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Guidelines for Implantation of Automatic Cardioverter/Defibrillators

released by the German Cardiac Society
reported by the Committee of Clinical Cardiology of the German Cardiac Society by S. H. Hohnloser (responsible), D. Andresen, M. Block, G. Breithardt, W. Jung, H. Klein, K. H. Kuck, B. Lüderitz, G. Steinbeck (chair)

The present guidelines for implantation of defibrillators (ICD) are based on a careful analysis of recent scientific data on the therapy of ventricular tachyarrhythmias. They represent a modified and updated version of the guidelines published by the German Cardiac Society in 1993 (1).

A Aim of ICD therapy

I. Primary aim

The primary goal of ICD therapy is the prolongation of life through a reduction of sudden cardiac death. Cardiac arrest due to hemodynamically not tolerated ventricular tachyarrhythmias should be terminated by automatic detection and termination of the arrhythmia by the implanted ICD.

II. Secondary aim

Automatic termination of ventricular tachycardia: Ventricular tachycardia

(VT) is detected by heart rate and other VT-features and is terminated by anti-tachycardia pacing or low energy cardioversion. Arrhythmia detection and termination is also accomplished in hemodynamically not compromising ventricular tachycardias.

Improvement in the quality of life: Quality of life can be improved by avoiding frequent hospitalizations resulting from recurrent VT-episodes. VT-termination by antitachycardia pacing is not associated with unpleasant symptoms thereby improving quality of life as well.

B Requirements

I. Diagnostic requirements

Prior to ICD implantation, non-invasive diagnostic evaluation should be performed according to the clinical situation of the patient. In most instances, coronary angiography as well as left ventricular angiography will be required. In addition, invasive electrophysiological testing should be considered.

It is of particular importance to document all spontaneous VT events as well as episodes of ventricular fibrillation in the surface ECG.

Exercise tolerance testing is often indicated to determine the response of heart rate to optimize the programming

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of intervention rates of the implanted device.

II. Requirements of the implanting center

Requirements in terms of personnel

Cardiologists and cardiac surgeons who implant ICDs need to have profound knowledge and extensive personal experience with respect to:

- a) invasive electrophysiology;
- b) implant technology;
- c) pharmacological therapy of patients with life threatening arrhythmias;
- d) catheter ablative therapy as well as antitachycardia surgery.

Further requirements:

- a) In case of emergencies during the implant procedure (i.e. perforation of electrodes with subsequent pericardial effusion), immediate adequate therapy must be available;
- b) follow-up of patients in the arrhythmia out-patient clinic must be accomplished by experienced personnel (cardiologist) with knowledge of the relevant technology;
- c) availability of a 24-hour emergency facility (including weekends and holidays);
- d) standardized continuous data documentation.

To achieve adequate standards in ICD-therapy, it is mandatory that a center implants at least 20 ICDs per year (23).

Specific requirements

- a) Ideally, ICD-implantation should be performed under aseptic surgical conditions. However, several reports suggest that ICD-implantation can be safely performed in electrophysiological laboratories if adequate sterile conditions are fulfilled.
- b) For ICD-implantation, a single plain X-ray system must be available along with a X-ray transparent oper-

ation table. The X-ray facilities need to meet predefined standards. An external defibrillator must be available during the entire implantation procedure.

ECG documentation: Ideally, two separate ECG-recording systems should be available. At least one of these systems should allow the simultaneous registration of multiple channels. The possibility of invasive and non-invasive hemodynamic monitoring along with continuous oxymetry is mandatory.

Following ICD-implantation, patients should stay for at least 48 hours in a cardiology unit. The personnel taking care of patients after ICD-implantation has to be able to typical post-operative complications, device-specific problems as well as life threatening arrhythmias. They need to be able to start adequate therapeutic measures without any delay.

C Indications

Indications for ICD-implantation are based on scientific data of different degrees of evidence and on the clinical experience of the members of this writing committee. The degree of scientific evidence on which these recommendations are based, are subdivided as follows according to the Task Force of the American College of Cardiology and the American Heart Association (16).

