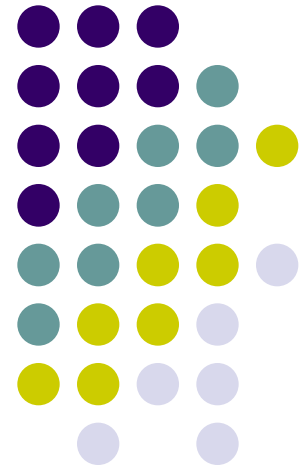
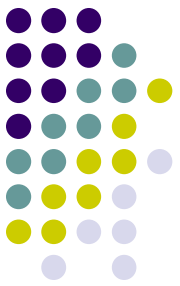


ICDs and patient driving: What are the regulations?

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Department of Heart Disease,
Haukeland University Hospital
Bergen, Norway





Background

- The first European recommendations on driving in ICD recipients published in 1997
- Increasing number of ICD implants for primary prevention
- In 2007, the European Heart Rhythm Association (EHRA) appointed new a task force

(Jung et al, Eur Heart J 1997;18:1210–19)

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 Botto², John Camm³, Carl-Johan Hoijer⁴, Werner Jung⁵, Jean-Yves Le Heuzey⁶, Andrzej Lubinski⁷, Tone M. Norekvål^{8†}, Maurizio Santomauro⁹, Martin Schalij¹⁰, Jean-Paul Schmid^{11‡}, and Panos Vardas¹²

¹Department of Cardiology, Virga Jesse Ziekenhuis, Hasselt, Belgium; ²Department of Cardiology, St. Anna Hospital, Como, Italy; ³Department of Cardiac and Vascular Sciences, St. George's University, London, United Kingdom; ⁴Department of Cardiology, Lund University Hospital, Lund, Sweden; ⁵Department of Cardiology, Academic Hospital Villingen, Villingen-Schwenningen, Germany; ⁶Department of Cardiology, Hôpital Européen Georges Pompidou, Paris, France; ⁷Department of Interventional Cardiology, Medical University of Lodz, Poland; ⁸Department of Heart Disease, Haukeland University Hospital, Bergen, Norway; ⁹Department of Cardiology, Federico II University Naples, Naples, Italy; ¹⁰Department of Cardiology, Leiden University Medical Center, Leiden, The Netherlands; ¹¹Department of Cardiology, Inselspital, Bern University Hospital and University of Bern, Switzerland; and ¹²Department of Cardiology, Heraklion University Hospital, Heraklion Crete, Greece

(Vijgen et al, Europace 2009; 11:1097-1107)

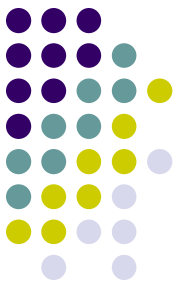
Consensus statement

Consensus statement of the European Heart Rhythm Association:
Updated recommendations for driving by patients with
implantable cardioverter defibrillators[☆]

Johan Vijgen^{a,*}, Gianluca Botto^b, John Camm^c, Carl-Johan Hoijer^d, Werner Jung^e,
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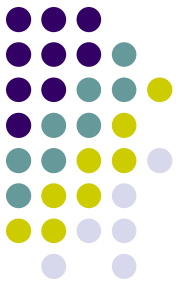
(Vijgen et al, European Journal of Cardiovascular Nursing 2010; 9: 3-14)

Is it reasonable to impose driving restrictions on ICD recipients?



- In primary prevention?
- When it results in loss of work?
- When it convenes family problems?
- In rural areas?
- When ICD recipients become isolated?
- What is the risk of an accident really?





