere with everyday life and undermine the patient's self-image, could explain why many patients ignore physician's advice.[45]

It was alarming that 55% of ICD patients who were driving large vehicles or driving professionally reported they had not been informed about the stricter limitations on their driving and 35% had resumed driving professionally. Both American and European guidelines agree that professional driving should be permanently banned due to the number of hours spent behind the wheel and the potential greater impact caused by larger vehicles.[4,5] Based on our results, special focus on identifying professional drivers seems reasonable.

Our study subjects reported a very low rate of ICD shocks while driving: only 0.2% reported receipt of an ICD shock while driving during a median of 2.3 years of follow-up, corresponding to 0.05 events per 10,000 person-hours spent driving. This rate is uncertain, since approximately 10% of eligible patients had died or emigrated before questionnaire distribution, and 29% never responded. However, in analysis of nationwide hospital encounters, non-responders and responders had similar rates of motor vehicle accidents requiring medical evaluation, suggesting that the estimate is not biased by survey non-response. Also, less than three ICD recipients otherwise eligible for study participation had died due to a motor vehicle accident prior to questionnaire distribution.

Few prior studies have investigated the risk of ICD discharge and arrhythmic symptoms while driving.[14–16,46] In a survey sub-study from the AVID (Antiarrhythmics vs. Implantable Defibrillators) trial, 8% of the 295 ICD recipients reported receiving an ICD shock while driving.[16] However, the AVID trial included survivors of ventricular arrhythmias between 1993 and 1997, prior to advances in medical treatment and device programming. Likewise in a secondary prevention ICD population, 7 of 1106 (0.6%) patients from the TOVA (Triggers of Ventricular Arrhythmia) trial experienced an ICD shock while driving over a median follow-up time of 562 days, and only one ICD shock resulted in an accident.[46] Lastly, in a more recent, but smaller study of 241 ICD patients, 8 patients (3.3%) received an ICD shock while driving, corresponding to an annual risk of shock while driving of 1.5%.[15] However, their shock rate was twice as high as in our cohort and half of shocks were inappropriate.

Using our data to calculate a potential RH, we estimated the risk of serious injury or death to other road users would be 0.0002% per person-year, lower than the typically accepted threshold of 0.005%.[4] There are several caveats in the RH formula, most importantly that the assumptions are based on historical data.[8,33] Moreover, the patients in our cohort might have driven less than the 7 hours per week used in the RH formula or been reluctant to answer truthfully. Still, when assuming the rate of ICD shocks while driving was 20 times higher than reported, the RH remained below 0.005%. Lastly, those refraining from driving might be more likely to have experienced symptoms of possible arrhythmia.

Nevertheless, the rates of ICD shock and syncope while driving in our cohort are the lowest reported yet, despite more than one third of patients recommencing driving within guideline-recommended restricted periods. While this study does not provide sufficient evidence to rescind current driving restrictions for ICD patients, we believe our data suggest the potential risk to other road users posed by contemporary ICD patients appears to be quite low.

Strengths and limitations

The major strengths of our study include its nationwide scope, real-life setting, the large size of the cohort, its linkage with administrative registers, and the high response rate to the survey. The study has the inherent limitations of all survey research.[47] By only including patients who were alive at time of questionnaire distribution, we have inevitably introduced a survivor and healthy participant bias. Similarly, we found the non-responders did in fact differ significantly from the responders and our results should be interpreted in this context. Patients who had ignored driving restrictions or experienced ICD shock while driving, may have been less likely to respond. Also, the risk that some patients may have answered untruthfully remains.