- Level A: Recommendation based on multiple randomized clinical trials involving a large number of individuals.
- Level B: Data were derived from a limited number of trials involving comparatively small numbers of patients or from well designed data analysis of non-randomized studies or observational data registries.
- Level C: Consensus of expert opinion was the primary source of recommendation.

The following classification indicates whether indication for ICD-therapy is 1. commonly accepted, 2. possible but controversially discussed or treatable

by alternative therapies, or 3. not indicated.

- Class I: Condition for which there is evidence or general agreement that a given procedure or treatment is beneficial, useful, and effective.
- Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
- Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

Since this classification can not take into account individual factors of each patient, the need for ICD-implantation has to be individually considered in each case.

The primary pre-requisite for ICD-implantation is the expectation that a patient will suffer from ventricular tachyarrhythmias and that the patient will thereby carry a significant risk of sudden cardiac death. If life expectancy is less than 6 months due to structural heart disease or due to concomitant diseases, ICD-implantation is not recommended. Implantation of an ICD in a patient without prior documentation of spontaneous ventricular arrhythmias is considered as prophylactic. In patients with prior documented ventricular tachyarrhythmias, potentially reversible causes have to be excluded. Prior to ICD-implantation, alternative therapies aiming at prevention of recurrent ventricular tachyarrhythmias have to be evaluated:

- Antiarrhythmic pharmacotherapy which can be empirically administered (in particular amiodarone, betablocker) or can be evaluated by programmed stimulation or Holter monitoring (in particular sotalol).
- Ablative technology (in case of inducible monomorphic VT) by means of surgical technologies (patients with other indications for heart surgery and with only regionally compromised LV-function) or by catheter ablative tech-

niques (in particular in idiopathic left- or right ventricular tachycardias).

The indications for ICD-therapy are detailed in Table 1 according to the predominant clinical presentation of the patient:

- Cardiac arrest
- Ventricular tachycardia
- Syncope
- Asymptomatic patient at risk

Indications for ICD-therapy with respect to the underlying heart disease

1. Coronary artery disease

The great majority of patients evaluated in controlled prospective studies suffered from coronary artery disease, prior myocardial infarction, and ventricular tachyarrhythmias outside acute infarction. Based on frequent adequate ICD-therapies in this population, a beneficial effect on total mortality as a result of ICD-therapy has been postulated for a long time (4, 29, 32). Several randomized studies have indicated the superiority of the ICD compared to therapy with betablockers (metoprolol), class I antiarrhythmic drugs (propafenone) and class III antiarrhythmic drugs (mainly amiodarone) (11, 12, 21, 36, 40, 43). In a retrospective case-control-study, electrophysiologically guided therapy with sotalol was found to be inferior to ICD-therapy (7). Even for patients with hemodynamically tolerated VT, there was a beneficial effect of the ICD with respect to mortality (5). In post-infarction patients with non-sustained VT, ejection fraction $\leq 35\%$, and inducible but not suppressible VT/VF, a significant survival benefit could be demonstrated when compared to antiarrhythmic standard therapy mainly with amiodarone (30). Even in patients in whom the induction of VT/VF was suppressible by class I antiarrhythmic drugs, there seems to be a significant risk for sudden cardiac death (15, 23). According to the results of the

MUSTT-trial this risk was similar to that of patients without antiarrhythmic pharmacotherapy (9). Post-infarction patients with syncope in whom VT/VF was inducible on electrophysiological testing experience frequent adequate ICD-shocks (25, 28). In contrast, in post-infarction patients without documented VT but late potentials on signal-averaged ECG and depressed left ventricular function, in whom coronary artery bypass grafting was performed, the ICD turned out to be of no benefit with respect to total mortality compared to usual care (3). At present, several randomized prospective studies investigate different risk stratifiers in order to identify patients who potentially could benefit from prophylactic ICD-implantation.

2. Dilative cardiomyopathy (DCM)

There are no prospective randomized studies in patients with DCM and VT/VF comparing ICD and antiarrhythmic pharmacotherapy. In studies in whom coronary patients and patients with DCM were included there was no significant influence of the underlying heart disease with respect to the ICD-derived survival benefit. Retrospective observational studies in patients with DCM have postulated the superiority of the ICD compared to pharmacological antiarrhythmic treatment (10, 29). Prophylactic ICD-implantation in patients with DCM (LVEF $\leq 30\%$) not listed for heart transplantation seems to be not indicated in the absence of ventricular tachyarrhythmias (22, 39). In contrast, patients with DCM and syncope of unknown origin, ICD-implantation is associated with frequent adequate shock delivery (20).

