Guidelines for Non-Pharmacotherapy of Cardiac Arrhythmias (JCS 2011)  
– Digest Version –

JCS Joint Working Group

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Introduction of the Revised Guidelines

In 2001 when the first edition of the Guidelines for Non-Pharmacotherapy of Cardiac Arrhythmias was published, a substantial number of patients underwent catheter ablation for the treatment of a wide variety of heart diseases including Wolff-Parkinson-White syndrome and supraventricular tachycardia, and the guidelines clearly described the indications of catheter ablation. However, catheter ablation for the treatment of complex arrhythmias such as atrial fibrillation (AF), atypical atrial flutter, and ventricular tachycardia associated with structural heart diseases was indicated for only selected patients. Three-dimensional (3D) mapping systems that have been developed since the 1990s have contributed to the clarification of the mechanisms of these complex arrhythmias and the improvement of the outcome of ablation procedures. After the approval of the CARTO system in 2000 and the EnSite system in 2006, catheter ablation therapy became available for many patients.
with arrhythmias not responding to the conventional treatment. Since catheter ablation became a standard procedure in the treatment of arrhythmia, the guidelines were revised in 2006 to expand the indications for catheter ablation for supraventricular tachycardia as well as complex arrhythmias including AF. After the revision in 2006, catheter ablation became more common especially in the treatment of paroxysmal AF in which pulmonary vein isolation became the standard catheter ablation procedure. In the “Guidelines for Pharmacotherapy of Atrial Fibrillation (JCS 2008)” and the “Guidelines for Drug Treatment of Arrhythmias (JCS 2009)”, catheter ablation is recommended as second-line therapy for drug-resistant AF. In these guidelines, catheter ablation is also recommended as second-line therapy for other types of arrhythmias not respond to pharmacotherapy and even as first-line therapy for selected patients. The performance of 3D mapping systems was improved as the CARTO XP and CARTO 3, the second and third generations of the CARTO system were approved in 2008 and 2011, respectively, and EnSite NavX, a new feature of EnSite, was approved in 2009. Irrigation tip catheters, that had been unavailable in Japan despite the availability in other countries, were introduced in Japan in 2009. With the advancement of these techniques to support catheter ablation, there is the need for wider and clearer indications of catheter ablation in the treatment of complex arrhythmias especially refractory ones such as AF and ventricular tachycardia.

When the first edition of the guidelines was prepared in 1999 to 2000, the use of implantable cardioverter-defibrillator (ICD) was quite limited in Japan, and almost no evidence was available. In the guidelines, ICD therapy was thus indicated mainly for secondary prevention of sudden cardiac death (SCD) according to the results of large-scale clinical studies in Europe and the United States and consensus of specialists in Japan, as well as for primary prevention of SCD in patients with a high risk of fatal arrhythmias who have either nonsustained ventricular tachycardia or syncope of unknown etiology, show ventricular dysfunction, and have inducible ventricular tachycardia/fibrillation in electrophysiological studies (EPS) according to the results of the MADIT (Multicenter Automatic Defibrillator Implantation Trial)-I in 1996 and the MUSTT (Multicenter Unsustained Tachycardia Trial) in 1999. After the publication of the first guidelines in 2001, investigators in Europe and the United States published the results of clinical studies of ICD therapy for primary prevention of SCD such as the MADIT-II in 2002 and the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) in 2005. The indications of ICD therapy for primary prevention of SCD were expanded accordingly. In Japan, investigations of ICD therapy for secondary prevention of SCD were clearly described, and that for primary prevention of SCD were expanded to patients who have symptomatic heart failure and ventricular dysfunction in the 2006 edition of the guidelines. With the technical advantages and miniaturization of the devices, more patients started to receive ICD therapy, and the guidelines were required to revise to reflect new evidence. In 2007, the Japanese Circulation Society (JCS) published the “Guidelines for Diagnosis and Management of Patients with Long QT Syndrome and Brugada Syndrome (JCS 2007)”, which described the indications of ICD therapy for the prevention of fatal arrhythmias in these patient populations. The present guidelines had to be revised to reflect these indications.

In parallel with the advancement of ICD therapy, biventricular pacing, which is referred to as cardiac resynchronization therapy (CRT) was developed and advanced as a treatment for patients with chronic heart failure associated with intraventricular conduction disturbance. A lot of clinical studies have demonstrated that CRT is effective in alleviating symptoms and improving exercise capacity and life prognosis especially in patients who have wide QRS complexes of left bundle branch block pattern, chronic heart failure (New York Heart Association [NYHA] Class III or IV symptoms) and ventricular dysfunction. In the United States, the Food and Drug Administration (FDA) approved CRT in 2001, and CRT device that incorporates both pacing and defibrillation capabilities (CRT-D) in 2002 according to the results of the COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure) study in which CRT-D was demonstrated to improve life prognosis of patients with chronic severe heart failure by preventing death due to heart failure and sudden death. In Japan, CRT and CRT-D were included in the National Health Insurance (NHI) price list in 2004 and 2006, respectively. Following the publication of the 2006 edition of the guidelines, investigators reported the benefits of CRT-D in patients with wide QRS complexes, ventricular dysfunction, and mild or moderate heart failure (NYHA Class II or III symptoms), and the investigators of the RAFT (Resynchronization-Defibrillation for Ambulatory Heart Failure Trial) in 2010 demonstrated that CRT-D was more effective than ICD in improving life prognosis in patients with NYHA Class II symptoms of heart failure. The guidelines should be revised to provide up-to-date indications of CRT and CRT-D, and we also have to consider the criteria for the indication of CRT such as the width of QRS complex, level of cardiac function, severity of heart failure and complication of AF.

With the recent advancement of medical engineering, non-pharmacotherapy of cardiac arrhythmias have improved significantly, and evidence supporting widespread use of such procedures has been obtained in many large-scale clinical studies. We thus modified the 2006 edition of the guidelines to prepare the 2011 edition.

I Background and Concept of the Guidelines

1. Current Status of Non-Pharmacotherapy of Cardiac Arrhythmias

In Japan, the use of implantable pacemakers for the treatment of bradyarrhythmia started to be covered with the NHI in 1974. It rapidly became common and widespread. The number of patients implanted with pacemakers increased over time in the 1980s as smaller and more physiological devices with a long battery life became available, and increased to about 42,700 patients in 2002 and about 57,500 patients (new device implantation in about 36,000 patients and device replacement in about 21,000 patients) in 2010. On the other hand, patients with tachyarrhythmia have been treated with drugs since the 1950s, but the report of the CAST (Cardiac Arrhythmia Suppression Trial) in 1989 significantly changed the methodology used to treat tachyarrhythmia, and enhanced the position of non-pharmacotherapy. Various surgical procedures to successfully treat tachyarrhythmia were developed in the 1970s and 1980s. Catheter ablation and ICD were developed in the 1980s and rapidly became common in Europe and the United States in 1999.
the 1990s. Catheter ablation has been established as a minimally invasive, curative technique to target the sources of arrhythmia. In the United States, about 400,000 people die from SCD each year, and 80 to 90% of them are considered to have ventricular fibrillation/tachycardia, and ICD therapy is positioned as the most effective preventive measure against sudden death. The presence of intraventricular conduction disturbance of left bundle branch block pattern, a finding observed in 20 to 30% of patients with chronic heart failure, was found to be an independent prognostic factor, and CRT (i.e., biventricular pacing) was established and rapidly becoming common in Europe and the United States. CRT-D were also developed on the basis of the finding that sudden death accounted for 40 to 50% of the deaths in patients with chronic heart failure, and ventricular fibrillation was considered the most common cause of sudden death in this population.

