31 GIORNATE CARDIOLOGICHE TORINESI

TURIN
October
24th-26th
2019

Driving restrictions in patients with cardioverter defibrillator and pacemakers

Riccardo Bessi

Specializzando in Malattie dell'apparato Cardiovascolare
Azienda Sanitaria Universitaria Integrata di Trieste

In place of…

Massimo Zecchin

Responsabile Elettrofisiologia ed Elettrostimolazione
SC di Cardiologia
Azienda Sanitaria Universitaria Integrata di Trieste

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

ACEA European Automobile Manufacturers Association

Total vehicles

	2012	2013	2014	2015	2016	%change 16/15
Austria	5,010,283	5,075,639	5,139,421	5,201,750	5,288,596	1.7
Belgium	6,183,942	6,241,017	6,328,169	6,425,839	6,538,095	1.7
Croatia	1,598,381	1,595,647	1,624,590	1,662,490	1,724,267	3.7
Czech Republic	5,403,947	5,501,892	5,614,994	5,847,361	6,119,478	4.7
Denmark	2,709,497	2,730,684	2,780,902	2,849,905	2,936,247	3.0
Estonia	694,489	719,703	754,189	783,131	816,206	4.2
Finland	2,968,004	2,985,879	3,007,744	3,028,333	3,048,059	0.7
France	38,138,000	38,200,000	38,407,000	38,567,670	38,651,953	0.2
Germany	46,538,124	47,014,699	47,647,581	48,427,094	49,285,424	1.8
Greece	6,218,035	6,192,499	6,190,701	6,199,759	6,235,761	0.6
Hungary	3,437,219	3,501,230	3,579,786	3,687,078	3,821,432	3.6
Ireland	2,229,029	2,268,722	2,302,123	2,356,901	2,409,983	2.3
Italy	41,999,986	41,776,186	41,893,839	42,241,934	42,862,046	1.5
Latvia	704,943	721,416	747,711	765,335	753,373	-1.6
Lithuania	1,947,997	2,031,444	1,210,487	1,254,204	1,295,630	3.3
Luxembourg	383,467	394,405	402,297	412,750	422,291	2.3
Netherlands	9,214,000	9,207,000	9,237,528	9,396,413	9,528,197	1.4
Poland	22,022,275	22,734,532	23,450,536	24,261,232	25,329,863	4.4
Portugal	5,807,100	5,753,200	5,747,500	5,781,700	5,824,700	0.7
Romania	5,266,680	5,503,408	5,764,023	6,065,901	6,408,904	5.7
Slovakia	2,138,684	2,198,463	2,272,506	2,367,911	2,461,598	4.0
Slovenia	1,198,349	1,205,856	1,221,964	1,247,935	1,284,382	2.9
Spain	27,480,341	27,154,604	27,114,855	27,462,976	28,026,696	2.1
Sweden	5,018,189	5,074,641	5,180,716	5,279,391	5,398,128	2.2
United Kingdom	35,760,901	36,282,603	37,113,358	38,219,610	39,240,439	2.7
EUROPEAN UNION	**280,071,860**	**282,065,369**	**284,734,520**	**289,794,603**	**295,711,748**	**2.0**
Norway	2,970,566	3,064,746	3,123,231	3,182,109	3,236,944	1.7
Switzerland	4,690,704	4,766,217	4,840,493	4,924,478	5,003,551	1.6
EFTA	**7,661,270**	**7,830,963**	**7,963,724**	**8,106,587**	**8,240,495**	**1.7**
Russia	46,442,021	47,287,010	48,916,237	48,883,765	49,695,059	1.7
Turkey	12,860,270	13,650,804	14,373,317	15,360,956	16,320,927	6.2
Ukraine	13,137,728	13,185,020	12,740,088	12,764,600	12,834,673	0.5
EUROPE	***360,173,148***	***364,019,166***	***368,727,886***	***374,910,511***	***382,802,902***	***2.1***

ACEA European Automobile Manufacturers Association

PARC DENSITY

Passenger cars

Per 1,000 inhabitants

	2012	2013	2014	2015	2016
Austria	542	546	547	546	550
Belgium	484	486	490	494	499
Croatia	339	338	345	355	371
Czech Republic	447	455	464	485	507
Denmark	397	403	410	419	431
Estonia	456	478	497	514	534
Finland	472	473	474	476	478
France	482	480	478	478	478
Germany	539	543	547	548	555
Greece	467	468	470	473	476
Hungary	301	307	315	325	338
Ireland	408	412	416	420	424
Italy	621	608	610	616	625
Latvia	305	317	331	344	340
Lithuania	590	624	381	399	418
Luxembourg	642	646	645	646	645
Netherlands	485	485	485	491	494
Poland	492	510	526	546	571
Portugal	429	430	433	439	446
Romania	224	235	247	261	278
Slovakia	338	348	360	376	391
Slovenia	525	527	532	541	553
Spain	476	474	474	481	492
Sweden	465	466	470	474	477
United Kingdom	493	496	503	513	522
EUROPEAN UNION	**490**	**492**	**495**	**502**	**511**
Norway	482	487	492	497	502
Switzerland	535	536	538	541	543
EFTA	**514**	**517**	**520**	**524**	**527**
Russia	268	274	284	284	289
Turkey	114	121	127	134	142
Ukraine	218	220	224	225	228
EUROPE	***397***	***400***	***405***	***410***	***417***

https://www.acea.be/uploads/statistic_documents/ACEA_Report_Vehicles_in_use-Europe_2018.pdf

Definition of Driving Licence Groups

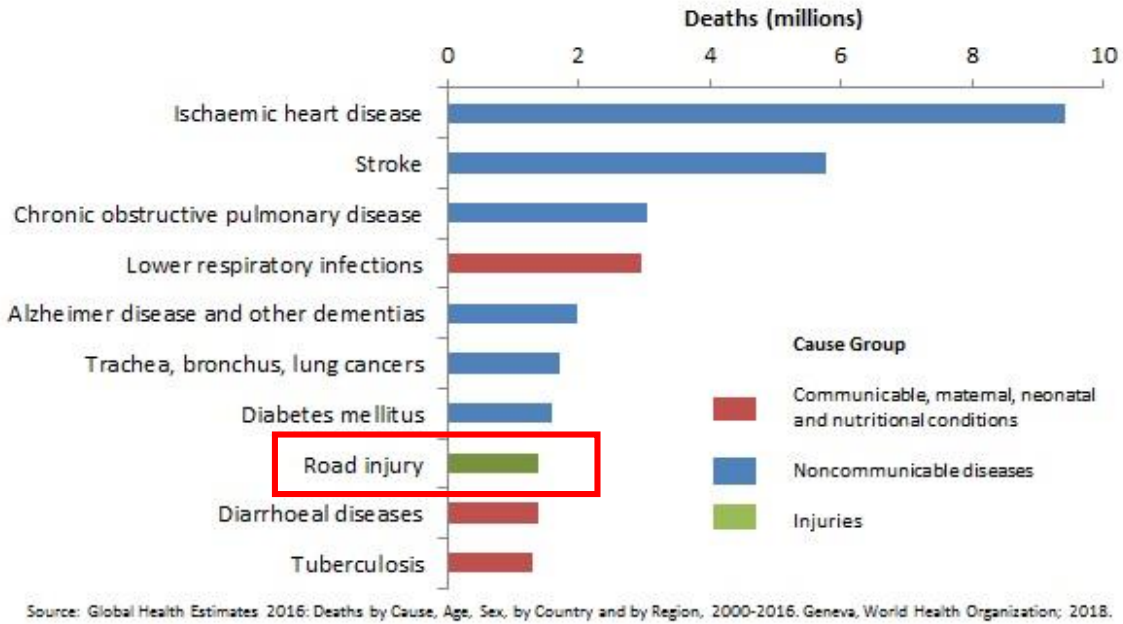
	EU	UK	US	Canada	Australia	Japan
Group 1	Ordinary motorcycles, cars, small vehicles with or without a trailer (categories A, B)	Similar to EU. Maximal vehicle weight <3,500 kg	Any not fulfilling commercial driver criteria	- Driver who drives <36,000 km/year, OR spends <720h/year behind the wheel AND - Drives a vehicle weighing <11 tonnes AND - Does not earn a living from driving	Drivers of cars and light rigid vehicles. Cars are defined as vehicles of <4.5 tonnes, and seating up to 12 adults (including the driver). Light rigid vehicles are defined as vehicles of between 4.5 and 8 tonnes (or 9 tonnes if having a trailer)	- Driver of motorcycles, automobiles, other vehicles with or without a trailer, AND - Does not earn a living from driving
Group 2	Drivers of vehicles weighing >3.5 tonnes. Drivers of passenger-carrying vehicles with more than 8 seats including the driver (categories C, D and E [vehicles with a trailer])	Similar to EU.	Any driver of: vehicles weighing >26,001 pounds; truck with double/triple trailers; truck carrying hazardous materials; passenger vehicles designed to carry >16 passengers including the driver	Any not fulfilling private driver criteria	Any two-axle or three-axle rigid vehicle of >8 tonnes (or 9 tonnes with a trailer)	Driver who earns a living from driving, including taxi, bus, ambulance