3. Advanced congestive heart failure

Patients with advanced congestive heart failure experience a high cardiac mortality even if sudden cardiac death

can be prevented. Therefore, NYHA IV patients should only receive an ICD if this device is implanted as a bridge to transplant. However, this indication has not been studied in a prospective way (17, 38).

4. Hypertrophic cardiomyopathy (HCM)

There is no prospective randomized study evaluating the benefits of ICD therapy in patients with HCM. In controlled ICD-studies, only few patients with HCM have been included. However, in patients with HCM fitted with an ICD after prior cardiac arrest, there seems to be a benefit of ICD therapy as indicated by observational studies (14, 34, 37). Prevention of arrhythmic death has not been demonstrated by the sole improvement of hemodynamics (beta-blocker, verapamil, DDD-pacemaker, septal ablation, myectomy) and/or antiarrhythmic pharmacotherapy with amiodarone. In patients without prior cardiac arrest, ICD-implantation can be discussed in cases with unexplained syncope, inducible VT/VF or with a strong family history of sudden cardiac death (46).

5. Arrhythmogenic right ventricular cardiomyopathy (ARCM)

There is no prospective randomized study evaluating the benefits of ICD-therapy in patients with ARCM. Observational studies have shown that patients with ARCM and prior cardiac arrest, hemodynamically intolerable VT or VT not suppressible by antiarrhythmic pharmacotherapy derive benefit from ICD-therapy (25, 44). In patients with hemodynamically tolerated and inducible VT without extensive angiographic evidence of dysplasia, alternatively catheter ablation and/or antiarrhythmic pharmacotherapy can be discussed.

Table 1 ICD-Indications for various clinical presentations

	Indication class		
	established	possible	not indicated
Cardiac arrest (11, 12, 21, 36, 40, 43)			
● VT/VF documented reversible cause acute myocardial infarction ≥ 48 hours WPW-syndrome	A		C C C
● VT/VF not documented defibrillation “successful” VT/VF inducible	B B		
Ventricular tachycardia (11, 12, 40, 43)			
● With hemodynamic instability (i.e. shock, synkope) (11, 12, 40)	A		
● Without hemodynamic relevance left ventricular ejection fraction < 35–40 % (11, 12, 40) > 35–40 % (4)	B	B	
● Incessant*			C
● Non-sustained – EF ≤ 35–40 % post myocardial infarction, inducible, not suppressible (9, 30) – EF ≤ 35–40 % post myocardial infarction, inducible, suppressible (9) – not at high risk for sudden cardiac death	B	B	C
● Idioventricular rhythm			C
● Idiopathic			C
Syncope without documented ventricular tachyarrhythmia after exclusion of different causes (20, 25, 28)			
● VT/VF inducible left ventricular ejection fraction ≤ 40 % > 40 %	B	C	
● VT/VF not inducible left ventricular ejection fraction ≤ 40 % > 40 %		C	C
Asymptomatic patient at risk			
● Postinfarction, late potentials in SAECG, EF ≤ 35 % and CABG surgery (3)			A
● Patient with DCM, EF ≤ 30 %, NYHA I–III (20)			B
● Patient with positive family history for sudden death, particularly in diseases which are genetically determined, such as hypertrophic cardiomyopathy, long QT-syndrome, or Brugada-syndrome		C	

A = recommendation based on multiple randomized clinical trials involving a large number of individuals, B = data derived from a limited number of trials involving comparatively a small number of patients or from well designed data analysis of non randomized study or observational data registries, C = consensus of expert opinion as the primary source of recommendation, EF = ejection fraction, NYHA = New York Heart Association, VT = ventricular tachycardia, VF = ventricular fibrillation, WPW = Wolff Parkinson White, Class I = condition for which there is evidence or general agreement that a given procedure or treatment is beneficial, useful, and effective, Class II = condition for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment, Class III = condition for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful, CABG = coronary artery bypass grafting, DCM = dilative cardiomyopathy, SAECG = signal-averaged ECG, *after successful termination of the incessant VT, ICD-implantation should be considered due to high VT-recurrence rate.