In Japan, catheter ablation, ICD therapy, CRT and CRT-D therapy were started to be covered with the NHI in 1994, 1996, 2004 and 2006, respectively (Figure 1). These non-pharmacological procedures are rapidly improving, and the numbers of patients receiving ICD therapy and CRT/CRT-D therapy have been increasing every year (Figure 2). Although much is still not known for SCD in Japan, it is estimated that 60,000 to 80,000 people died from it each year. Although investigators believe that the most common direct cause of SCD is ventricular tachyarrhythmia, but the distribution of underlying heart diseases in Japanese patients differ from that in Western patients. Coronary artery disease is less common, and dilated cardiomyopathy, hypertrophic cardiomyopathy and idiopathic ventricular fibrillation are more common in Japanese patients (Figure 3). Physicians should select the most appropriate option from drugs and various non-pharmacological procedures including catheter ablation, ICD therapy and surgery to treat patients with tachyarrhythmia. It is of great clinical significance to provide updated guidelines for non-pharmacotherapy of patients with tachyarrhythmia.

2. Contents of the Guidelines

The present revised guidelines propose indications for non-pharmacological procedures for the treatment of cardiac arrhythmias according to the latest findings. The present guidelines describe the significance and indications of clinical cardiac EPS, which is essential to determine whether non-pharmacological procedures are indicated and assess the efficacy of such procedures, and list indications of cardiac pacing, catheter ablation, ICD therapy, CRT-D therapy and surgery. The guidelines also describe cardiac pacing for patients with hypertrophic obstructive cardiomyopathy and biventricular pacing (i.e., CRT) for patients with heart failure.

It is difficult to provide evidence-based recommendations for non-pharmacotherapy of children with tachyarrhythmia because they are extremely small in number and few clinical studies have been conducted in this patient population. In the present guidelines, many recommendations on the indications...
of catheter ablation and ICD therapy in children are graded considering the particularity of these procedures according to the consensus of the members of Joint Working Groups.

3. Evidence and Class of Recommendations

In Japan, non-pharmacological procedures for the treatment of arrhythmias other than cardiac pacing have not been exten-
sively developed and not commonly used. Evidence on the benefits of non-pharmacological procedures for the treatment of arrhythmias is thus limited. In the preparation of the present guidelines, we reviewed the literature providing evidence in Europe and the United States, critically examined the level of evidence, and collected data in Japan to discuss the relevant literature and data at the Joint Working Groups meetings and determine the level of evidence according to the experience and opinions of the members of Joint Working Groups and collaborators. Although the Joint Working Groups reviewed previous and latest American College of Cardiology/American Heart Association (ACC/AHA) guidelines as well as guidelines by the Canadian Diabetes Association as references, we did not provide level of evidence in the present guidelines as in the previous editions since it is difficult to evaluate evidence available in Japan. The following Class of Recommendations are used in the present guidelines, according to the grading system used in ACC/AHA guidelines as well as the four-rank grading proposed by the Canadian Diabetes Association.

1. **Class I**: There is evidence and/or general agreement that a given procedure or treatment is useful and indicated.
2. **Class IIa**: Weight of opinion is in favor of usefulness.
3. **Class IIb**: Usefulness is less well established by opinion.
4. **Class III**: General agreement that the procedure or treatment is not useful or may even be harmful and is not indicated.

### 4. Matters to Be Considered in Determining the Indications for Non-Pharmacotherapy

Non-pharmacotherapy of cardiac arrhythmia is performed to 1) prevent SCD and improve life prognosis (reduce mortality); 2) alleviate symptoms related to arrhythmias and improve well-being (reduce morbidity); and 3) improve satisfaction with social life of the patients. The items 2) and 3) are necessary to improve the quality of life (QOL) of the patients. In other words, non-pharmacological procedures should therefore be evaluated and selected from the medical (biological) and social aspects of each patient. The medical aspects include whether the patient has Adams-Strokes attack (symptoms of cerebral ischemia such as syncope and dizziness with black out), palpitations, chest distress, chest pain, symptoms of heart failure, and hemodynamic instability in association with arrhythmias and whether these symptoms may become fatal. Also, the patient should be evaluated for the presence and severity of underlying heart diseases, cardiac functions, type of arrhythmias (tachyarrhythmia or bradyarrhythmia), and effects of drugs and exercise, and should undergo clinical EPS, signal-averaged electrocardiography (ECG), and T wave alternans measurement and others. The social aspects should be evaluated to understand his or her personality and what makes him/her satisfied and what he/she wants in the workplace, community and home. Physicians should consider the patient’s occupation (e.g., airline pilot, car/train driver, or a worker engaged in potentially hazardous activities such as high place work); younger people; especially desire to continue sports, become pregnant, and/or drive; living place (whether living in a remote place where access to medical services is limited); frequency of recreational travel or business trip (especially overseas business trips facing time differences); and stress during work (whether having a physically and mentally demanding job).

### 5. Requirements for Physicians Providing Non-Pharmacological Procedures of Arrhythmias

Non-pharmacological procedures of arrhythmias are rapidly evolving field and require advanced medical techniques. Procedures listed in the present guidelines must be performed by experienced physicians in suitable medical institutions. Physicians must meet the following requirements:

1. Physicians must have sufficient knowledge and experience in clinical cardiac EPS.
2. Physicians must have sufficient knowledge and experience in treatment with anti-arrhythmic drugs.
3. Physicians must have sufficient knowledge and medical techniques in non-pharmacological procedures for the treatment of arrhythmias such as cardiac pacing, catheter ablation, ICD therapy, CRT/CRT-D therapy and surgeries, and must be able to conduct emergency surgery or other appropriate measures to cope with complications.

#### 1. Implantable-Cardioverter Defibrillator

In the NHI Price List 2010, the following requirements for medical institutions are set for reimbursement of fee for ICD implantation.

1. Medical institutions shall have notified the prefectural government office to provide medical services of cardiology and cardiovascular surgery.
2. Medical institutions shall have performed a minimum of 50 cardiac EPS annually, including a minimum of 5 studies in patients with ventricular tachyarrhythmia.
3. Medical institutions shall have performed a minimum of 30 cases of open heart surgery, coronary bypass surgery or aortocoronary bypass surgery annually and a minimum of 10 cases of pacemaker implantation annually.
4. Medical institutions shall have a minimum of two full-time cardiologists and two full-time cardiovascular surgeons, and at least two of them must have completed required training.

#### 2. Catheter Ablation

In 1990, the Japanese Society of Cardiac Pacing and Electrophysiology (currently named: the Japanese Heart Rhythm Society) proposed the following requirements for medical institutions performing catheter ablation, many of which are still valid.

1. Medical institutions must have physicians with sufficient knowledge and experience in cardiac EPS.
2. Medical institutions must have physicians who have sufficient knowledge and experience in treatment with anti-arrhythmic drugs.
3. Medical institutions must have physicians who have sufficient knowledge and experience in pacemaker therapy.
4. Medical institutions must ensure that during catheter ablation cardiovascular surgeons and medical staffs are ready for emergency surgery whenever required.