Recall bias is also a significant concern, especially because of our relatively long follow-up of up to 4.5 years, high median age of responders, and potentially affected neurocognition of cardiac arrest survivors.[48–50] Since our shock data are patient-reported, there is a risk of both under- and overreporting and misclassification of shock appropriateness. Nevertheless, the shock rates reported by our responders were comparable to prospective Danish register studies.[51,52] Unfortunately, we were not able to adjudicate patient-reported events of ICD therapy while driving with hospital records,

nor do we have information about device programming. Furthermore, the questionnaire did not include questions regarding motor vehicle accidents in general, so we cannot report what proportion of accidents were due to ICD therapy. Lastly, although our results on recall of restrictions and the adherence to them were comparable to published data from other societies, cross-country generalization can be problematic due to differences in health care systems, driving culture, and legislation.

Conclusion

In this large nationwide survey study, up to 58% of ICD patients were unaware of the driving restrictions, and more than one-third, including professional drivers, resumed driving within the restricted periods. Despite a high proportion of patients resuming driving prematurely, only 0.2% of respondents reported receipt of ICD shock while driving. This corresponded to an estimated RH of 0.0002% per person-year, suggesting a low RH to other road users posed by ICD patients.

Supplementary material

Supplementary material is available at *European Heart Journal* online.

Funding

This work was supported by the Danish Heart Foundation [16-R107-A6633 to J.B.]; Arvid Nilssons Foundation [to J.B.]; and Fraenkels Mindefond [to J.B.].

Data availability

The data underlying this article cannot be shared publicly due to the privacy of individuals that participated in the study.

Conflict of interest: J.B.J. reports personal fees from Medtronic, personal fees from Biotronik, and non-financial support from Merit Medical, outside the submitted work. J.C.N. reports grants from Novo Nordisk Foundation, outside the submitted work. A.-C.R. reports personal fees from Novartis, outside the submitted work. C.T.-P. reports grants from Bayer and grants from Novo Nordisk, outside the submitted work.