Source: Watanabe E et al.[19]; DVLA 2018[33]; EUR-Lex Directive 2006/126/EC[39]; The Expert Group on Driving and Cardiovascular Disease[40]; Lococo et al.[2]; Canadian Council of Motor Transport Administration[43]; Austroads.[44]

Margulescu AD and Anderson MH. Arrhythmia & Electrophysiology Review 2019;8:90–8.

World Health Organization

Top 10 global causes of deaths, 2016

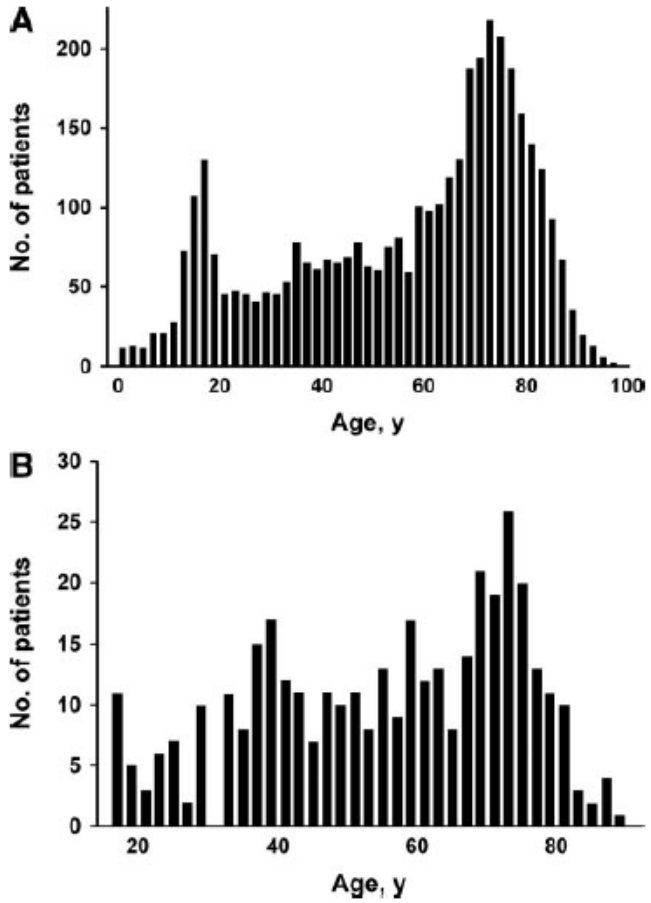


Source: Global Health Estimates 2016: Deaths by Cause, Age, Sex, by Country and by Region, 2000-2016. Geneva, World Health Organization; 2018.

https://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death

Age distribution of patients

Age at first evaluation for syncope at Mayo Clinic



All patients (n=3877)

Patients who had syncope while driving (n=381).

Sorajja D et al Circulation. 2009;120:928-34

Causes of syncope

Cause of Syncope	Group,* n (%) Driving (n=381)	Nondriving (n=3496)	P
Neurally mediated	142 (37.3)	1247 (35.7)	0.54
Bradyarrhythmia	25 (6.6)	221 (6.3)	0.86
Supraventricular tachyarrhythmia	8 (2.1)	71 (2.0)	0.93
Ventricular tachyarrhythmia	20 (5.2)	130 (3.7)	0.14
Structural cardiopulmonary disease	1 (0.3)	9 (0.3)	0.99
Cerebrovascular disease	14 (3.7)	100 (2.9)	0.37
Carotid sinus hypersensitivity	12 (3.1)	100 (2.9)	0.75
Orthostatic intolerance	18 (4.7)	223 (6.4)	0.20
Others	87 (22.8)	1044 (29.9)	0.004
Unknown	90 (23.6)	622 (17.8)	0.005

Driving Group:

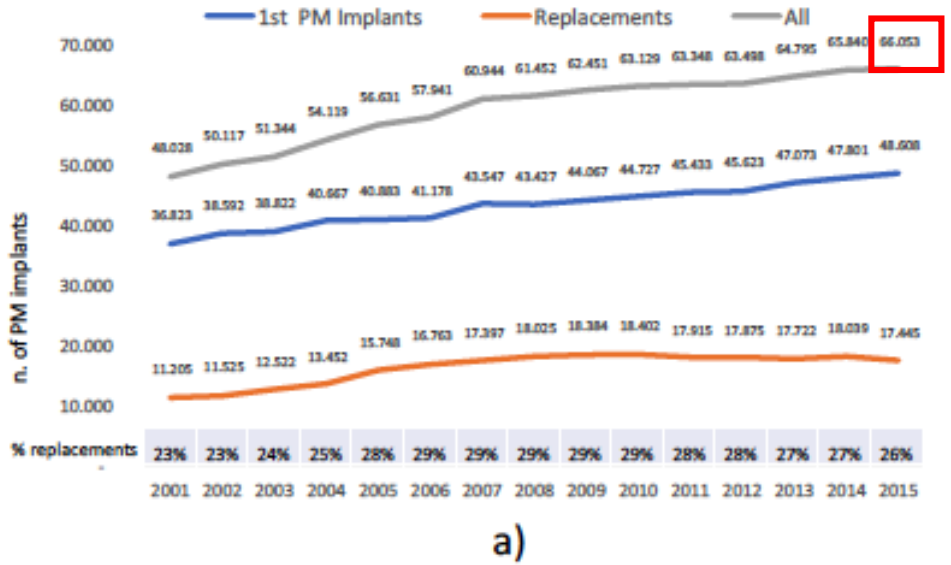
- Recurrent syncope in 72 patients (8-year probability, 25.1%)
- Actuarial recurrence of syncope at 6 months was 12.0%
- **Actuarial recurrence of syncope at 12 months was 14.1%**
- 61 (84.7%) had a prior history of syncope.
- 37 (51.3%) of recurrences occurred within 6 months
- **44 (61.1%) of recurrences occurred within 12 months.**

Sorajja D et al Circulation. 2009;120:928-34

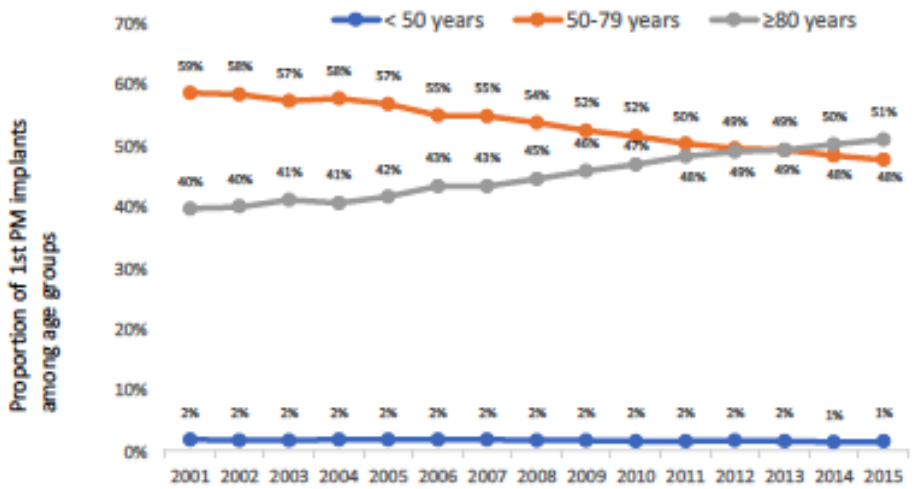
Table 2. Prodrome Symptoms, Recovery Symptoms, and Injury