Catheter ablation, which is referred to as percutaneous catheter-based ablation of the myocardium in the NHI Price List, is listed as a Category 1 procedure required to be performed in institutions that meet the following standards for those performing procedures listed in the items 5 and 6 of the General Rules of the Chapter 2, Section 10: Surgeries in of the NHI.
Price List in 2010.

1. Medical institutions shall have systems to perform the procedure including those to cope with emergent situations in association with the procedure.
2. Medical institutions shall have physicians required to conduct the procedure.
3. Medical institutions shall indicate the number of cases per year for the relevant procedure at a place easily visible to patients and visitors.
4. Medical institutions shall ensure that all patients are explained about their surgery using appropriate documents.

3. Cardiac Pacing

In the NHI Price List 2010, the following requirement for medical institutions is set for reimbursement of fee for cardiac pacing.

1. Medical institutions shall have a minimum of one physician who has practiced in cardiology or cardiovascular surgery for 5 years or more. Medical institutions categorized into clinics may notify to the relevant governmental office as an institution where the procedure is provided.

Although not mentioned in the above requirement, it is preferable that medical institutions also be able to perform cardiac EPS and outpatient services for pacemaker users as well.

4. Cardiac Resynchronization Therapy

In the NHI Price List 2010, the following requirements for medical institutions are set for reimbursement of fee for CRT.

1. Medical institutions shall have notified the prefectural government office to provide medical services of cardiology and cardiovascular surgery.
2. Medical institutions shall have performed a minimum of 50 cardiac EPS annually, including a minimum of 5 studies in patients with ventricular tachyarrhythmia.
3. Medical institutions shall have performed a minimum of 50 cases of open heart surgery, aortocoronary bypass surgery or coronary bypass surgery annually and a minimum of 10 cases of pacemaker implantation annually.
4. Medical institutions shall have sufficient experience in treating patients with severe heart failure using mechanical cardiac assist systems including external devices.
5. Medical institutions shall have a minimum of two full-time cardiologists and two full-time cardiovascular surgeons, and at least two of them must have completed required training.

In addition to the above requirements, it is necessary to ensure appropriate human resources, equipment, and operating systems with the aim of performing non-pharmacological procedures effectively and safely.

In Japan, the Japanese Heart Rhythm Society has held education/training seminars on catheter ablation, ICD therapy, CRT/CRT-D therapy, and others to provide basic/standard knowledge and up-to-date information. The Japanese Heart Rhythm Society and the Japanese Society of Electrocardiology are cooperatively developing a system to certify specialists in cardiac arrhythmia who can provide appropriate and up-to-date treatment, and will implement the certification system in 2012. Also, the Japanese Heart Rhythm Society has provided “Cardiac Pacemaker Technician Training Seminars” to foster healthcare professionals specialized in cardiac arrhythmia, EPS, pacemaker therapy, ICD/CRT-D therapy, catheter ablation and other advanced techniques, and issued certificates of Cardiac Device Representatives (CDR) who are working in manufactures of cardiac devices such as pacemaker and ICD to provide device information.

6. Informed Consent

When a patient decides whether he/she will receive advanced medical technique treatment such as non-pharmacotherapy of cardiac arrhythmia, he/she must be fully explained the treatment in words which can be understood and express informed consent to treatment of his/her own will. Although information provided should be selected by individual physicians based on their knowledge and experience and may differ among physicians, the following information should be provided, basically: 1) Information about the disease (e.g., type and severity of arrhythmia, and underlying heart disease); 2) Information about the contents of treatment procedures and its effects (in addition to general information, the results in the medical institution should be provided) such as the purpose and contents of treatment procedures (including the model name and manufacturer of the pacemaker, ICD or CRT/CRT-D to be used), the clinical efficacy and success rate; the type, severity and incidence of acute phase complications; the type, severity and frequency of long-term complications, and reasons for selection of the treatment procedure; 3) Information about alternative treatment procedures (pharmacotherapy, other non-pharmacological procedures, and procedures also available in other institutions) and their expected effects (e.g., success rates and complications for the procedures mentioned); 4) Information about consequences when the disease is left untreated without undergoing the treatment procedure (e.g., expected outcomes and likelihood); and 5) Information about the position of the treatment procedure for different types of arrhythmias, the possibility of occurring unexpected short- and long-term complications, and expected advancement of antiarrhythmic treatment in the future. When the patient seeks second opinions by other physicians and medical institutions, the physician must cooperate with the patient.

However, it is not easy to provide the above information to patients undergoing non-pharmacotherapy of cardiac arrhythmia in the clinical setting due to some incompleteness of the current medicine, limited knowledge and experience of the attending physician, or the attending physician’s concern that explanation may lead to confusion. Selection of appropriate and necessary contents to be communicated is an important issue. It is expected that medical institutions will be required to disclose whether the institution meets the relevant requirements and the physicians have been certified by the relevant academic societies as well as the number of cases and the results (success rates and incidence of complications) in the future.

Although the “will of the patient” is the most important factor in determining whether non-pharmacotherapy of cardiac arrhythmia should be performed, physicians should not overestimate the “strong desire” and “unwillingness” of the patient since he/she may have made his/her decision based on biased medical information. Physicians should be committed to be able to clearly explain accurate and up-to-date information to the patients and their family members based on the level of their understanding, and should be aware that informed consent is an only opportunity for the patient to weigh the merits and demerits of the treatment procedure and select a way to experience the “true benefits”.

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## Clinical Cardiac Electrophysiological Study

### 1. Bradyarrhythmia

#### Cardiac Electrophysiological Study for Diagnosis of Bradyarrhythmia

**Class I**
1. Patients with symptoms such as syncope and dizziness in whom a causal relation between bradycardia and the symptoms is unclear.
2. Patients with syncope and dizziness that are suspected to be caused by bradycardia.

**Class IIa**
1. Patients with sinus node dysfunction or atrioventricular (AV) block who are indicated for pacemaker therapy and require evaluation of sinus node function and AV conduction disturbance.
2. Asymptomatic patients with Mobitz type II second degree AV block, third degree AV block, bifascicular block or trifascicular block for whom the site of block must be specified and sinus node function must be evaluated.

**Class IIb**
1. Asymptomatic patients with chronic bifascicular block.

**Class III**
1. Patients with asymptomatic sinus bradycardia, first degree AV block, or Wenckebach second degree AV block.

#### Cardiac Electrophysiological Study to Evaluate the Efficacy of Pharmacotherapy for Bradyarrhythmia

**Class I**
None.

**Class IIa**
1. Evaluation of drug efficacy and proarrhythmic effects of drugs in patients with sustained monomorphic ventricular tachycardia.
2. Patients who need long-term follow-up of catheter ablation for ventricular tachycardia.

**Class IIb**
1. Evaluation of the efficacy in patients with AV nodal reentrant tachycardia or AV reciprocating tachycardia.
2. Evaluation of drug efficacy in patients with sinus nodal reentrant tachycardia, atrial tachycardia or atrial flutter.

The efficacy of drugs is evaluated by their ability in preventing the inducibility of tachycardia during EPS. This style of treatment is referred to as EPS-guided antiarrhythmic therapy. Although it has been reported that EPS-guided or Holter ECG-guided therapy is useful to ensure the efficacy of amiodarone, empiric therapy is still prevalent. In the AVID (Antiarrhythmics Versus Implantable Defibrillators) study, ICD therapy was superior in improving the prognosis as compared to pharmacotherapy for secondary prevention of ventricular tachycardia/fibrillation. Since ICD therapy is now quite common, EPS-guided therapy only plays a supplemental role such as reducing the incidence of recurrence.