6. Long QT-syndrome

There is no prospective randomized study evaluating the benefits of ICD-therapy in patients with the long QT-syndrome. Since the prognosis of these patients is excellent in the absence of arrhythmogenic death, control of polymorphic VT (Torsade de pointes) is of exceptional importance. Therefore, pa-

tients with recurrent VT or syncope despite adequate therapy with beta-blockers, AAI pacemaker-therapy, and/or left cervico-thoracic sympathectomy are recommended to receive an ICD (18). In patients with cardiac arrest in the setting of the long QT-syndrome or with a strong family history of sudden cardiac death, prophylactic ICD-therapy can be discussed.

7. Idiopathic ventricular fibrillation and idiopathic ventricular tachycardia

There is no prospective randomized study evaluating the benefits of ICD-therapy in patients with idiopathic VF. Since the prognosis of these patients in the absence of VF is excellent, control of VT/VF is of exceptional importance (33). There is no hard evidence that

pharmacological therapy by means of betablocker or other antiarrhythmic drugs will prevent recurrent VF. ICD-implantation should be strongly consid-

ered (2, 13, 26, 27, 35, 41, 42, 45). Similar recommendations are valid for patients with the so called Brugada-syndrome (8). In contrast, patients with

monomorphic idiopathic right or left ventricular tachycardia, catheter ablation should be considered as the prime mode of therapy (17).