Symptom	Group, n (%) Driving (n=381)	Nondriving (n=3496)	P
Prodrome symptoms			
Any prodrome	333 (87.4)	2982 (85.3)	0.27
Light-headedness	229 (60.1)	2058 (58.9)	0.64
Nausea	102 (26.8)	770 (22.0)	0.04
Diaphoresis	81 (21.3)	824 (23.6)	0.31
Palpitations	73 (19.2)	516 (14.8)	0.02
Chest pain	57 (15.0)	380 (10.9)	0.02
Dyspnea	50 (13.1)	310 (8.9)	0.007
Vertigo	46 (12.1)	367 (10.5)	0.34
Fatigue	34 (8.9)	232 (6.6)	0.09
Abdominal cramps	31 (8.1)	230 (6.6)	0.25
Vomiting	23 (6.0)	207 (5.9)	0.93
Ear ringing	9 (2.4)	33 (0.9)	0.01
Recovery symptoms			
Confusion	35 (9.2)	309 (8.8)	0.82
Incontinence	22 (5.8)	248 (7.1)	0.34
Dyspnea	6 (1.6)	35 (1.0)	0.30
Injury			
Any injury	109 (28.6)	829 (23.7)	0.03
Injury requiring hospital care	65 (17.1)	528 (15.1)	0.31

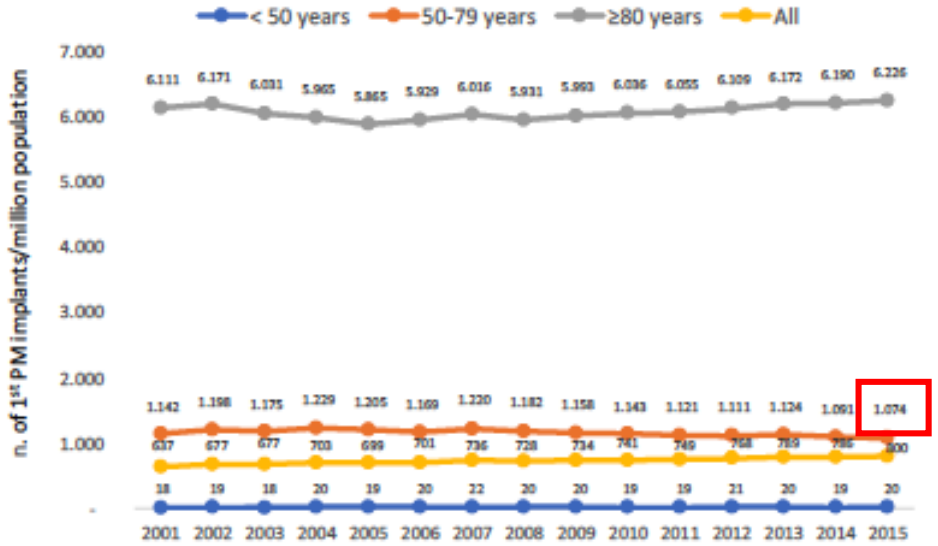
PM implant procedures



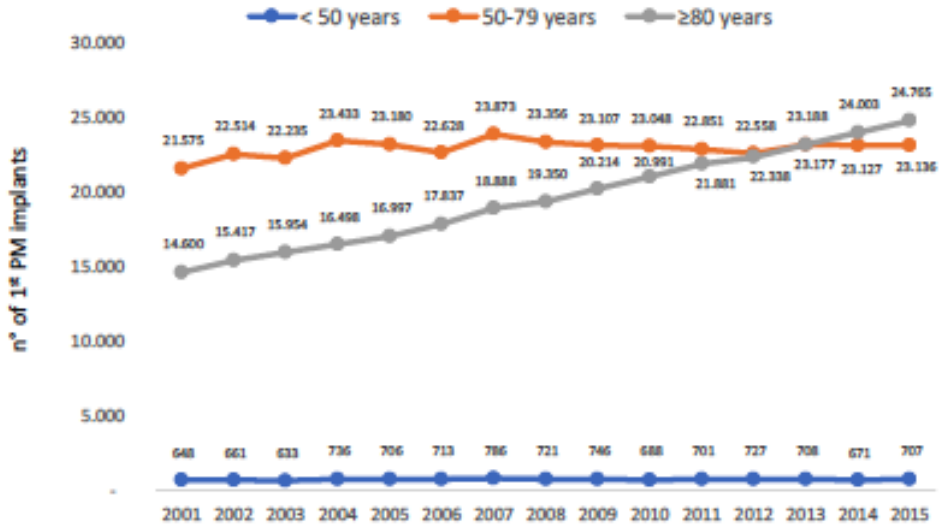
a)



b)



c)

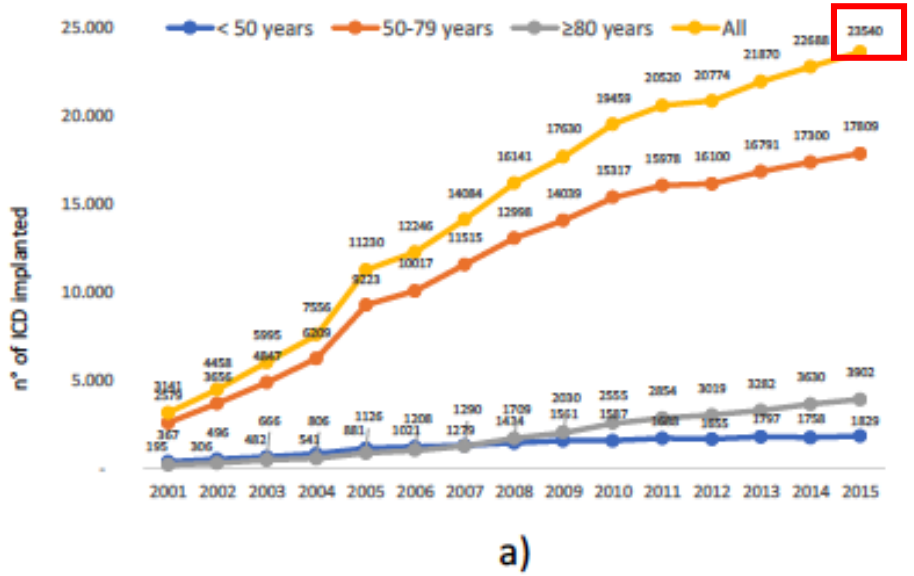


d)

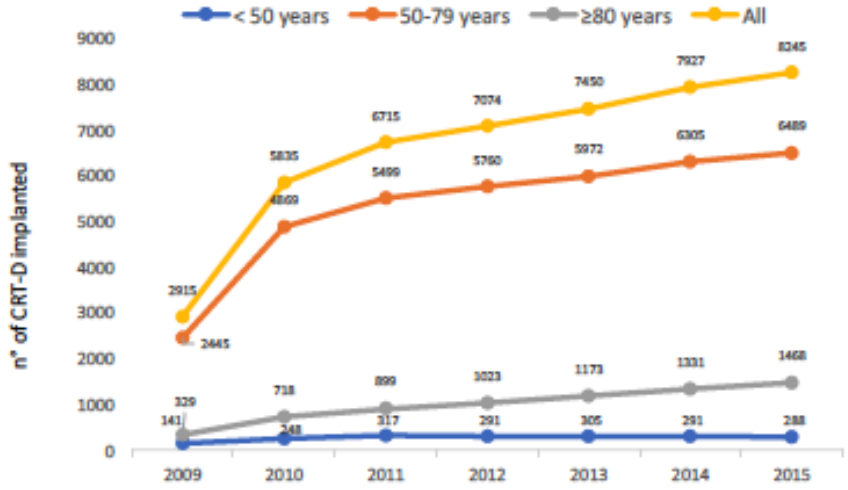
REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