References

1. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, Greene HL, Boczor S, Domanski M, Follmann D, Gent M, Roberts RS. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. *Eur Heart J* 2000;**21**:2071–8.
2. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS, Daubert JP, Higgins SL, Brown MW, Andrews ML; Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;**346**:877–83.
3. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R, Domanski M, Troutman C, Anderson J, Johnson G, McNulty SE, Clapp-Channing N, Davidson-Ray LD, Fraulo ES, Fishbein DP, Luceri RM, Ip JH; Sudden Cardiac Death in Heart Failure Trial Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;**352**:225–37.
4. Vijgen J, Botto G, Camm J, Hoijer CJ, Jung W, Le Heuzey JY, Lubinski A, Norekval TM, Santomauro M, Schalij M, Schmid JP, Vardas P. Consensus statement of the European Heart Rhythm Association: updated recommendations for driving by patients with implantable cardioverter defibrillators. *Europace* 2009;**11**:1097–107.
5. Epstein AE, Baessler CA, Curtis AB, Estes NA, 3rd, Gersh BJ, Grubb B, Mitchell LB; American Heart Association, Heart Rhythm Society. Addendum to "Personal and public safety issues related to arrhythmias that may affect consciousness: implications for regulation and physician recommendations: a medical/scientific statement from the American Heart Association and the North American Society of Pacing and Electrophysiology": public safety issues in patients with implantable defibrillators: a scientific statement from the American Heart Association and the Heart Rhythm Society. *Circulation* 2007;**115**:1170–6.
6. Timmermans I, Jongejan N, Meine M, Doevendans P, Tuinenburg A, Versteeg H. Decreased quality of life due to driving restrictions after cardioverter defibrillator implantation. *J Cardiovasc Nurs* 2018;**33**:474–480.
7. Thijssen J, Borleffs CJW, van Rees JB, de Bie MK, van der Velde ET, van Erven L, Bax JJ, Cannegieter SC, Schalij MJ. Driving restrictions after implantable cardioverter defibrillator implantation: an evidence-based approach. *Eur Heart J* 2011;**32**:2678–2687.
8. Margulescu AD, Anderson MH. A review of driving restrictions in patients at risk of syncope and cardiac arrhythmias associated with sudden incapacity: Differing global approaches to regulation and risk. *Arrhythm Electrophysiol Rev* 2019;**8**:90–98.
9. Moss AJ, Schuger C, Beck CA, Brown MW, Cannom DS, Daubert JP, Estes NAM, Greenberg H, Hall WJ, Huang DT, Kautzner J, Klein H, McNitt S, Olshansky B, Shoda M, Wilber D, Zareba W; MADIT-RIT Trial Investigators. Reduction in inappropriate therapy and mortality through ICD programming. *N Engl J M* 2012;**367**:2275–2283.
10. Gasparini M, Proclemer A, Klersy C, Kloppe A, Lunati M, Ferrer JBM, Hersi A, Gulaj M, Wijfels MCEF, Santi E, Manotta L, Arenal A. Effect of long-detection interval vs standard-detection interval for implantable cardioverter-defibrillators on antitachycardia pacing and shock delivery: the ADVANCE III randomized clinical trial. *JAMA* 2013;**309**:1903–1911.