#### Cardiac Electrophysiological Study to Confirm the Efficacy of Cardiac Pacing

**Class I**
1. Patients with neurally mediated syncope or hypertrophic obstructive cardiomyopathy in whom temporary pacing is used to confirm the efficacy of cardiac pacing.

**Class IIa**
1. Patients with bradycardic AF in whom temporary pacing is used to evaluate the efficacy of cardiac pacing and decide whether an implantable pacemaker is indicated or not.
2. Patients with heart failure in whom temporary pacing is used to confirm the efficacy of biventricular pacing (i.e., CRT).

### 2. Tachyarrhythmia

#### Cardiac Electrophysiological Study for Diagnosis of Tachyarrhythmia

**Class I**
1. Symptomatic patients with narrow QRS tachycardia.
2. Patients with wide QRS tachycardia.
3. Patients with WPW syndrome who have palpitation attacks associated with syncope and dizziness.
4. Patients with syncope and dizziness that may be caused by tachycardia.

**Class IIa**
1. Patients with palpitation attacks of which the cause is suspected to be tachyarrhythmia but could not confirmed with ECG or other tests.
2. Asymptomatic patients with narrow QRS tachycardia.

EPS is useful for symptomatic patients with narrow QRS (less than 120 msec) tachycardia and asymptomatic and symptomatic patients with wide QRS tachycardia including ventricular tachycardia since reentry may be a cause. Patients possibly requiring catheter ablation often undergo EPS and catheter ablation at the same time.

#### Cardiac Electrophysiological Study to Evaluate the Efficacy of Pharmacotherapy for Tachyarrhythmia

**Class I**
None.

**Class IIa**
1. Evaluation of drug efficacy and proarrhythmic effects of drugs in patients with sustained monomorphic ventricular tachycardia.
2. Patients who need long-term follow-up of catheter ablation for ventricular tachycardia.

**Class IIb**
1. Evaluation of the efficacy in patients with AV nodal reentrant tachycardia or AV reciprocating tachycardia.
2. Evaluation of drug efficacy in patients with sinus nodal reentrant tachycardia, atrial tachycardia or atrial flutter.
Cardiac Electrophysiological Study to Assess the Risk of Patients

Class I
1. Patients resuscitated from cardiac arrest.
2. Patients with nonsustained ventricular tachycardia associated with structural heart disease who have syncopal attacks of unknown etiology and/or left ventricular dysfunction.
3. Patients who have a family history of sudden death or engage in dangerous occupations.

Class IIa
1. Patients with nonsustained ventricular tachycardia or frequent episodes of premature ventricular contractions who have structural heart disease and positive ventricular late potentials on signal-averaged ECG.
2. Patients with Brugada syndrome who have a history of syncope and/or a family history of sudden death.

Class IIb
1. Patients with nonsustained ventricular tachycardia who have structural heart disease without ventricular dysfunction.
2. Patients with frequent episodes of premature ventricular contractions or with nonsustained ventricular tachycardia who show positive ventricular late potentials on signal-averaged ECG but do not have structural heart disease.
3. Patients with long QT syndrome (LQTS) who have a history of or family history of palpitation attacks with syncope and/or dizziness.

The risk of sudden death is assessed by examining whether fatal arrhythmia may be induced or not, but it is not easy to specify high-risk patients. It should be evaluated comprehensively using Holter ECG, exercise stress tests, signal-averaged ECG, and T wave alternans measurement. Risk assessment using EPS should be actively conducted in patients with nonsustained ventricular tachycardia who have structural heart disease and left ventricular dysfunction.

EPS are less useful in risk assessment in patients with LQTS. There is controversy regarding whether electrical induction of ventricular fibrillation should be used or not to assess the risk in patients showing Brugada type ECG. It is believed that EPS are less useful in patients with frequent episodes of premature ventricular contractions without structural heart disease.

III Cardiac Pacing

Since the launch of commercially available implantable pacemakers in the 1960s, the devices have been improved year by year, and smaller sophisticated devices have been launched. With the rapid downsizing, pacemakers have significantly advanced in terms of function. Currently-available devices can mimic physiological heart rates almost completely using AV sequential pacing and rate responsive pacing. Although permanent cardiac pacing has been established as the leading treatment method for bradyarrhythmia that is far more beneficial than other procedures including pharmacotherapy and is being used to improve the life prognosis and QOL, investigators have pointed out ethical and economic problems caused by overuse. In the light of these problems, physicians have called for more strict guidelines for the use of implantable pacemakers. In the United States, the ACC/AHA Task Force published the first guidelines for implantation of cardiac pacemakers and antiarhythmia devices in 1984 which were substantially revised in 1991 and 1998 before publishing the latest revision. In Japan, physicians have considered the use of implantable devices according to the AHA/ACC guidelines, but the Japanese Society of Cardiac Pacing and Electrophysiology (currently named: the Japanese Heart Rhythm Society) published its guidelines for implantation of cardiac pacemakers in 1995.

When cardiac pacing is considered, it is most important to understand the nature and severity of symptoms and a causal relationship between symptoms and bradyarrhythmia. Symptoms of bradyarrhythmia include syncope, black out, severe dizziness, and light-headedness caused by transient cerebral ischemia, and decreased exercise capacity and symptoms of heart failure caused by long-lasting bradycardia. Physicians should also assess their patients for underlying cardiac diseases that may be exacerbated by bradycardia, and cerebrovascular lesions that may lead to cerebral infarction when bradycardia occurs, especially when they need treatment with drugs that may exacerbate bradycardia. Abnormal findings of Holter ECG and cardiac EPS are important as well.

Physicians should also consider the age, occupation (e.g., working in places easily exposed to electromagnetic interference and high places, car drivers), physical activity, family environment, living environment, personality, and patient’s and his/her family members’ desire.

1. Atrioventricular Block

Class I
1. Patients with second degree, high-grade or third degree AV block who exhibit clear symptoms due to bradycardia.
2. Patients with high-grade or third degree AV block who have at least one of the following conditions.
   1) Patients in whom AV block is induced by drug(s) which cannot be discontinued.
   2) Patients who have postoperative AV block that cannot be predicted to improve or not in the future.
   3) Patients who underwent catheter ablation of AV junction.
   4) Patients with AV block associated with progressive neuromuscular disease.
   5) Patients who have substantial bradycardia or long-lasting ventricular arrest during awakening.

Class IIa
1. Asymptomatic patients with persistent third degree AV block.
2. Asymptomatic patients with second degree or high-grade AV block with one of the following conditions.
   1) Patients with a block within or below the bundle of His.
   2) Patients with progressive cardiomegaly in association with bradycardia.
   3) Patients in whom exercise or atropine stress test does not improve or impairs AV conduction.
3. Patients who are symptomatic possibly caused by bradycardia and otherwise unexplained first degree AV block within or below the bundle of His.
1. Patients with symptoms such as syncope, convulsion, black out, dizziness, shortness of breath and easy fatigability, or heart failure that have been confirmed due to bradycardia, sinoatrial block, or sinus arrest associated with sinus node dysfunction or blunted heart rate response during exercise, including patients whose symptoms are caused by long-term treatment with drug(s) which cannot be discontinued.

2. Patients with chronic bifascicular or trifascicular block who have syncopal attacks of unknown etiology.

3. Patients with chronic bifascicular or trifascicular block who have structural heart disease and show conduction delay or block below the bundle of His during EPS.