Zecchin et al. Submitted to Am J Cardiol

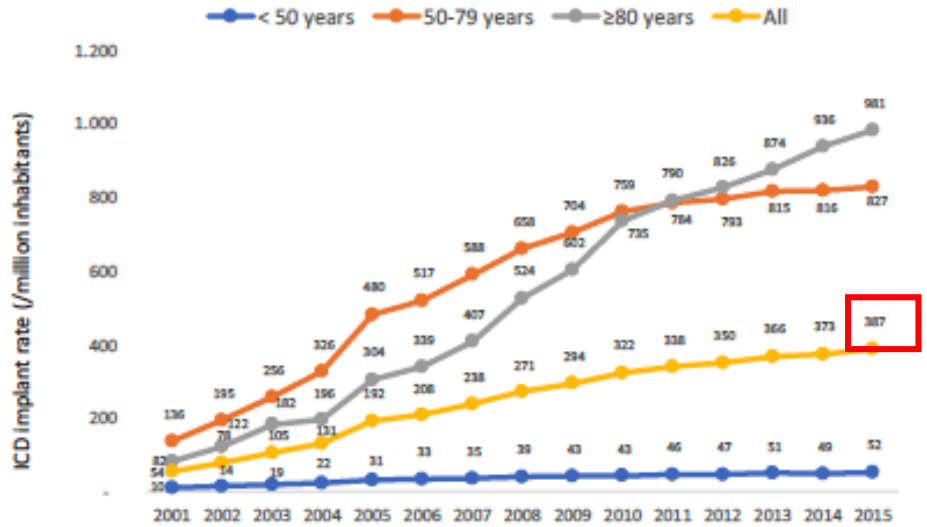
ICD implant procedures



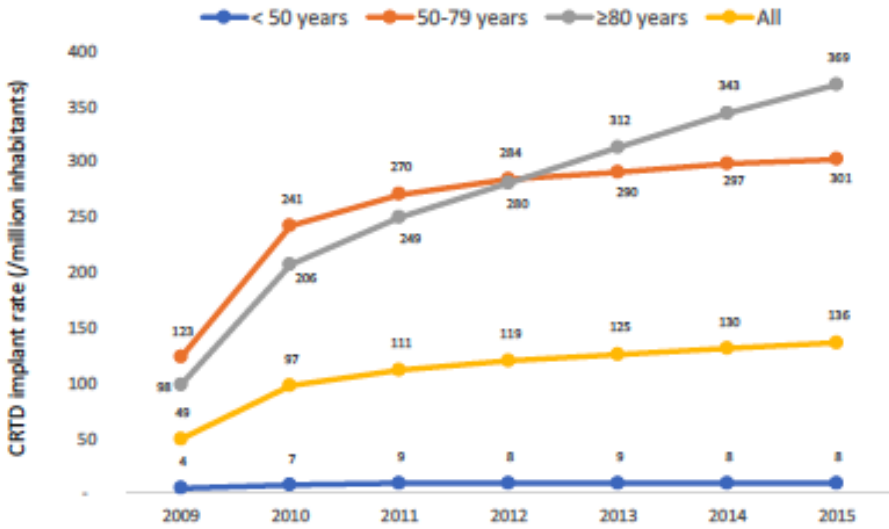
a)



b)



c)



d)

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

Zecchin et al. Submitted to Am J Cardiol

Annual Risk of Harm (RH) as a result of driving

(1992 Canadian Cardiovascular Society, updated in 2003)

RH = TD x V x SCI x Ac

where:

- **TD** is the time spent driving; **TD is 0.25 (25%) for professional drivers** because the average time spent driving is 6 hours per day; and **0.04 (4%) for social drivers** because they spend, on average, 1 hour driving per day
- **V** is the type of vehicle; **V is 1 for trucks** and **0.28 for family cars because**, on average, accidents involving trucks cause 7.2% of fatalities, despite causing only 2.0% of road accidents (2.0 ÷ 7.2% = 0.28).
- **SCI** is the risk of sudden incapacitation; SCI is 0.01 (1%), which was the estimated annual risk of SCD of a truck driver who had not had an acute MI within the previous 3 months, is in functional class I, has a negative exercise tolerance test, is able to perform at least 7 METS during the treadmill test, and has no documented ventricular arrhythmia
- **Ac** is the probability that an episode of sudden incapacitation will result in a fatal or injury-producing accident. Ac is 0.02 (2%) because only 2% of accidents caused by drivers suffering SCD or sudden incapacity while driving has resulted in harm or death of other road traffic users or bystanders

Margulescu AD and Anderson MH. Arrhythmia & Electrophysiology Review 2019;8:90–8.

OMNI - multicenter postmarket observational study

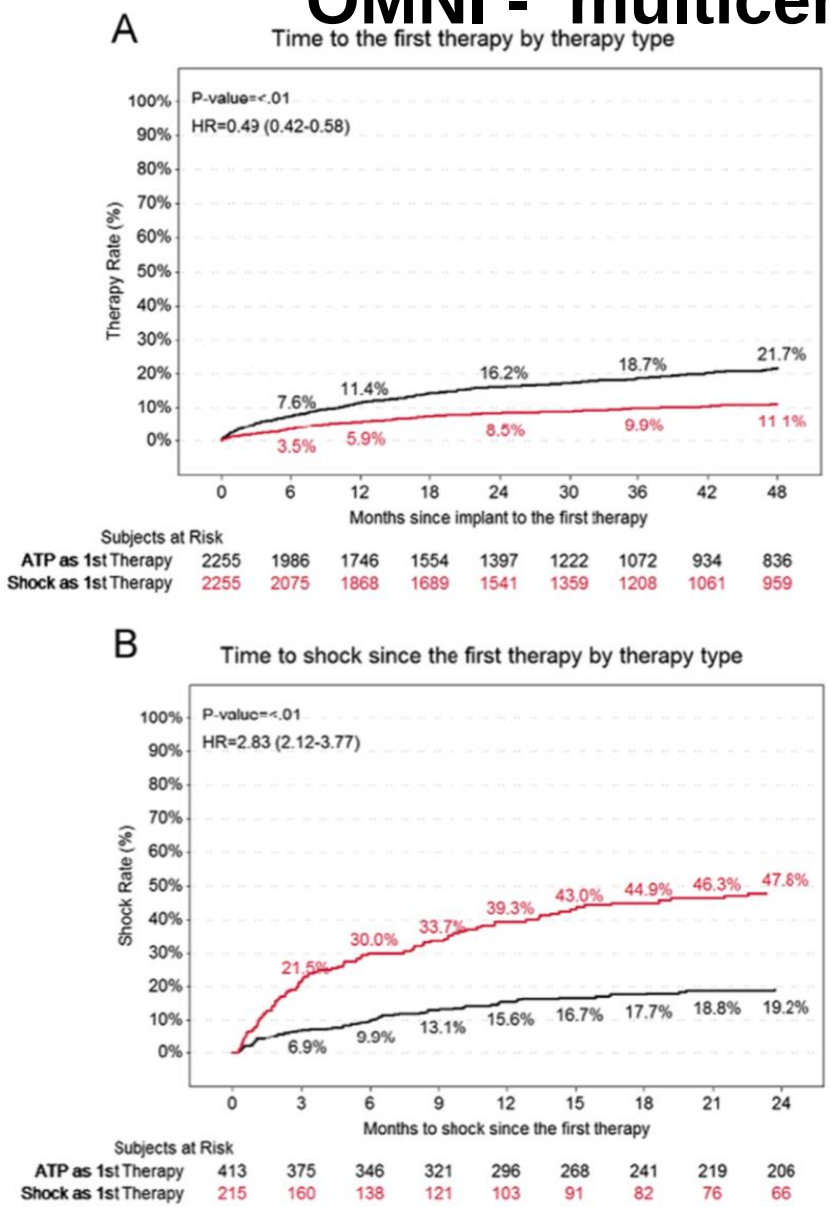


Table 2 Yearly risk of SCI based on the 6- and 12-mo event rates of shock since the first therapy and first/second/third shock