11. Shen L, Jhund PS, Petrie MC, Claggett BL, Barlera S, Cleland JGF, Dargie HJ, Granger CB, Kjekshus J, Køber L, Latini R, Maggioni AP, Packer M, Pitt B, Solomon SD, Swedberg K, Tavazzi L, Wikstrand J, Zannad F, Zile MR, McMurray JJV. Declining risk of sudden death in heart failure. *N Engl J Med* 2017;**377**:41–51.
12. Shivkumar K. Catheter ablation of ventricular arrhythmias. *N Engl J Med* 2019;**380**:1555–1564.
13. Raatikainen MJP, Arnar DO, Merkely B, Nielsen JC, Hindricks G, Heidbuchel H, Camm J. A decade of information on the use of cardiac implantable electronic devices and interventional electrophysiological procedures in the European Society of Cardiology countries: 2017 report from the European Heart Rhythm Association. *Europace* 2017;**19**(Suppl 2):1–90.
14. Conti JB, Woodard DA, Tucker KJ, Bryant B, King LC, Curtis AB. Modification of patient driving behavior after implantation of a cardioverter defibrillator. *Pacing Clin Electrophysiol* 1997;**20**:2200–4.
15. Mylotte D, Sheahan RG, Nolan PG, Neylon MA, McArdle B, Constant O, Diffley A, Keane D, Nash PJ, Crowley J, Daly K. The implantable defibrillator and return to operation of vehicles study. *Europace* 2013;**15**:212–8.
16. Akiyama T, Powell JL, Mitchell LB, Ehlert FA, Baessler C; Antiarrhythmics versus Implantable Defibrillators Investigators. Resumption of driving after life-threatening ventricular tachyarrhythmia. *N Engl J Med* 2001;**345**:391–7.
17. Craney JM, Powers MT. Factors related to driving in persons with an implantable cardioverter defibrillator. *Prog Cardiovasc Nurs* 1995;**10**:12–7.
18. Køber L, Thune JJ, Nielsen JC, Haarbo J, Videbæk L, Korup E, Jensen G, Hildebrandt P, Steffensen FH, Bruun NE, Eiskjær H, Brandes A, Thøgersen AM, Gustafsson F, Egstrup K, Videbæk R, Hassager C, Svendsen JH, Høfsten DE, Torp-Pedersen C, Pehrson S; DANISH Investigators. Defibrillator implantation in patients with nonischemic systolic heart failure. *N Engl J Med* 2016;**375**:1221–30.
19. Priori SG, Blomström-Lundqvist C, Mazzanti A, Blom N, Borggrefe M, Camm J, Elliott PM, Fitzsimons D, Hatala R, Hindricks G, Kirchhof P, Kjeldsen K, Kuck K-H, Hernandez-Madrid A, Nikolaou N, Norekvål TM, Spaulding C, Van Veldhuisen DJ; ESC Scientific Document Group. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: the Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC). Endorsed by: association for European Paediatric and Congenital Cardiology (AEPC). *Eur Heart J* 2015;**36**:2793–2867.
20. Retningslinjer for udstedelse af kørekort hos patienter med hjertelidelser [in Danish]. In: *Dansk Cardiologisk Selskab*; 2012. p13–14.
21. Bjerre J, Rosenkranz SH, Christensen AM, Schou M, Jons C, Gislason G, Ruwald AC. Driving following defibrillator implantation: development and pilot results from a nationwide questionnaire. *BMC Cardiovasc Disord* 2018;**18**:212.
22. Selskab DC. (2018) Kørekort hos patienter med hjertelidelser.
23. *SurveyXact by Ramboll A/S*. https://www.surveyxact.com.
24. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Risk factors for lead complications in cardiac pacing: a population-based cohort study of 28,860 Danish patients. *Heart Rhythm* 2011;**8**:1622–8.