4. Patients with bradycardia-tachycardia syndrome in whom AV block is likely to be induced by drug(s) which cannot be discontinued.

5. Patients with chronic bifascicular or trifascicular block and Wenckebach second degree AV block in whom occurrence of high-grade AV block is suspected to cause syncopal attacks.

6. Patients with the above-mentioned symptoms as well as bradycardia and/or ventricular arrest, but the relationships between these are unclear.

5. Hypersensitive Carotid Sinus Syndrome and Reflex Syncope

1. Patients with hypersensitive carotid sinus syndrome or reflex syncope who do not show a cardioinhibitory response to head-up tilt testing.

In many clinical studies of reflex syncope (neurally mediated syncope), the indications for and efficacy of cardiac pacing have been evaluated using head-up tilt testing. Although it has been reported that cardiac pacing can prevent syncope in about 50% of patients with a cardioinhibitory response on head-up tilt testing, the corresponding percentage in double blind studies was as low as 17%, and the treatment effect of cardiac pacing is unclear. Also, patients with hypersensitive carotid sinus syndrome with a marked cardioinhibitory response to head-up tilt testing are expected to improve by cardiac pacing. However, physicians should be aware that physical counterpressure maneuvers are the first-line therapy since reflex syncope is mainly caused by a decrease in blood pressure.

6. Hypertrophic Obstructive Cardiomyopathy

1. Patients with hypertrophic obstructive cardiomyopathy who have a significant outflow gradient that causes symptoms negatively affecting QOL and have other reasons justify the use of an implantable pacemaker (including patients with drug-induced bradycardia).

2. Patients with hypertrophic obstructive cardiomyopathy who have a significant outflow gradient that causes symptoms negatively affecting QOL and in whom the severity of symptoms is related to outflow gradient, pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions, and other options are inappropriate.

3. Patients with hypertrophic obstructive cardiomyopathy with neither an outflow gradient nor bradycardia indicated for pacemaker implantation.

It has been reported that cardiac pacing in patients with hypertrophic obstructive cardiomyopathy is effective in alleviating symptoms caused by left ventricular outflow tract obstruction,
and considered that the efficacy correlates with the reduction of outflow gradient. Maron et al. reported that symptomatic improvement perceived after cardiac pacing was most consistent with a substantial placebo effect, and the efficacy of cardiac pacing is not enough among patients other than elderly patients. On the other hand, in the PIC (Pacing in Cardiomyopathy) study, patients who responded favorably to temporary pacing without compromising the outflow gradient had a pacemaker implanted, and showed benefits of permanent pacing. Although patients with hypertrophic obstructive cardiomyopathy have undergone surgeries, and percutaneous transluminal septal myocardial ablation (PTSMA) is listed as a treatment method for this disease by the NHI, pacemaker therapy is safer than these invasive measures, and is expected to be effective when patient selection and implantation are carefully performed. However, pacing for patients with hypertrophic obstructive cardiomyopathy is not covered with the NHI. Patients who may benefit the most are those with a resting gradient of 30 mmHg or more, a provoked gradient of 50 mmHg or more, and considered that the efficacy correlates with the reduction of outflow gradient. Maron et al. reported that symptomatic improvement perceived after cardiac pacing was most consistent with a substantial placebo effect, and the efficacy of cardiac pacing is not enough among patients other than elderly patients. On the other hand, in the PIC (Pacing in Cardiomyopathy) study, patients who responded favorably to temporary pacing without compromising the outflow gradient had a pacemaker implanted, and showed benefits of permanent pacing. Although patients with hypertrophic obstructive cardiomyopathy have undergone surgeries, and percutaneous transluminal septal myocardial ablation (PTSMA) is listed as a treatment method for this disease by the NHI, pacemaker therapy is safer than these invasive measures, and is expected to be effective when patient selection and implantation are carefully performed. However, pacing for patients with hypertrophic obstructive cardiomyopathy is not covered with the NHI. Patients who may benefit the most are those with a resting gradient of 30 mmHg or more, a provoked gradient of 50 mmHg or more, and secondary to antiarrhythmic treatment).

7. Pacing in Children

The most common indications for permanent pacemaker implantation in children are 1) symptomatic sinus bradycardia, 2) bradycardia-tachycardia syndrome, and 3) high-grade or complete AV block. Although the general indications for pacemaker implantation in children are similar to those in adults, there are several important considerations in young patients: 1) Patients with prior congenital heart surgery may have symptoms due to sinus bradycardia or loss of AV synchrony at heart rates, and appropriate heart rates, which differ from those for children with normal cardiovascular physiology, should be set; 2) the clinical significance of bradycardia is age dependent; 3) transvenous lead implantation may be extremely difficult among infants and young children or children with venous anomaly or congenital heart disease, and epicardial pacing lead implantation should be considered; and 4) because there are no randomized clinical studies of cardiac pacing in children or patients with congenital heart disease, the Level of Evidence for most recommendations is C.

Additional details that need to be considered in pacemaker implantation in children include risk of paradoxical embolism due to thrombus formation on an endocardial lead system. Physicians should also select an appropriate lead implantation technique to reserve the transvenous routes for future use.

Indications for Permanent Pacing in Children and Patients With Congenital Heart Disease

Class I
1. High-grade or complete AV block associated with symptomatic bradycardia, ventricular dysfunction, or low cardiac output.
2. Sinus node dysfunction with correlation of symptoms during age-inappropriate bradycardia (the definition of bradycardia varies with the patient’s age and target heart rate).
3. High-grade or complete AV block that persists at least 7 days after cardiac surgery.
4. Congenital complete AV block with a wide QRS escape rhythm, premature ventricular contractions, or ventricular dysfunction.
5. Congenital complete AV block in the infant with a ventricular rate less than 55 bpm or with congenital heart disease and a ventricular rate less than 70 bpm.

Class IIa
1. Patients with congenital heart disease and sinus node dysfunction who have recurrent episodes of intra-atrial reentrant tachycardia (sinus node dysfunction may be intrinsic or secondary to antiarrhythmic treatment).
2. Congenital complete AV block beyond the first year of life with an average heart rate of 50 bpm or less, abrupt pauses in ventricular rate that are 2 or 3 times the basic cycle length, or associated with symptomatic bradycardia.
3. Sinus bradycardia with complex congenital heart disease with a resting heart rate of 40 bpm or less, or abrupt pauses in ventricular rate longer than 3 seconds.
4. Patients with congenital heart disease and impaired hemodynamics due to sinus bradycardia or loss of AV synchrony.
5. Syncope of unknown etiology in the patients with prior congenital heart surgery complicated by transient AV block and residual bundle branch block.

Class IIb
1. Patients with prior congenital heart surgery complicated by transient complete AV block and residual bifascicular block.
2. Congenital complete AV block in asymptomatic children with a rate appropriate to their age, a no QRS prolongation, and normal cardiac function.

Class III
1. Patients with prior congenital heart surgery complicated by asymptomatic transient AV block, and AV conduction returns to normal.
2. Bifascicular block with or without first degree AV block after surgery for congenital heart disease in the absence of prior complete AV block.
3. Asymptomatic Wenckebach second degree AV block.
4. Asymptomatic sinus bradycardia with the longest RR interval less than 3 seconds and a minimum heart rate of 40 bpm or more.