		Event rate		Risk of SCI	
Event	ICD indication	Observed 6-mo	Observed 12-mo	Based on 6-mo event rate	Based on 12-mo event rate
Shock since the first therapy	ATP as the first therapy	9.9%	15.6%	0.058	0.048
	Shock as the first therapy	30.0%	39.3%	0.158	0.122
	Primary prevention	13.6%	19.4%	0.079	0.060
	Secondary prevention	21.7%	30.3%	0.120	0.094
	Primary prevention, ATP as the first therapy	6.8%	11.3%	0.041	0.035
	Secondary prevention, APT as the first therapy	16.1%	23.2%	0.092	0.072
	Primary prevention, shock as the first therapy	26.8%	35.3%	0.144	0.109
	Secondary prevention, shock as the first therapy	33.4%	45.0%	0.172	0.140
First shock since implant	All	4.9%	8.2%	0.003	0.025
	Primary prevention	3.5%	6.2%	0.021	0.019
	Secondary prevention	8.8%	13.7%	0.052	0.042
Second shock since the first shock	All	24.8%	34.3%	0.135	0.106
	Primary prevention	21.7%	30.7%	0.120	0.095
	Secondary prevention	29.2%	40.1%	0.155	0.124
Third shock since the second shock	All	40.5%	54.0%	0.200	0.167
	Primary prevention	41.2%	53.7%	0.203	0.166
	Secondary prevention	41.2%	56.7%	0.203	0.176

None of the SCI risk was > 0.223

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

Kim et al Time Course of ICD Therapy and Driving, Heart Rhythm 2015

MADIT - RIT

Table 2. First Occurrence, Any Occurrence, and Total Occurrences of Appropriate and Inappropriate Device Therapy According to Treatment Group.*

Variable	Conventional Therapy (N=514)	High-Rate Therapy (N=500)	Delayed Therapy (N=486)	P Value for High-Rate Therapy vs. Conventional Therapy	P Value for Delayed Therapy vs. Conventional Therapy
First occurrence of therapy — no. of patients (%)					
Appropriate therapy	114 (22)	45 (9)	27 (6)	<0.001	<0.001
Shock	20 (4)	22 (4)	17 (3)	0.68	0.74
Antitachycardia pacing	94 (18)	23 (5)	10 (2)	<0.001	<0.001
Inappropriate therapy	105 (20)	21 (4)	26 (5)	<0.001	<0.001
Shock	20 (4)	11 (2)	13 (3)	0.12	0.28
Antitachycardia pacing	85 (17)	10 (2)	13 (3)	<0.001	<0.001
Any occurrence of therapy — no. of patients (%)					
Appropriate therapy					
Shock	28 (5)	26 (5)	19 (4)	0.86	0.25
Antitachycardia pacing	111 (22)	38 (8)	20 (4)	<0.001	<0.001
Inappropriate therapy					
Shock	31 (6)	14 (3)	15 (3)	0.01	0.03
Antitachycardia pacing	104 (20)	20 (4)	25 (5)	<0.001	<0.001
Total occurrences of therapy — no. of occurrences					
Appropriate therapy	517	185	196	<0.001	<0.001
Shock	71	72	53	0.35	0.15
Antitachycardia pacing	446	113	143	<0.001	<0.001
Inappropriate therapy	998	75	264	<0.001	<0.001
Shock	105	25	49	0.001	0.16
Antitachycardia pacing	893	50	215	<0.001	<0.001

Moss el al et al NEJM 2012

Cumulative probability of first occurrence of arrhythmogenic syncope MADIT-RIT subanalysis

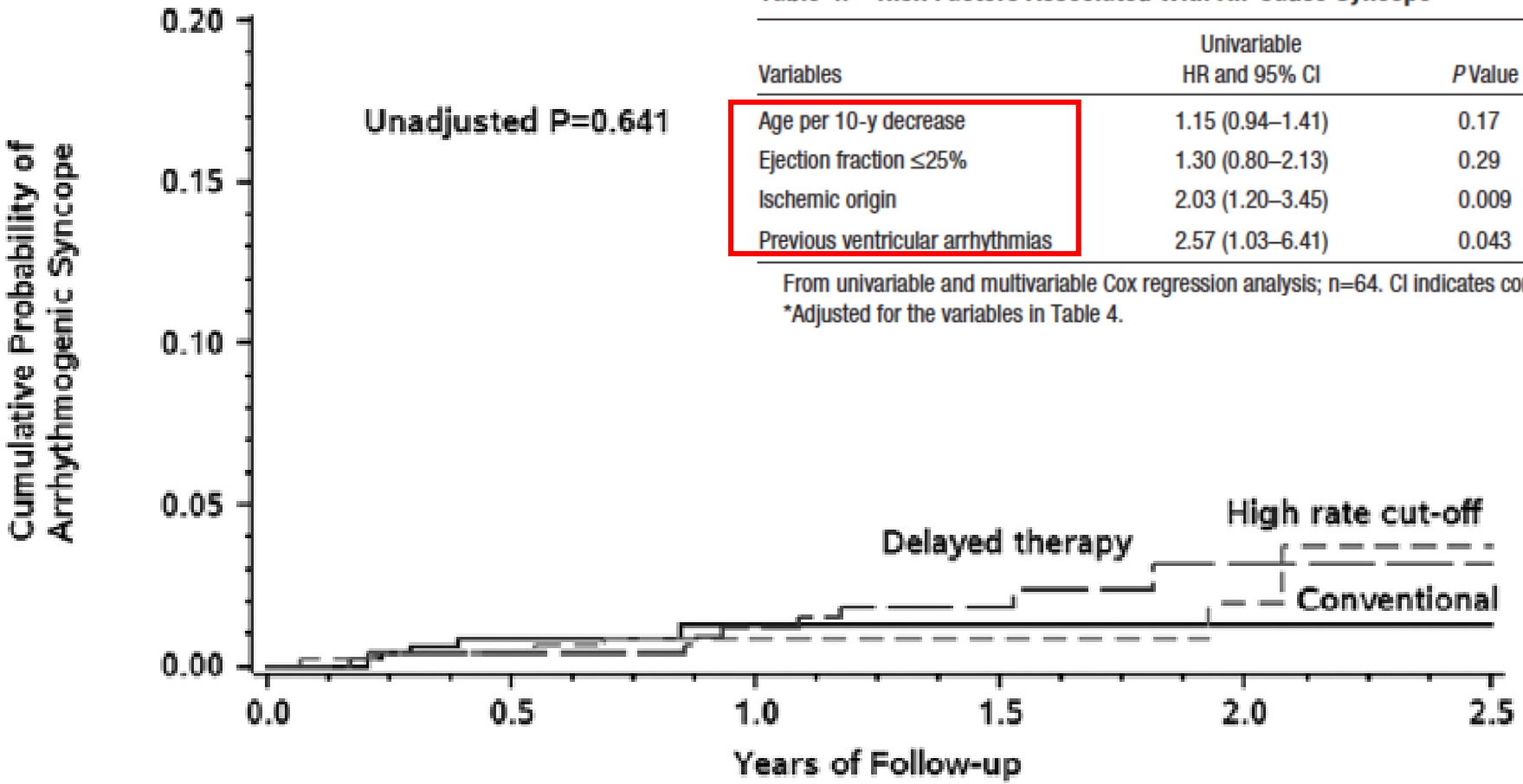


Table 4. Risk Factors Associated With All-Cause Syncope

Variables	Univariable HR and 95% CI	*P* Value	Multivariable* HR and 95% CI	*P* Value
Age per 10-y decrease	1.15 (0.94–1.41)	0.17	1.25 (1.00–1.52)	0.046
Ejection fraction ≤25%	1.30 (0.80–2.13)	0.29	1.65 (0.98–2.77)	0.059
Ischemic origin	2.03 (1.20–3.45)	0.009	2.48 (1.42–4.34)	0.002
Previous ventricular arrhythmias	2.57 (1.03–6.41)	0.043	2.99 (1.18–7.59)	0.021

From univariable and multivariable Cox regression analysis; n=64. CI indicates confidence interval; and HR, hazard ratio.
*Adjusted for the variables in Table 4.