References

- Andresen D, Block M, Borggreffe M, Brachmann J, Goedel-Meinen L, Gonska BD, Hohnloser SH, Kuck KH, Kunze KP, Trappe J, Treese N, Volkmann HJ. (1993) Empfehlung zur Implantation von Defibrillatoren. *Z Kardiol* 82:242-246
- Belhassen B, Viskin S (1993) Idiopathic ventricular tachycardia and fibrillation. *J Cardiovasc Electrophysiol* 4:356-368
- Bigger JT, for the Coronary Artery Bypass Graft (CABG) Patch Trial Investigators (1997) Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary artery bypass graft surgery. *N Engl J Med* 337:1569-1575
- Böcker D, Block M, Isbruch F, Wietholt D, Hammel D, Borggreffe M, Breithardt G (1993) Do patients with an implantable defibrillator live longer? *J Am Coll Cardiol* 21:1638-1648
- Böcker D, Block M, Isbruch F, Fastenrath C, Castrucci M, Hammel D, Scheld HH, Borggreffe M, Breithardt G (1995) Benefits of treatment with implantable cardioverter defibrillators in patients with stable ventricular tachycardia without cardiac arrest. *Br Heart J* 73:158-163
- Böcker D, Haverkamp W, Block M, Borggreffe M, Breithardt G (1996) Comparison of d,l Sotalol and implantable defibrillators for treatment of sustained ventricular tachycardia of fibrillation in patients with coronary artery disease. *Circulation* 94: 151-157
- Böcker D, Bänsch D, Heinecke A, Weber M, Brunn J, Hammel D, Borggreffe M, Breithardt G, Block M (1998) Potential benefit from ICD therapy in patients with and without heart failure. *Circulation* 97: 98:1636-1643
- Brugada J, Brugada R, Brugada . (1998) Right bundle-branch block and ST-segment elevation in leads V1 through V3: a marker for sudden death in patients without demonstrable structure heart disease. *Circulation* 97:547-560.
- Buxton AE, Lee KL, Fischer JD, Josephson ME, Prystowsky EN, Gail Hafley, for the multicenter Unsustained Tachycardia Trial Investigators (1999). A randomized study of the prevention of sudden death in patients with coronary artery disease. *N Engl J Med*; 341:1882-90
- Chen X, Shenasa M, Borggreffe M, Block M, Hindricks G, Martinez-Rubio A, Haverkamp W, Willems S, Böcker D, Mäki-ijärvi M, Breithardt G (1994) Role of programmed ventricular stimulation in patients with idiopathic dilated cardiomyopathy and documented sustained ventricular tachyarrhythmias: Inducibility and prognostic value in 102 patients. *Eur Heart J* 15:76-82
- Connolly SJ, Gent M, Roberts RS, Dorian P, Green MS, Klein GJ, Mitchell LB, Sheldon RS, Roy D (1993) Canadian Implantable Defibrillator Study (CIDS): Study design and organization. *Am J Cardiol* 72:103F-108F
- Connolly SJ (1998) The Canadian Implantable Defibrillator Study. Presented at the American College of Cardiology 47th Annual Scientific: March 1998: Atlanta, USA
- Crijns HJGM, Wiesfeld ACP, Posma JJ, Lie KI (1995) Favourable outcome in idiopathic ventricular fibrillation with treatment aimed at prevention of high sympathetic tone and suppression of inducible arrhythmias. *Br Heart J* 74:408-41
- Fananapazir L, Epstein SE (1991) Hemodynamic and electrophysiologic evaluation of patients with hypertrophic cardiomyopathy surviving cardiac arrest. *Am Coll Cardiol* 67:280-287
- Giorgberidze I, Saksena S, Krol RB, Munisif AN, Kolettis T, Mathew P, Varanasi S, Prakash A, Delfaut P, Lewis CB (1997) Risk stratification and clinical outcome of minimally symptomatic and asymptomatic patients with nonsustained ventricular tachycardia and coronary disease. A prospective single-center study. *Am J Cardiol* 80:3F-9F
- Gregoratos G, Cheitlin MD, Conill A, Epstein AE, Fellows C, Ferguson TB Jr., Freedman RA, Hlatky MA, Naccarelli GV, Saksena S, Schlant RC, Silka MJ (1998) ACC/AHA guidelines for implantation of cardiac pacemakers and antiarrhythmic devices: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation). *J Am Coll Cardiol* 31:1175-1209
- Grimm M, Wieselthaler G, Avanesian R, Grimm G, Schmidinger H, Schreiner W, Podczek A, Wolner E, Laufer G (1995) The impact of implantable cardioverter defibrillators on mortality among patients on the waiting list for heart transplantation. *J Thorac Cardiovasc Surg* 110:532-539
- Groh WJ, Silka MJ, Oliver RP, Halperin BD, McAnulty JH, Kron J (1996) Use of implantable cardioverter-defibrillators in the congenital long QT syndrome. *Am J Cardiol* 78:703-706
- Klein LS, Shih HT, Hackett FK, Zipes DP, Miles WM (1992) Radiofrequency catheter ablation of ventricular tachycardia in patients without structural heart disease. *Circulation* 85:1666-1674
- Knight BP, Strickberger SA, Daoud EG, Goyal R, Souza J, Zivin A, Morady F (1997) Outcome of patients with nonischemic dilated cardiomyopathy and unexplained syncope treated with an implantable cardioverter defibrillator. *Circulation* 96 (Suppl):1-708
- Kuck KH (1998) The Cardiac Arrest Study Hamburg. Presented at the American College of Cardiology 47th Annual Scientific: March 1998: Atlanta, USA
- Kuck KH (1998) The Cardiomyopathy Trial. Presented at the German Society of Cardiology 63th Annual Scientific: April 1998: Mannheim, Germany
- Levine JH, Waller T, Hoch D, Greenberg S, Goldberger J, Kadish A (1996) Implantable cardioverter defibrillator: use in patients with no symptoms and at high risk. *Am Heart J* 131:59-65
- Levy S, Hauer RNW, Raviele A, Daubert JC, Campbell RWF, Breithardt G. Recommendations for qualification of centres implanting and following defibrillators. *Eur Heart J* 17:1796-1799
- Link MS, Costeas XF, Griffith JL, Colburn CD, Estes III NAM, Wang PJ (1997) High incidence of appropriate implantable cardioverter defibrillator therapy in patients with syncope of unknown etiology and inducible ventricular arrhythmias. *J Am Coll Cardiol* 29:370-375
- Meissner MD, Lehmann MH, Steinmann RT, Mosteller RD, Akhtar M, Calkins H, Cannom DS, Epstein AE, Fogoros RN, Liem LB, Marchlinski FE, Myerburg RJ, Veltri EP (1993) Ventricular fibrillation in patients without significant structural heart disease: A multicenter experience with implantable cardioverter-defibrillator therapy. *J Am Coll Cardiol* 21:1406-1412
- Mewis C, Kühlkamp V, Spyridopoulos I, Bosch RF, Seipel L (1998) Late outcome of survivors of idiopathic ventricular fibrillation. *Am J Cardiol* 81:999-1003
- Militianu A, Salacata A, Seibert K, Kehoe R, Baga JJ, Meissner MD, Pires LA, Schuger CD, Steinman RT, Mosteller RD, Palti AJ, David JB, Lessmeier TJ, Lehmann