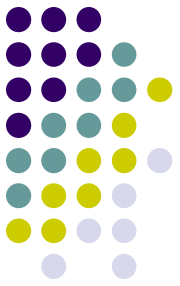
Living with an ICD

- Treatment with ICDs affect the lives of patients and their families
- Concerns centre on the device
- Limitations on lifestyle
- Research on psychosocial effects of driving restriction in ICD patients is scarce
- Studies have reported the driving ban as difficult for patients and their family

(Fridlund et al, J Clin Nurs. 2000 Jan;9(1):37-45)

(Dunbar, Am J Crit Care. 2005 Jul;14(4):294-303)

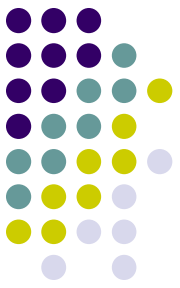
(Carroll & Hamilton. Am J Crit Care 2008;17(3):222-30)



The burden of not driving

- Feelings of resentment and anger
- Increased dependence on others
- Lacking confidence in driving
- Imposed family sanctions when driving
- Relationship conflicts over driving

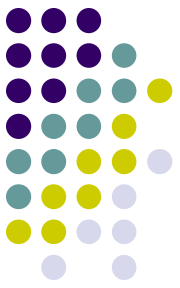
(James et al, Coronary Health Care 2001;5:80-88)



”The worst thing for George was not being able to drive....and the worst thing for me was having to learn to drive....and of course I can never do it good enough! The worst thing of all is the fact he could not drive for a whole year, that was really, really hard for him and me, he is not a good passenger.”

(James et al, Coronary Health Care 2001;5:80-88)

Ethics - conflicting principles

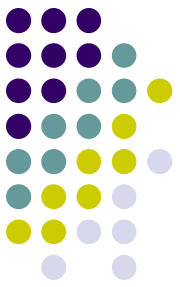


- Limitations on the lives of the ICD recipient and their family
- Public safety
- Experiencing ventricular arrhythmias followed by loss of consciousness while driving may result in death or injury to the patient, other passengers as well as members of the public

(Vijgen et al, Europace 2009; 11:1097-1107)



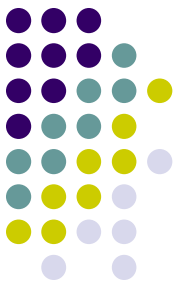
Ethics - conflicting principles



- The aim of ethics as well as legislation is
 - to ensure that the rights of the individual do not exceed the safety of fellow citizens
 - the rights of society to restrict individual action are limited
- Conflicting principles;
 - the rights of the individual
 - the good of the society
- The Task force has sought to balance these principles in its recommendations

(Vijgen et al, Europace 2009; 11:1097-1107)

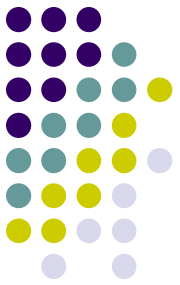
Basis for recommendations



- Recommendations based on descriptive studies and expert opinion
- Secondary prevention: TOVA study: risk for ICD shock not elevated during driving and absolute risk low
- Primary prevention: mortality data, rates of sudden cardiac death, and rate of ICD discharges reported in trials
- A risk of harm formula was used to differentiate the risk for private and professional drivers

(Albert et al, JACC 2007;50:2233-40)

(Vijgen et al, Europace 2009; 11:1097-1107)



Risk of harm formula

$$RH = TD \times V \times SCI \times Ac$$

RH = risk of harm

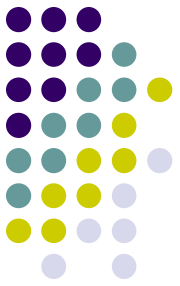
TD = time driving

V = type of vehicle

SCI = yearly risk of sudden cardiac incapacitation

Ac = probability that SCI will result in a fatal accident

What are the regulations?



Restriction for private driving

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

(Vijgen et al, Europace 2009; 11:1097-1107)

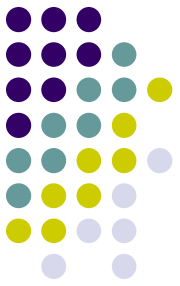
Patients refusing ICD implantation



- Driving restrictions could be one of the reasons for a patient to refuse ICD
- Recommendations based on Larsen et al:
 - 17% (N=501) of CA patients experienced a syncope or recurrent arrhythmia after 1 year
 - Hazard rates were highest in the **first month** after discharge and intermediate for **months 2-7**