IV Catheter Ablation

1. Wolff-Parkinson-White Syndrome and Atrioventricular Nodal Reentrant Tachycardia

Wolff-Parkinson-White Syndrome
Class I
1. Patients with a history of life-threatening AF or other serious symptoms such as syncope or patients who had tachycardia episodes that were mild but significantly deteriorated QOL.
2. Patients who had tachycardia episodes with or without preexcitation and desire to undergo catheter ablation.
3. Patients who have preexcitation without tachycardia episodes, and are engaged in occupations such as airline pilots and mass transit drivers with a risk of fatal accidents if an
2. Atrial Fibrillation

Class I
1. Patients with drug-resistant symptomatic paroxysmal AF with neither severe left atrial enlargement, severe left ventricular dysfunction, nor severe pulmonary disease who are to undergo catheter ablation in medical institutions performing a minimum of 50 catheter ablation procedures for AF annually.

Class IIa
1. Symptomatic drug-resistant paroxysmal or persistent AF.
2. Patients engaged in occupations such as airline pilots and mass transit drivers in which the presence of AF affect their operations.
3. Patients in whom pharmacotherapy is effective but desire to undergo catheter ablation for AF.

Class IIb
1. Symptomatic drug-resistant paroxysmal or persistent AF with severe left atrial enlargement and/or severe left ventricular dysfunction.
2. Paroxysmal or persistent AF without symptoms or significant deterioration of QOL.

Class III
1. Patients suspected to have left atrial thrombus.
2. Patients contraindicated for anticoagulation therapy.

There are two approaches, rhythm control and rate control, to the treatment of AF. In the AFFIRM (Atrial Fibrillation Follow-up Investigation of Rhythm Management), RACE (Rate Control versus Electrical Cardioversion for Persistent Atrial Fibrillation) and STAF (Strategies of Treatment of Atrial Fibrillation) studies mainly in patients with persistent AF, no differences were found between the two approaches in terms of life prognosis. In the J-RHYTHM (Japanese Rhythm Management Trial for Atrial Fibrillation) study, a clinical study conducted in Japan mainly in patients with paroxysmal AF, there were no significant differences between the two approaches in terms of mortality, incidence of cerebral infarction, and hospitalization rate. However, the prognosis was better in patients maintaining sinus rhythm in a subanalysis of the AFFIRM study, and the results suggest that any beneficial antiarrhythmic effects of antiarrhythmic drugs are offset by their adverse effects. On the other hand, many studies have reported that pulmonary vein isolation ablation is better than pharmacotherapy of arrhythmia in terms of maintaining sinus rhythm. Since many patients with paroxysmal AF have AF triggers originating in the pulmonary veins, bilateral pulmonary vein isolation, an ablation technique to electrically isolate the bilateral pulmonary veins from the left atrium, may prevent the recurrence of AF. Currently, extensive pulmonary vein isolation, a procedure to create an ablation circle around the superior and inferior pulmonary veins on both sides, and pulmonary vein isolation to ablate around the orifice of each of the four pulmonary veins are used. Patients with recurrent AF after the procedure need repeated ablation procedures. The success rate ranges from 45 to 94%, and recent studies have reported that successful treatment was achieved in more than 80%.

In an analysis of the prevalence and causes of fatal outcome in catheter ablation of AF in 45,115 procedures performed from 1995 to 2006, the mortality was 0.98 per 1,000 patients (0.098%). In the present guidelines, catheter ablation for patients symptomatic drug-resistant paroxysmal AF is listed as a Class I indication provided that “this procedure is performed in medical institutions performing a minimum of 50 catheter ablation procedures annually”, since advanced technique, experience and equipment are necessary to ensure the safe and consistent implementation of this procedure. Evidence regarding the usefulness of catheter ablation has been obtained in medical institutions with a large number of procedures, and constant implementation is believed to be related to the efficacy and safety of catheter ablation for AF.

Furthermore, extensive pulmonary vein isolation ablation is better than pharmacotherapy of arrhythmia in terms of maintaining sinus rhythm, and pulmonary vein isolation is associated with a lower rate of recurrence. In another study, pulmonary vein isolation ablation is better than pharmacotherapy of arrhythmia in terms of mortality, incidence of cerebral infarction, and hospitalization rate. However, the prognosis was better in patients maintaining sinus rhythm in a subanalysis of the AFFIRM study, and the results suggest that any beneficial antiarrhythmic effects of antiarrhythmic drugs are offset by their adverse effects. On the other hand, many studies have reported that pulmonary vein isolation ablation is better than pharmacotherapy of arrhythmia in terms of maintaining sinus rhythm. Since many patients with paroxysmal AF have AF triggers originating in the pulmonary veins, bilateral pulmonary vein isolation, an ablation technique to electrically isolate the bilateral pulmonary veins from the left atrium, may prevent the recurrence of AF. Currently, extensive pulmonary vein isolation, a procedure to create an ablation circle around the superior and inferior pulmonary veins on both sides, and pulmonary vein isolation to ablate around the orifice of each of the four pulmonary veins are used. Patients with recurrent AF after the procedure need repeated ablation procedures. The success rate ranges from 45 to 94%, and recent studies have reported that successful treatment was achieved in more than 80%.
underwent additional linear ablation), 87% of patients maintained sinus rhythm 2 years after ablation (72% achieved AF elimination without antiarrhythmic drugs, and 15% needed antiarrhythmic drugs), and 13% had recurrent AF. QOL scores started to improve significantly at month 3, and continued for 2 years.\(^{101}\)

In a retrospective analysis in patients after successful catheter ablation of AF, the incidences of cerebral embolism and massive bleeding during the follow-up period of about 2 years were significantly lower in patients who discontinued anticoagulation therapy 3 to 6 months after ablation than patients who continued anticoagulation therapy.\(^{102}\) Patients with a high risk of thromboembolism should continue anticoagulation therapy after catheter ablation.\(^{103}\)

### 3. Atrial Flutter and Atrial Tachycardia

#### Atrial Flutter (Typical and Atypical Atrial Flutter)

**Class I**

1. Patients with atrial flutter who have tachycardia, syncope, symptoms of heart failure, and deterioration of QOL.
2. Patients with typical atrial flutter that developed during pharmacotherapy of AF.
3. Patients with typical atrial flutter that confirmed before or developed during catheter ablation for AF.

**Class IIa**

1. Patients in whom typical atrial flutter was induced by chance during catheter ablation for other types of tachycardia.
2. Patients with drug-resistant, atypical atrial flutter.
3. Patients engaged in occupations such as airline pilots and mass transit drivers in which the presence of atrial flutter affects their operations.

**Class IIb**

1. Patients in whom atypical atrial flutter was induced by chance during catheter ablation for other types of tachycardia.

Atrial flutter is a type of supraventricular tachycardia characterized by a regular flutter wave morphology with an atrial rate of about 300 bpm (240 to 440 bpm). Atrial flutter is classified into type I and type II: the atrial rate is relatively slow (240 to 340 bpm) in type I and faster (350 to 450 bpm) in type II. Many cases of type I atrial flutter, referred to as “typical atrial flutter”, are macro-reentrant right atrial tachycardia that involves circulation of the reentrant impulse around the tricuspid annulus, and the ECG displays a sawtooth waveform in the inferior leads. Typical atrial flutter is further divided into two subtypes, known as counterclockwise atrial flutter and clockwise atrial flutter based on the flutter wave polarity in the inferior leads (negative and positive, respectively). Atypical atrial flutter (i.e., type II atrial flutter) is caused by a macro-reentrant circuit rotating around an area other than the tricuspid annulus. Its clinical aspects are similar to AF but the mechanisms differ among subtypes.