- MH (1997) Implantable cardioverter defibrillator utilization among device recipients presenting exclusively with syncope or near-syncope. *J Cardiovasc Electrophysiol* 8:1087–1097
29. Mirowski M, Reid PR, Winkle RA, Mower MA, Watkins L, Stinson EB, Griffith LSC, Kallman CH, Weisfeldt ML (1983) Mortality in patients with implanted automatic defibrillators. *Ann Int Med* 98:585–588
 30. Moss AJ, Hall WJ, Cannom DS, Daubert JP, Higgins SL, Klein H, Levine JH, Sakseena S, Waldo AL, Wilber D, Brown MW, Heo M, for the Multicenter Automatic Defibrillator Implantation Trial Investigators (1996) Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. *N Engl J Med* 335:1933–1940
 31. Osswald S, Trouton TG, O’Nunain SS, Roelke M, Powell AC, Sosa-Suarez GE, McGovern BA, Garan H, Cannom DS, Ruskin JN (1996) Impact of the implantable cardioverter-defibrillator on long-term outcome in survivors of out-of-hospital cardiac arrest with idiopathic dilated cardiomyopathy. *Eur J Card Pacing Electrophysiol* 6:148–154
 32. Powell AC, Fuchs T, Finkelstein DM, Garan H, Cannom DS, McGovern BA, Kelly E, Vlahakes GJ, Torchiana DF, Ruskin JN (1993) Influence of implantable cardioverter defibrillators on the long term prognosis of survivors of out of hospital cardiac arrest. *Circulation* 88:1083–1092
 33. Priori SG, Paganini V, Bocalatte L, Schwartz PJ (1995) Idiopathic ventricular fibrillation: From anecdotal reports to a prospective evaluation. *G Ital Cardiol* 25:149–158
 34. Primo J, Geelen P, Brugada J, Filho AL, Mont L, Wellens F, Valentino M, Brugada P (1998) Hypertrophic cardiomyopathy: Role of the implantable defibrillator. *J Am Coll Cardiol* 31:1081–1085
 35. Schneider MAE, Siebels J, Ruppel R, Kuck KH, and the CASH Investigators (1993) Idiopathic ventricular fibrillation: Risk stratification and 24 months follow up in 16 patients. *PACE* 16:949
 36. Siebels J, Kuck KH (1994) Implantable cardioverter defibrillator compared with antiarrhythmic drug treatment in cardiac arrest survivors (the Cardiac Arrest Study Hamburg). *Am Heart J* 127:1139–1144
 37. Silka MJ, Kron J, Dunnigan A, Dick M II (1993) Sudden cardiac death and the use of implantable cardioverter defibrillators in pediatric patients. *Circulation* 87:800–807
 38. Sweeney MO, Ruskin JN, Garan H, McGovern BA, Guy ML, Torchiana DF, Vlahakes GJ, Newell JB, Semigran MJ, Dee GW (1995) Influence of the implantable cardioverter/defibrillator on sudden death and total mortality in patients evaluated for cardiac transplantation. *Circulation* 92:3273–3281
 39. The Cardiomyopathy Trial Investigators (1993) Cardiomyopathy Trial. *PACE* 16 (Pt II):576–581
 40. The Antiarrhythmics Versus Implantable Defibrillators (AVID) Investigators (1997) A comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from near fatal ventricular arrhythmias. *N Engl J Med* 337:1576–1583
 41. Tsai CF, Chen SA, Tai CT, Chiang CE, Ding YA, Chang MS (1998) Idiopathic ventricular fibrillation: clinical, electrophysiologic characteristics and long-term outcomes. *Int J Cardiol* 64:47–55
 42. Wever EF, Hauer RN, Oomen A, Peters RH, Bakker PF, Robles de Medina EO (1993) Unfavorable outcome in patients with primary electrical disease who survived an episode of ventricular fibrillation. *Circulation* 88:1021–1029
 43. Wever EFD, Hauer RNW, van Capelle FJL, Tijssen JGP, Crijns HJGM, Algra A, Wiesfeld ACP, Bakker PFA, Robles de Medina EO (1995) Randomized study of implantable defibrillator as first choice therapy versus conventional strategy in post-infarct sudden death survivors. *Circulation* 91:2195–2203
 44. Wichter T, Breithardt G, Block M, Haverkamp W, Borggrefe M (1994) Management of patients with arrhythmogenic right ventricular cardiomyopathy – results in 127 patients. *New Trends in Arrhythmias* 9:749–755
 45. Wichter T, Borggrefe M, Block M, Oen H, Böcker D, Breithardt G (1996) Implantable cardioverter-defibrillator therapy improves long-term prognosis of patients with idiopathic ventricular fibrillation. *Eur Heart J* 17(Suppl):504
 46. Zhu DW, Sun H, Hill R, Roberts R (1998) The value of electrophysiology study and prophylactic implantation of cardioverter defibrillator in patients with hypertrophic cardiomyopathy. *PACE* 21:291–302