(Larsen et al, JAMA 1994; 271:1335-9)

Patients refusing ICD implantation



Patients refusing ICD with indication for:

Driving restriction

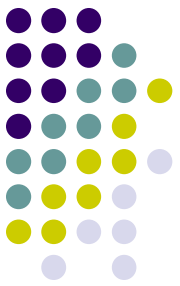
Primary prevention

No restriction

Secondary prevention

Seven months

(Vijgen et al, Europace 2009; 11:1097-1107)

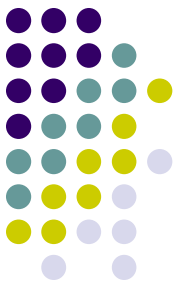


Secondary prevention

- TOVA study: 193 ICD shocks – 7 while driving – 1 accident
(1188 pt followed for 562 days)
- No increased risk of ICD shock during driving

(Albert et al, JACC 2007;50:2233-40)

Secondary prevention



Type of licence

**Indication for ICD
implantation**

**Driving
restriction**

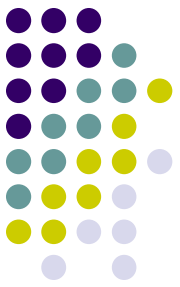
Private driving

Secondary prevention

Three months

(Vijgen et al, Europace 2009; 11:1097-1107)

Primary prevention



Type of licence

**Indication for ICD
implantation**

**Driving
restriction**

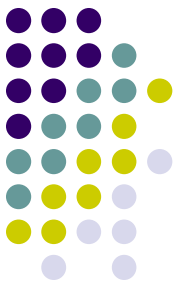
Private driving

Primary prevention

Four weeks

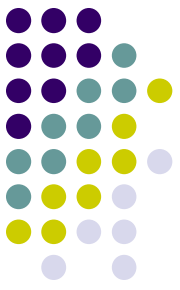
(Vijgen et al, Europace 2009; 11:1097-1107)

Following replacement



Type of licence	Following replacement	Driving restriction
Private driving	Replacement of the ICD	1 week
Private driving	Replacement of lead system	4 weeks

(Vijgen et al, Europace 2009; 11:1097-1107)



After ICD therapy

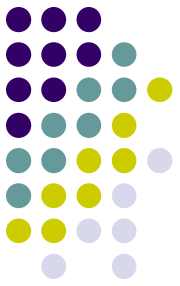
- After appropriate ICD therapy the risk of recurrent arrhythmia is of concern
- Freedberg et al:
 - 46% of the patients received ICD therapy
 - 21% remained free of further ICD therapy
 - Mean time to second ICD therapy was 66 days
- MADIT II: 17.8-fold increased risk of death in the first 3 months after electrical storm
- SCH-HeFT: 5.7-fold increase in mortality after appropriate shock

(Freedberg et al, JACC 2001;37:1910-15)

(Moss et al, Circulation 2004;110:3760-65)

(Poole et al, N Engl J Med 2008;359:1009-17)

After ICD therapy



After ICD therapy

Driving restriction

Appropriate therapy

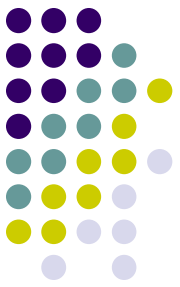
Three months

Inappropriate therapy

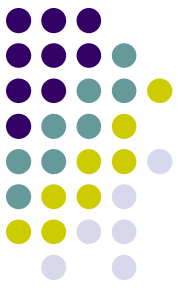
Until measures to prevent subsequent inappropriate therapy are taken

(Vijgen et al, Europace 2009; 11:1097-1107)

Professional driving



Type of licence	Indication for ICD implantation	Driving restriction
Professional driving	Primary prevention	Permanent
Professional driving	Secondary prevention	Permanent



Adherence

- Zilo et al: 91% continued to drive after implant
- Crayney et al: 74% resumed driving despite ban; due to work (62%) and social reasons (58%)
 - 86% driving as important for maintaining lifestyle
 - 58% was the primary driver in the family
 - 62% experienced symptoms
 - 43% had a shock within the past year
- Trappe et al: against advice 76% continued to drive