Ruwald et al Circulation 2014;129:545-552

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

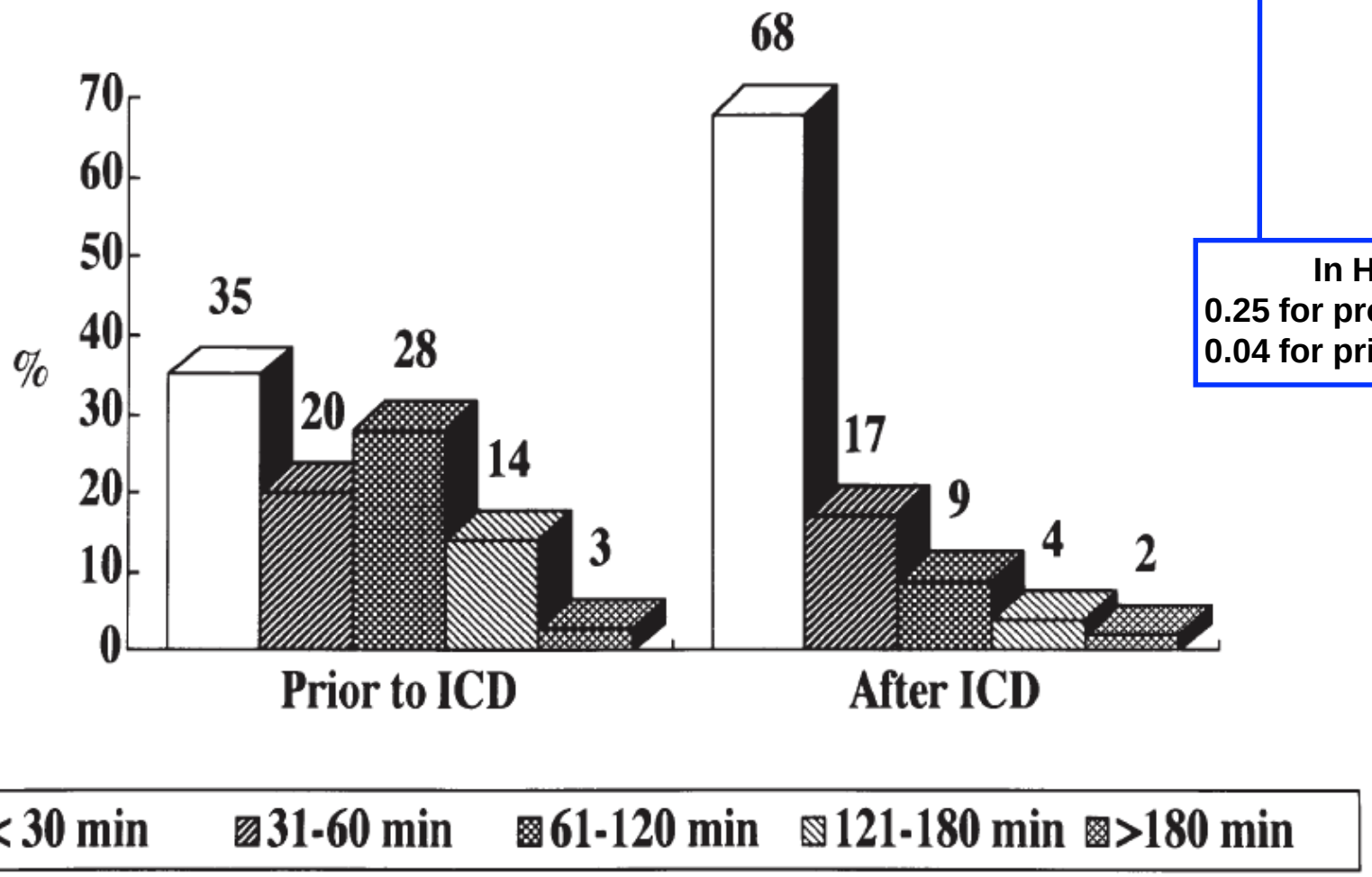
Motor Vehicle Accidents in Patients With an ICD

Surveys sent to all 742 physicians in the United States involved in ICD implantation and follow-up (**1995**)

- Surveys were returned by 452 physicians (61%).
- 30 motor vehicle accidents related to shocks from ICD were reported by 25 physicians over a 12-year period (1980-1992)
- 9 were fatal accidents involving 8 patients with a defibrillator and one passenger in a car driven by a patient.
- 21 nonfatal accidents involving 15 patients, 3 passengers and 3 bystanders.
- Estimated fatality rate for patients with a defibrillator: **7.5/100,000 patient-years (general population: 18.4/100,000 patient-years, $p < 0.05$).**
- Estimated **injury rate, 17.6/100,000 patient-years (general population 2,224/100,000 patient-years, $p < 0.05$).**
- **10.5% (30 of 286) of all ICD discharges during driving resulted in accidents**