25. Schmidt M, Schmidt SA, Sandegaard JL, Ehrenstein V, Pedersen L, Sorensen HT. The Danish National Patient Registry: a review of content, data quality, and research potential. *Clin Epidemiol* 2015;**7**:449–90.
26. *NOMESCO classification of external causes of injury*. 4th ed. Copenhagen: Nordic Medico-Statistical Committee; 2007.
27. Strøbæk L FE, Ryd JT, Davidsen M, Eriksen L, Jensen HAR, White ED, Juel K. *Sygdomsbyrden i Danmark—ulykker, selvskade og selvmord [in Danish]*. Copenhagen: National Institute of Public Health, University of Southern Denmark; 2017.
28. Kildemoes HW, Sorensen HT, Hallas J. The Danish National Prescription Registry. *Scand J Public Health* 2011;**39**:38–41.
29. Helweg-Larsen K. The Danish Register of Causes of Death. *Scand J Public Health* 2011;**39**:26–29.
30. *Urbaniseringsgrad (DEGURBA)—Danmarks Statistik, v1.0*. https://www.dst.dk/da/Statistik/dokumentation/nomenklaturer/urbaniseringsgrad–degurba——eurostat .
31. *Standard Definitions: Final Dispositions of Case Codes and Outcome Rates for Surveys. 9th ed. American Association for Public Opinion Research*; 2016.
32. Tan VH, Ritchie D, Maxey C, Sheldon R. Prospective assessment of the risk of vasovagal syncope during driving. *JACC Clin Electrophysiol* 2016;**2**:203–208.
33. Assessment of the cardiac patient for fitness to drive. *Can J Cardiol* 1992;**8**:406–19.
34. Watanabe E, Abe H, Watanabe S. Driving restrictions in patients with implantable cardioverter defibrillators and pacemakers. *J Arrhythm* 2017;**33**:594–601.
35. Freedberg NA, Hill JN, Fogel RI, Prystowsky EN. Recurrence of symptomatic ventricular arrhythmias in patients with implantable cardioverter defibrillator after the first device therapy: implications for antiarrhythmic therapy and driving restrictions. CARE Group. *J Am Coll Cardiol* 2001;**37**:1910–5.
36. Ruwald MH, Okumura K, Kimura T, Aonuma K, Shoda M, Kutyifa V, Ruwald AC, McNitt S, Zareba W, Moss AJ. Syncope in high-risk cardiomyopathy patients with implantable defibrillators: frequency, risk factors, mechanisms, and association with mortality: results from the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy (MADIT-RIT) study. *Circulation* 2014;**129**:545–52.
37. Simpson C, Dorian P, Gupta A, Hamilton R, Hart S, Hoffmaster B, Klein G, Krahn A, Kryworuk P, Mitchell LB, Poirier P, Ross H, Sami M, Sheldon R, Stone J, Surkes J, Brennan FJ. Assessment of the cardiac patient for fitness to drive: drive subgroup executive summary. *Can J Cardiol* 2004;**20**:1314–20.
38. Baessler C, Murphy S, Gebhardt L, Tso T, Ellenbogen K, Leman R. Time to resumption of driving after implantation of an automatic defibrillator (from the Dual chamber and VVI Implantable Defibrillator [DAVID] trial). *Am J Cardiol* 2005;**95**:665–6.
39. Imberti JF, Vitolo M, Proietti M, Diemberger I, Ziacchi M, Biffi M, Boriani G. Driving restriction in patients with cardiac implantable electronic devices: an overview of worldwide regulations. *Expert Rev Med Devices* 2020;**17**:297–308.
40. Hoek AE, Anker SCP, van Beeck EF, Burdorf A, Rood PPM, Haagsma JA. Patient discharge instructions in the emergency department and their effects on comprehension and recall of discharge instructions: a systematic review and meta-analysis. *Ann Emerg Med* 2020;**75**:435–444.
41. Horwitz LI, Moriarty JP, Chen C, Fogerty RL, Brewster UC, Kanade S, Ziaeian B, Jenq GY, Krumholz HM. Quality of discharge practices and patient understanding at an academic medical center. *JAMA Intern Med* 2013;**173**:1715–22.
42. Albrecht JS, Gruber-Baldini AL, Hirshon JM, Brown CH, Goldberg R, Rosenberg JH, Comer AC, Furuno JP. Hospital discharge instructions: comprehension and compliance among older adults. *J Gen Intern Med* 2014;**29**:1491–8.
43. Griffey RT, Shin N, Jones S, Aginam N, Gross M, Kinsella Y, Williams JA, Carpenter CR, Goodman M, Kaphingst KA. The impact of teach-back on comprehension of discharge instructions and satisfaction among emergency patients with limited health literacy: a randomized, controlled study. *J Commun Healthc* 2015;**8**:10–21.
44. Koelling TM, Johnson ML, Cody RJ, Aaronson KD. Discharge education improves clinical outcomes in patients with chronic heart failure. *Circulation* 2005;**111**:179–85.
45. Johansson I, Stromberg A. Experiences of driving and driving restrictions in recipients with an implantable cardioverter defibrillator–the patient perspective. *J Cardiovasc Nurs* 2010;**25**:E1–E10.
46. Albert CM, Rosenthal L, Calkins H, Steinberg JS, Ruskin JN, Wang P, Muller JE, Mittleman MA; TOVA Investigators. Driving and implantable cardioverter-defibrillator shocks for ventricular arrhythmias: results from the TOVA study. *J Am Coll Cardiol* 2007;**50**:2233–40.
47. Choi BC, Pak AW. A catalog of biases in questionnaires. *Prev Chronic Dis* 2005;**2**:A13.
48. Coughlin SS. Recall bias in epidemiologic studies. *J Clin Epidemiol* 1990;**43**:87–91.
49. Moulaert VR, Verbunt JA, van Heugten CM, Wade DT. Cognitive impairments in survivors of out-of-hospital cardiac arrest: a systematic review. *Resuscitation* 2009;**80**:297–305.
50. McGuire LC. Remembering what the doctor said: organization and adults' memory for medical information. *Exp Aging Res* 1996;**22**:403–28.
51. Weeke P, Johansen JB, Jorgensen OD, Nielsen JC, Moller M, Videbaek R, Hojgaard MV, Riahi S, Jacobsen PK. Mortality and appropriate and inappropriate therapy in patients with ischaemic heart disease and implanted cardioverter-defibrillators for primary prevention: data from the Danish ICD Register. *Europace* 2013;**15**:1150–7.
52. Ruwald MH, Ruwald AC, Johansen JB, Gislason G, Lindhardt TB, Nielsen JC, Torp-Pedersen C, Riahi S, Vinther M, Philbert BT. Temporal incidence of appropriate and inappropriate therapy and mortality in secondary prevention ICD patients by cardiac diagnosis. *JACC Clin Electrophysiol* 2021. doi:10.1016/j.jacep.2020.11.005.