The severity of symptoms caused by atrial flutter depends on the rate of AV conduction. Although some patients remain asymptomatic, others may develop 1:1 AV conduction and syncope. Typical atrial flutter can be successfully treated with catheter ablation by creating a line of conduction block at the isthmus between the tricuspid annulus and the inferior vena cava.\(^{104,105}\) Since atypical atrial flutter other than right atrial flutter due to lower loop reentry\(^{106}\) is right atrial isthmus-independent, targets of catheter ablation differ among patients. Atypical atrial flutter may be caused by intra-atrial reentry in some cases and abnormal automaticity in others. 3D mapping systems are useful to localize the reentry circuit and the origin of tachycardia, so as to examine thoroughly the pattern of conduction in the fluttering right or left atrium.

#### Atrial Tachycardia

**Class I**

1. Symptomatic patients with drug-resistant recurrent atrial tachycardia with a focal origin.
2. Patients with incessant atrial tachycardia.

**Class IIa**

1. Symptomatic patients with atrial tachycardia with a focal origin that responds to pharmacotherapy.
2. Patients with asymptomatic atrial tachycardia and ventricular dysfunction.

Atrial tachycardia may arise from a focal origin, as in cases of abnormal automaticity (i.e., ectopic automaticity, and triggered activity) and micro-reentry, and from macro-reentry circuits in others. It is difficult to clearly differentiate the latter cases from isthmus-independent atrial flutter.\(^{107-110}\) Atrial tachycardia arising from a focal origin includes sinus node reentry tachycardia, AV nodal reentrant tachycardia, and other types of reentry tachycardia. Abnormal automaticity is commonly observed in the pulmonary vein, superior vena cava, coronary veins, atrial appendage, crista terminalis, and others.\(^{111}\) Catheter ablation is recommended even for asymptomatic patients since long-lasting atrial tachycardia may induce left ventricular dysfunction by causing tachycardia-induced cardiomyopathy.

### 4. Atrioventricular Junction Ablation for Supraventricular Tachyarrhythmia

**Class I**

1. Patients with supraventricular tachyarrhythmia who have serious symptoms or severe ventricular dysfunction due to tachycardia, in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions and for whom conventional catheter ablation for supraventricular arrhythmia was not successful or cannot be performed.

**Class IIa**

1. Patients with supraventricular tachyarrhythmia and substantial deterioration of QOL in whom pharmacotherapy is ineffective or difficult to perform and for whom conventional catheter ablation for supraventricular arrhythmia was not successful or cannot be performed.

**Class III**

1. Patients in whom AV conduction should be maintained considering the risk and benefit of the procedure.

### 5. Premature Ventricular Contraction

**Class I**

1. Patients in whom premature ventricular contraction trigger polymorphic ventricular tachycardia or ventricular fibrillation and in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.
2. Patients with frequent premature ventricular contractions who have a substantial deterioration of QOL or heart failure in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.

3. Patients in whom CRT is not effective due to ineffective biventricular pacing caused by frequent premature ventricular contractions and pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.

Class IIa
1. Patients with frequent premature ventricular contractions originating from the ventricular outflow tract who have ventricular dysfunction or structural heart disease.

2. Patients with frequent premature ventricular contractions originating from the ventricular outflow tract who desire to undergo catheter ablation even though pharmacotherapy is effective or has not been initiated.

Since premature ventricular contraction may trigger polymorphic ventricular tachycardia or ventricular fibrillation, catheter ablation for premature ventricular contraction may prevent occurrence of polymorphic ventricular tachycardia or ventricular fibrillation. Since frequent premature ventricular contractions may also deteriorate cardiac function, catheter ablation may improve ventricular dysfunction. Frequent premature ventricular contractions may cause ineffective biventricular pacing in patients receiving CRT. Treatment of premature ventricular contraction may improve ventricular dysfunction by improving the efficacy of biventricular pacing. Catheter ablation may be considered for patients with frequent premature ventricular contractions originating from the ventricular outflow tract and patients with ventricular dysfunction.

6. Ventricular Tachycardia

Class I
1. Patients with monomorphic ventricular tachycardia associated with ventricular dysfunction or heart failure in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.

2. Patients with frequent ICD discharges and in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.

3. Patients in whom CRT is not effective due to ineffective biventricular pacing caused by monomorphic ventricular tachycardia and pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions.

4. Patients with symptomatic idiopathic ventricular tachycardia and deterioration of QOL who desire to undergo catheter ablation even though pharmacotherapy is effective or has not been initiated.

Class IIa
1. Patients with asymptomatic idiopathic ventricular tachycardia originating from the ventricular outflow tract and an extremely rapid heart rate.

2. Patients with idiopathic ventricular tachycardia originating from the ventricular outflow tract who desire to undergo catheter ablation even though pharmacotherapy is effective or has not been initiated.

Catheter ablation techniques for the treatment of idiopathic ventricular tachycardia have achieved stable results for years. However, catheter ablation of ventricular tachycardia associated with structural heart disease such as myocardial infarction and cardiomyopathy is often not successful, and arrhythmias often recur. When patients receiving ICD therapy have deterioration of QOL due to episodes of tachycardia and frequent ICD discharges, catheter ablation may be an effective treatment option to decrease the frequency of episodes of ventricular tachycardia.

7. Special Considerations for Children

The use of catheter ablation for children should be carefully considered on the basis of the indications for adult patients with arrhythmias as well as specific features in children. In children, catheter ablation is conducted for the treatment of severe conditions such as arrhythmias associated with congenital heart diseases and incessant tachycardia complicated by tachycardia-induced ventricular dysfunction. It is desirable that these patients be treated with physicians who have experience and knowledge in the treatment of congenital heart disease and catheter ablation for children.

Class I
1. Children with WPW syndrome or ventricular tachycardia who have a history of near-miss sudden death or syncope.

2. Children with supraventricular tachycardia or ventricular tachycardia who have ventricular dysfunction due to sustained tachycardia.

3. Children with hemodynamically significant drug-resistant ventricular tachycardia.

Class IIa
1. Children with drug-resistant recurrent or symptomatic supraventricular tachycardia.

2. Children with tachycardia associated with congenital heart diseases (especially in children in whom catheterization would be difficult after surgery).

3. Children with incessant supraventricular tachycardia.


5. Children with palpitation in whom supraventricular tachycardia is induced during cardiac EPS.

6. Children with WPW syndrome who or whose family member desire to undergo catheter ablation after careful consideration of the natural history and complications of the disease.

Class IIb
1. Children with supraventricular tachycardia responding to pharmacotherapy.

2. Catheter ablation of AV junction and pacemaker implantation in children with recurrent or drug-resistant intra-atrial reentrant tachycardia in whom prior catheter ablation was failed (consider referral to a medical institution with a large number of cases).

3. Children with ventricular tachycardia for which pharmacotherapy is effective but abnormal hemodynamics remain.

4. Children with nonsustained ventricular tachycardia or non-sustained supraventricular tachycardia.
The indications for ICD therapy are classified into primary prevention and secondary prevention. Secondary prevention refers to the prevention of SCD in those patients who have survived a previous cardiopulmonary arrest, or ECG-documented sustained ventricular tachycardia, or ventricular fibrillation. Primary prevention refers to the prevention of SCD in patients with nonsustained ventricular tachycardia, patients who have syncope but ECG findings suggesting arrhythmia have not been obtained, or patients with ventricular dysfunction and a high risk of sudden death or arrhythmic death.