Curtis et al J Am Coll Cardiol 1995;26:180-4

Driving behaviour prior to and after ICD implantation: the TD factor

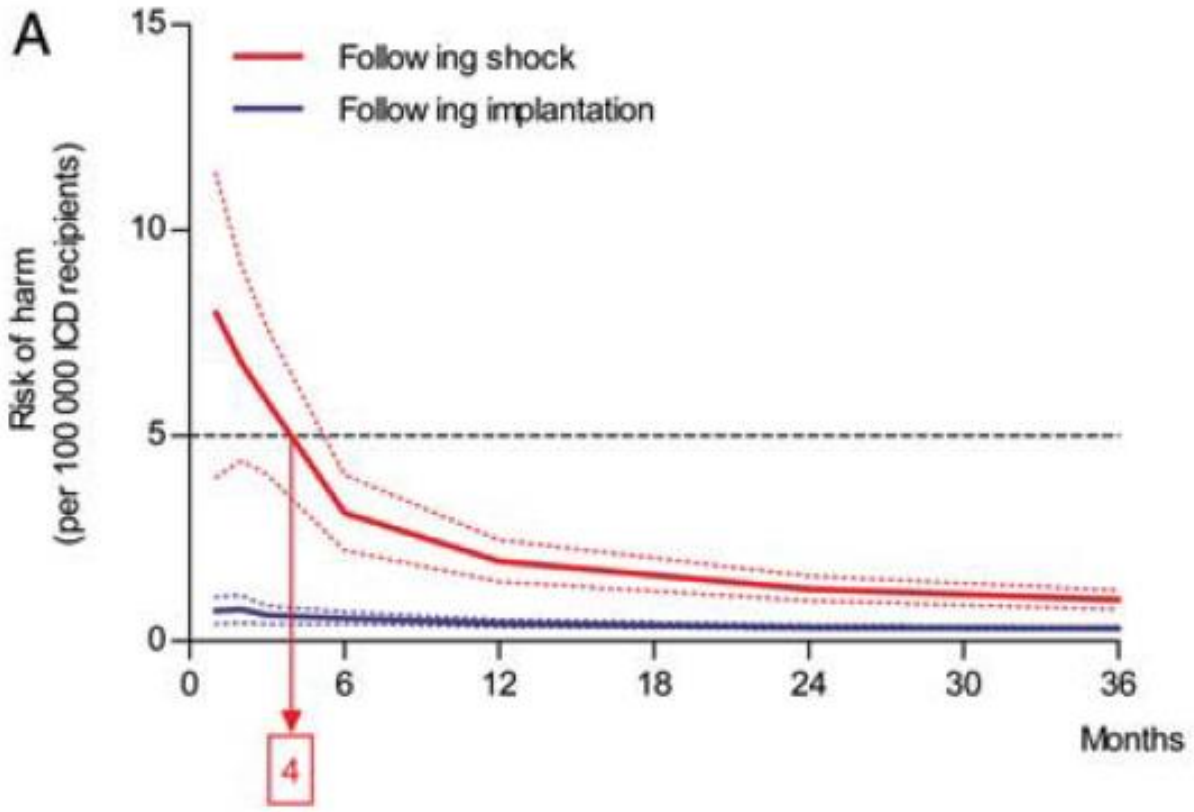


In HR-formula
0.25 for profesional drivers
0.04 for private drivers

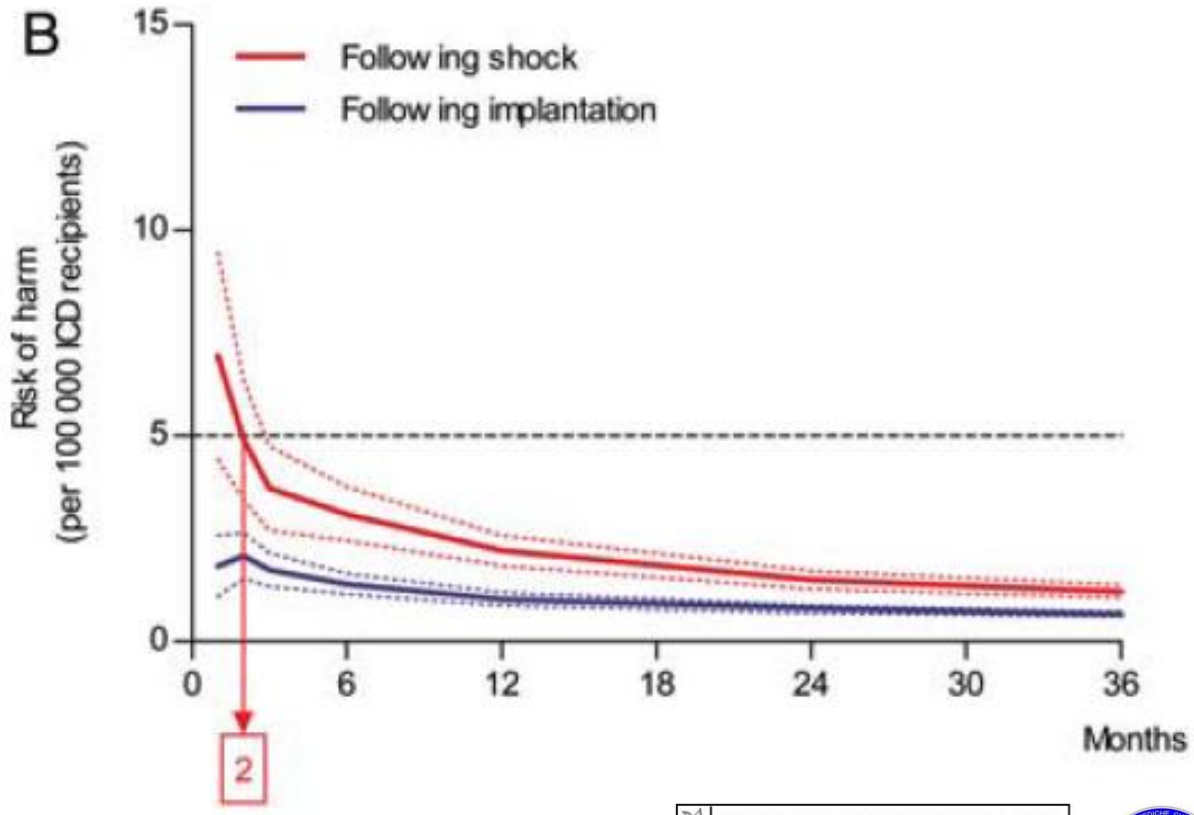
Trappe et al Journal of Interventional Cardiac Electrophysiology 1998;2:193–201

Annual Risk of Harm: appropriate interventions
(Accepted level of RH: 5 per 100 000)

Primary prevention



Secondary prevention



Thijssen et al European Heart Journal 2011;32:2678–87

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

Europace (2009) **11**, 1097–1107
doi:10.1093/europace/eup112

CONSENSUS STATEMENT

Consensus statement of the European Heart Rhythm Association: updated recommendations for driving by patients with implantable cardioverter defibrillators

Task force members: Johan Vijgen (chairman)[1,*], Gianluca Botto[2], John Camm[3], Carl-Johan Hoijer[4], Werner Jung[5], Jean-Yves Le Heuzey[6], Andrzej Lubinski[7], Tone M. Norekvål[8†], Maurizio Santomauro[9], Martin Schalij[10], Jean-Paul Schmid[11‡], and Panos Vardas[12]

New Standards for Driving and Cardiovascular Diseases

	Restriction for private driving	Restriction for professional driving
ICD implantation for secondary prevention	Three months	Permanent
ICD implantation for primary prevention	Four weeks	Permanent
After appropriate ICD therapy	Three months	Permanent
After inappropriate ICD therapy	Until measures to prevent inappropriate therapy are taken	Permanent
After replacement of the ICD	One week	Permanent
After replacement of the lead system	Four weeks	Permanent
Patients refusing ICD for primary prevention	No restriction	Permanent
Patients refusing ICD implantation for secondary prevention	Seven months	Permanent

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

DIFFERENCES BETWEEN PM AND ICD

While **pacemakers can effectively prevent** the occurrence of bradyarrhythmias, **ICDs** do not prevent VT/VF but **treat those rhythms once they happen** by either overdrive antitachycardia pacing (ATP) or internal cardioversion. **Syncope may still occur in patients who develop VT/VF despite having an ICD** because of the time delay between arrhythmia occurrence, effective treatment and restoration of normal brain perfusion.

Conduction Disorder/Arrhythmia	Group 1	Group 2
Sinus Bradycardia	no restriction unless dizziness or syncope	no restriction unless dizziness or syncope
Sick sinus syndrome	If the patient has had a history of syncope, driving must cease until the condition has been satisfactorily treated/controlled (most often by a pacemaker).	If the patient has had a history of syncope or sudden incapacitation, driving must cease until the condition has been satisfactorily treated/controlled (most often by a pacemaker). Driving can be resumed only after medical assessment.
AV conduction block (excluding bundle branch block and congenital AV-block, see below)	If history of syncope and/or sudden incapacity, driving must cease until a pacemaker has been implanted or the conduction block is eliminated by other means.	If history of syncope , driving must cease until a pacemaker has been implanted or the conduction block eliminated by other means. Driving can be resumed only after medical assessment.
Bi- and trifascicular blocks	If syncopal episodes have occurred, a pacemaker should be implanted before driving can be resumed.	If syncopal episodes have occurred, a pacemaker should be implanted before driving can be resumed. In alternating RBBB and LBBB, a pacemaker must be implanted, regardless of symptoms.
Congenital AV-block	If patients have had syncopal episodes or other significant symptoms, driving must cease until a pacemaker has been implanted	Driving is not allowed unless a pacemaker is implanted