D Driving recommendations

Driving restrictions may negatively impact on the quality of life of ICD-recipients (1, 2). In Germany approximately 8000 lethal traffic accidents occur annually. The vast majority of these traffic accidents is related to non-medical causes such as fatigue or alcohol consumption whereas only approximately 5% of all lethal traffic accidents are related to medical causes (i.e. epilepsy, arrhythmias). Thus, arrhythmic sudden death while driving is a rare event (3). Less than 2% of all sudden losses of consciousness will lead to death or serious injuries. It remains to be determined whether certain patients at risk such as ICD recipients are responsible for a higher arrhythmia-related incidence of traffic accidents. When considering dri-

ving restrictions based on risk assessment, the frequency and the time course of recurrent arrhythmias, the incidence of arrhythmia-related syncope (4), the risk of arrhythmia-related accidents and the likelihood that such an accident will lead to severe injuries or death of the patient or other traffic participants need to be considered (5).

Patients with cardiac rhythm disorders applying for a driving license or already having one are not capable to drive a car if the arrhythmia has led to recurrent presyncope or even syncope due to impaired cerebral blood flow. Such a decision must be based on careful medical and cardiac examination including 24-h-Holter-monitoring and additional tests as required (6).

If a patient has received an ICD, it is assumed that this patient can resume driving on a non-commercial basis if

his/her cardiac function is stable and if there is no recurrent presyncope or syncope over the course of 6 months. In Table 2, recommendations for driving of ICD-patients as summarized.

Taking all the available but still limited information into account for assessing the fitness of the ICD-patient to drive, the following recommendations are grouped into 3 different categories:

- Class I: No restriction
- Class II: Restriction for defined time period
 - A: without arrhythmia recurrence
 - B: until confirmation of absence of disabling symptoms at the time of ICD therapy
- Class III: Total restriction

Patients grouped into class I category have no restrictions to drive. After recovery from ICD-implantation (in most instances approximately after 3 months)

Table 2 Recommendations for driving of ICD-patients

Class	Patient	Recommendation
I:	prophylactic implantation	no restrictions
II:	all other ICD-patients	Driving restriction for a defined period of time
A:	low risk: no recurrent VT/VF	6 months
B:	medium risk: patients with tolerated VT	until documentation of absence of symptoms associated with ICD-therapy
III:	high risk: unstable VT	total restriction

these patients can resume driving. Patients classified as class II are restricted for a defined time period without arrhythmia recurrence. Patients classified

as class III have a high risk of hemodynamically unstable ventricular tachyarrhythmia. These patients have a total restriction of driving. It is important to

emphasize that the prerequisites to accomplish commercial driving are not present in ICD-patients of class II and III.