(Zilo et al. PACE 1994; 17 (Part II):781)

(Crayney et al. Progr Cardiovasc Nurs. 1995;10:12-7)

(Trappe et al. J Card Electrophys 1998;2:193-201)

Adherence

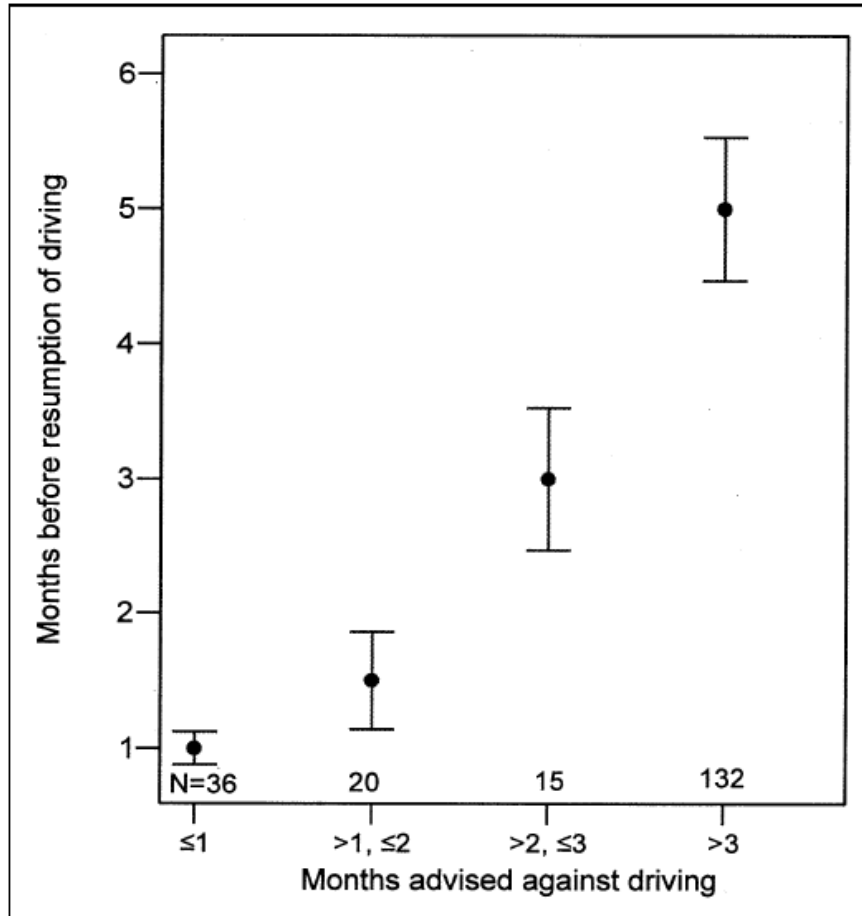
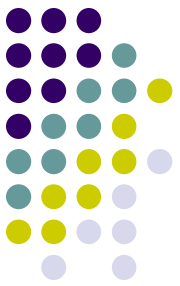
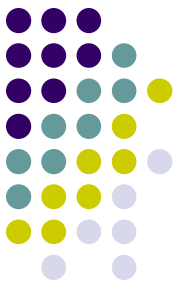


FIGURE 1. Median and 95% confidence interval for the median months before resumption of driving by months advised against driving.

Recommendations given by:

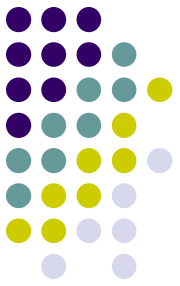
- 51% physician and nurse
- 7% physician only
- 10% nurse only

(Baessler et al, Am J Cardiol 2005;95:665-6)



Follow-up

- Studies on adherence to driving recommendations are contradictory
- An adequate discharge education and follow-up is pivotal
- Demands healthcare professionals to discuss alternative practical solutions
- Nurses and allied health-care professionals are key people and should take action



Thank you