Driving Regulations and Expert Consensus Documents

	License type	Japan	UK	USA	EU
Pacemaker implant	Class 1 Class 2	Cease driving for 1 week Disqualified until pacemaker integrity is ascertained.	Cease driving for 1 week Cease driving for 6 weeks	Cease driving for 1 week Cease driving for 4 weeks	Cease driving for 1 week Disqualified if persistent symptoms.
ICD implant for VT/VF with incapacity (secondary prevention)	Class 1	Cease for 6 months after first implant	Cease for 6 months after first implant	Cease for 6 months after first implant	Cease for 3 months
	Class 2	Permanently bars	Permanently bars	Permanently bars	Permanently bars
ICD implant for sustained VT without incapacity (secondary prevention)	Class 1	Cease for 6 months after first implant	Cease for 1 month after first implant provided all of the following are met: (a) LVEF >35% (b) No fast VT on EPS (c) Any induced VT could be pace-terminated by the ICD twice, without acceleration, during the post-implantation study.	Cease for 6 months after implant	Cease for 3 months after implant
	Class 2	Permanently bars	Permanently bars	Permanently bars	Permanently bars
Prophylactic ICD implantation (primary prevention)	Class 1 Class 2	Cease for 1 week Permanently bars	Cease for 1 month Permanently bars.	Cease for 1 week Permanently bars	Cease for 4 weeks Permanently bars.
ICD and lead system replacement	Class 1	Cease for 1 week after replacement of the lead system or replacement of the ICD.	Cease for 1 month after a revision of the leads or antiarrhythmic drug change.	No specific guidance	Cease for 4 weeks after replacement of the ICD and lead system or the lead system alone. Cease for 1 week after replacement of ICD.
Delivery of ICD therapy	Class 1	Cease for 3 months after appropriate therapy Inappropriate therapy: no restrictions for asymptomatic episodes. Cease for 3 months in case of syncope.	Appropriate shock+symptomatic ATP: Cease for 6 months with corrective measures to prevent recurrence provided no further symptomatic therapy Inappropriate therapy: cease for 1 month after the cause of the inappropriate therapy was corrected.	Cease for 6 months after appropriate therapy Inappropriate therapy: no distinction made from appropriate therapy.	Cease for 3 months after appropriate therapy Inappropriate therapy: cease until cause of inappropriate therapy was corrected.

Watanabe E. Journal of Arrhythmia 2017;33:594–601

Driving characteristics following ICD implantation

Variable	All patients (*n* = 241)	Primary prevention (*n* = 178)	Secondary prevention (*n* = 63)	*P* value
Driving a necessity	192 (79.7)	142 (79.8)	50 (79.4)	0.999
Limited driving	74 (30.7)	52 (29.2)	22 (34.9)	0.429
Recall of medical instructions	152 (63.1)	105 (59.0)	47 (74.6)	0.033
Adhered to medical instructions	117 (77.0)	81 (77.1)	36 (76.6)	0.999
Driving abstinence recommended (months)	2.9 ± 2.3	2.6 ± 1.9	4.0 ± 5.5	0.022
Recommenced driving (months)	2.6 ± 3.7	2.2 ± 2.9	3.6 ± 5.3	0.01
Number of patients driving at:				
1 month	119 (49.4)	96 (53.9)	23 (36.5)	0.019
3 months	194 (80.5)	149 (83.7)	45 (71.4)	0.042
6 months	226 (93.8)	168 (94.4)	58 (92.1)	0.547
Presyncope while driving	23 (9.5)	16 (9.0)	7 (11.1)	0.622
Shock while driving	8 (3.3)	5 (2.8)	3 (4.7)	0.434
Annual risk of shock while driving (%)	1.5	1.3	2.2	
RTA after ICD	14 (5.8)	11 (6.2)	3 (4.8)	0.999

RTA, road traffic accident; ICD, implantable cardioverter defibrillator.

Mylotte et al Europace 2013;15:212–8

Contents lists available at ScienceDirect

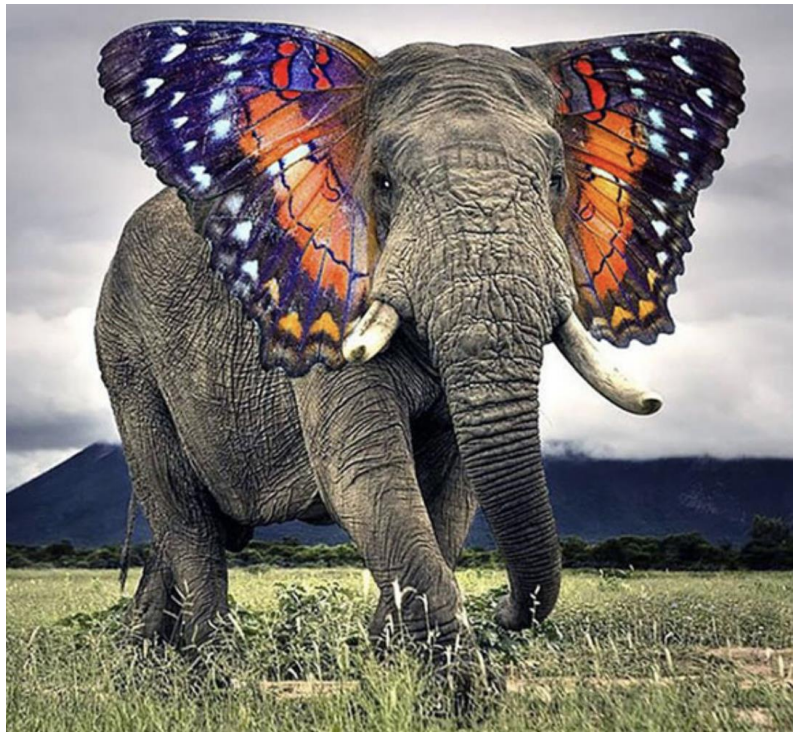
International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Safety and interaction of patients with implantable cardiac defibrillators driving a hybrid vehicle

Fernando Tondato, M.D., Jane Bazzell, R.N., Linda Schwartz, R.N., Bruce W. Mc Donald, R.N., Robert Fisher, R.N., S. Shawn Anderson, R.N., Arcenio Galindo, CRC, Amylou C. Dueck, Ph.D, Luis R. Scott, M.D. *

Heart Rhythm Section, Department of Cardiology, Mayo Clinic, AZ, United States



A B S T R A C T

Background: Electromagnetic interference (EMI) can affect the function of implantable cardioverter defibrillators (ICD). Hybrid electric vehicles (HEV) have increased popularity and are a potential source of EMI. Little is known about the *in vivo* effects of EMI generated by HEV on ICD.

Objective: This study evaluated the *in vivo* interaction between EMI generated by HEV with ICD.

Methods and results: Thirty patients (73 ± 9 y/o; 80% male) with stable ICD function were exposed to EMI generated by a Toyota Prius Hybrid®. The vehicle was lifted above the ground, allowing safe changes in engine rotation and consequent variations in electromagnetic emission. EMI was measured (NARDA STS® model EHP-50C) and expressed in A/m (magnetic), Volts/m (electrical), and Hertz (frequency). Six positions were evaluated: driver, front passenger, right and left back seats, outside, at the back and front of the car. Each position was evaluated at idle, 30 mph, 60 mph and variable speeds (acceleration-deceleration-brake). All ICD devices were continuously monitored during the study.

The levels of EMI generated were low (highest mean levels: 2.09 A/m at right back seat at 30 mph; and 3.5 V/m at driver seat at variable speeds). No episode of oversensing or inadvertent change in ICD programming was observed.

Conclusion: It is safe for patients with ICD to interact with HEV. This is the first study to address this issue using an *in vivo* model. Further studies are necessary to evaluate the interaction of different models of HEV or electric engine with ICD or unipolar pacemakers.

Conclusions

- In Europe and in Italy there is about 1 car every 2 inhabitants and each year approximately 45.000 PM and 24.000 ICD are implanted
- Car accidents are 1 of the 10 leading causes of death in the world
- Despite a not negligible risk of discharge, accidents, injuries and fatalities are rare in ICD patients
- Driving behaviour changes in most patients after ICD implantation and restrictions are not always attended
- For PM implantation, ICD in primary prevention and PM/ICD replacement driving restrictions are due to wound healing only
- For ICD in secondary prevention and after ICD appropriate interventions restrictions vary from 3 to 6 months
- Considering more recent data, driving restrictions could be less restrictive in low-risk patients
- For patient refusing ICD for secondary prevention driving should be withheld for 7 months after the VA
- Professional driving is not allowed in patients with an ICD or with an indication to implantation.

REGIONE AUTONOMA FRIULI VENEZIA GIULIA
Azienda Sanitaria Universitaria Integrata di Trieste

31 GIORNATE CARDIOLOGICHE TORINESI

TURIN
October
24th-26th
2019

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

Azienda Sanitaria Universitaria Integrata di Trieste