References

- Jung W, Lüderitz B (1996) Quality of life and driving in recipients of the implantable cardioverter-defibrillator. *Am J Cardiol*; 78:51–56
- Jung W, Deister A, Grädtz S, Manz M, Lüderitz B (1995) Lebensqualität und psychosoziale Probleme bei der Betreuung von Patienten mit implantierbarem Kardioverter-Defibrillator. *Herzschr Elektrophys*; 6 (Suppl 1):21–28
- Jung W, Lüderitz B (1996) Driving and the implantable cardioverter defibrillator. *Lancet*; 348:687–688
- Bänsch D, Brunn J, Castrucci M, Weber M, Gietzen F, Borggreffe M, Breithardt G, Block M (1998) Syncope in patients with an implantable cardioverter-defibrillator: incidence, prediction and implications for driving restrictions. *J Am Coll Cardiol*; 31: 608–615
- Jung W, Lüderitz B (1996) European policy on driving for patients with implantable cardioverter-defibrillators. *PACE*; 19:981–984
- Schriftenreihe des Bundesministeriums für Verkehr: Krankheit und Kraftverkehr. Gutachten des Gemeinsamen Beirates für Verkehrsmedizin. 1996; Heft 73
- Jung W, Anderson M, Camm J, Jordaens L, Petch M, Rosenqvist M, Santini M, Lüderitz B (1997) Recommendations for driving of patients with implantable cardioverter defibrillators. *Eur Heart J*; 18:1210–1219
- Epstein AE, Miles WM, Benditt DG, et al (1996) Personal and public safety issues related to arrhythmias that may affect consciousness: implications for regulation and physician recommendations. A medical/scientific statement from the AHA and the NASPE. *Circulation*; 94:1147–1166

E Follow-up

Adequate follow-up of ICD-patients needs to be ascertained. This follow-up includes

- (1) evaluation of the integrity of the ICD and lead system with respect to battery life, capacitor function and, when appropriate, signal amplitude and pacing threshold;
- (2) assessment of device efficacy; programming of ICD-functions in order to optimize on an individual basis during clinical follow-up and in order to minimize ICD-related complications;
- (3) ongoing patient care.

General requirements:

As with pacemaker follow-up, ICD-devices can only be interrogated and programmed with the respective programmers. This implies that a follow-up center must have a wide selection of ICD-programmers available in order to adequately take care of ICD-patients particularly in emergency cases.

Interrogation and programming of ICD-devices should be performed only by physicians who have undergone extensive education with respect to the different programmers and who have extensive experience acquired at an ICD implantation center. Repeat educational sessions with respect to device interrogation is needed on a regular basis to cope with the ongoing technical innovations of modern ICD-systems.

The personnel in follow-up centers

also need to have profound knowledge on ICD-indications, implantation techniques, and alternative therapeutic approaches (pharmacotherapy, ablation).

Follow-up of ICD patients is performed in the out-patient setting. Preferably, follow-up centers should be located at institutions at which ICD-implantation is performed and at which experience in treating various cardiac rhythm disorders is available. If ICD follow-up is carried out in non-implanting institutions, close cooperation between this institution and the ICD implanting center is to be maintained.

In the follow-up of ICD recipients, visits are grouped in routine clinical visits, urgent visits, and visits due to emergencies. It is important to emphasize that a 24-hour emergency service is available.

Routine visits:

The intervals for routine visits of ICD-patients is determined by the clinical condition of the patient as well as by the respective ICD-system. Most commonly, routine visits are taking place every three to six months. On these visits, battery status, elective replacement indicators, Holter functions, tachycardia and bradycardia events need to be checked. In addition, a careful clinical history including questions assessing the quality of life and a careful physical examination is needed. Patients are recom-

mended to participate in patient education seminars alone or together with their spouses.

Urgent visits:

In the following situations urgent follow-up visits of ICD recipients are needed:

- suspected infection of the ICD-system;
- first shock;
- several ICD interventions within a short period of time (days);

- new palpitations;
- increasing psychological distress.

Emergency visits:

Emergency visits are necessary in case of one of the following situations:

- frequent ICD shock delivery within a short period of time (hours);
- incessant tachycardia;
- development or aggravation of congestive heart failure;
- syncope following ICD-implantation.