1. Implantable Cardioverter-Defibrillator Therapy for Secondary Prevention

Class I
1. Patients with clinically documented ventricular fibrillation.
2. Patients with structural heart disease and sustained ventricular tachycardia and who meet one or more of the following conditions:
   1) Patients with syncope in association with ventricular tachycardia.
   2) Patients with a blood pressure of 80 mmHg or less, symptoms of cerebral ischemia or chest pain in association with tachycardia.
   3) Patients with polymorphic ventricular tachycardia.
   4) Patients with hemodynamically stable nonsustained ventricular tachycardia in whom pharmacotherapy is ineffective or cannot be continued due to adverse drug reactions, or cannot be assessed for drug efficacy, or catheter ablation is ineffective or impossible.

Class IIa
1. Patients with structural heart disease in whom sustained ventricular tachycardia becomes no longer inducible after catheter ablation.
2. Patients with sustained ventricular tachycardia associated with structural heart disease for whom effective pharmacotherapy was established by detailed follow-up and drug efficacy evaluation.

Class IIb
1. Patients who are more likely to develop ventricular tachycardia or ventricular fibrillation triggered by an acute reversible disorder (e.g., acute ischemia, electrolyte abnormality, and drugs) and are at high risk for exposure to the disorder again despite sufficient treatment.

Class III
1. Patients with ventricular fibrillation or ventricular tachycardia caused by conditions that can be successfully treated with catheter or surgical ablation (e.g., AF/atrial flutter with rapid ventricular rate associated with WPW syndrome, and idiopathic sustained ventricular tachycardia).
2. Patients whose life expectancy is less than 12 months.
3. Patients who cannot express consent or cooperate with treatment due to mental disorder or other reasons.
4. Patients with ventricular tachycardia/fibrillation with a known acute reversible disorder (e.g., acute ischemia, electrolyte abnormality, and drugs) in whom ventricular tachycardia/fibrillation is expected to be prevented by eliminating the cause.

5. Patients with frequent ventricular tachycardia/fibrillation that cannot be controlled with antiarrhythmic drugs and/or catheter ablation.
6. Patient with severe drug-resistant congestive heart failure and NYHA Class IV symptoms who are not indicated for heart transplantation, CRT, or left ventricular assist device (LVAD).

Many large-scale studies have been conducted to investigate the effects of ICD therapy and pharmacotherapy in patients with sustained ventricular tachycardia and ventricular fibrillation associated with structural heart diseases, and the results demonstrated that ICD therapy was more effective than pharmacotherapy in improving prognosis regardless of the type of structural heart diseases.36,141,142

1. Sustained Ventricular Tachycardia and Ventricular Fibrillation Associated With Coronary Artery Disease

In large-scale studies mainly conducted in Europe and the United States, 70 to 80% of patients had coronary artery diseases, and results indicated that ICD therapy show a favorable effect in the secondary prevention of fatal arrhythmias in patients with coronary artery diseases.36,141,142,145 The mean left ventricular ejection fraction (LVEF) among patients enrolled in these studies ranged 32 to 45%. It is expected that ICD therapy are especially effective among patients with a LVEF of 35% or less. ICD therapy may not always be indicated for patients with acute coronary syndrome (ACS),145 since sustained ventricular tachycardia and ventricular fibrillation developing in the acute phase of ACS (the first 48 hours after onset) often do not recur after ischemia is treated and the arrhythmic substrate is stabilized.

2. Sustained Ventricular Tachycardia and Ventricular Fibrillation Associated With Nonischemic Dilated Cardiomyopathy

Prospective clinical studies conducted until now have demonstrated that ICD therapy is superior to antiarrhythmic drugs in improving the life prognosis in patients with sustained ventricular tachycardia and ventricular fibrillation associated with nonischemic dilated cardiomyopathy as in the case of patients with coronary artery diseases.36,141,142

2. Primary Prevention in Patients With Structural Heart Disease

Class I
1. Patients with chronic heart failure due to coronary artery disease or dilated cardiomyopathy who have NYHA Class II or III symptoms of heart failure, a LVEF of 35% or less and nonsustained ventricular tachycardia.
2. Patients with NYHA Class I symptoms of heart failure who have left ventricular dysfunction (LVEF of 35% or less) associated with coronary artery disease or dilated cardiomyopathy and nonsustained ventricular tachycardia in whom sustained ventricular tachycardia or ventricular fibrillation induced during EPS.

Class IIa
1. Patients with chronic heart failure associated with coronary artery disease or dilated cardiomyopathy who have NYHA
1. Patients without ventricular dysfunction in whom the presence of causes of fatal arrhythmias such as hypertrophic cardiomyopathy, Brugada syndrome (including drug-induced Brugada syndrome), preexcitation syndrome and short QT syndrome is excluded, and ventricular tachycardia/fibrillation is not induced during EPS.

Since ventricular tachycardia/fibrillation are major and significant causes of syncope, ICD therapy is indicated for patients with syncope suspected to be due to ventricular tachycardia/fibrillation.

Even patients with mild or moderate ventricular dysfunction (LVEF 36 to 50%) due to coronary artery disease or nonischemic dilated cardiomyopathy and NYHA Class I symptoms should be considered at a high risk of sudden death when ventricular tachycardia/fibrillation is induced during EPS, and may be indicated for ICD therapy.150–155

### 4. Implantable Cardioverter-Defibrillator Therapy in Specific Cardiac Diseases

#### 1. Hypertrophic Cardiomyopathy

**Class I**

1. Patients with a history of sustained ventricular tachycardia, ventricular fibrillation or cardiopulmonary arrest.

**Class IIa**

1. Patients who have nonsustained ventricular tachycardia; a family history of sudden death; syncope; a left ventricular wall thickness of 30 mm or more; or abnormal blood pressure response during exercise.

Hypertrophic cardiomyopathy is an important myocardial disease that causes sudden death especially in young patients under 40 years of age, and is often inheritable.154,155 Since patients with a history of sustained ventricular tachycardia or ventricular fibrillation have a recurrence rate of about 10% per year, widespread use of ICD therapy is recommended.156 It has been reported that major risk factors for consideration of primary prevention with ICD therapy include nonsustained ventricular tachycardia; a family history of sudden death; syncope; a left ventricular wall thickness of 30 mm or more; and abnormal blood pressure response during exercise.

#### 2. Arrhythmogenic Right Ventricular Cardiomyopathy/Dysplasia

**Class I**

1. Patients with a history of cardiac arrest, ventricular fibrillation, or hemodynamically unstable sustained ventricular tachycardia.

**Class IIa**

1. Patients diagnosed with arrhythmogenic right ventricular cardiomyopathy/dysplasia who have syncope of unknown etiology.

Arrhythmogenic right ventricular cardiomyopathy/dysplasia is a major underlying heart disease that may cause SCD in young patients.157–161 Factors predicting appropriate ICD discharge include a history of cardiac arrest and hemodynamically unstable sustained ventricular tachycardia.162 Regarding the use of the ICD for primary prevention of SCD, a history of syncope is believed to predict appropriate ICD discharge.163
3. Brugada Syndrome

Class I

1. Patients resuscitated from cardiac arrest.
2. Patients with documentation of spontaneously terminating ventricular fibrillation or polymorphic ventricular tachycardia.

Class IIa

1. Patients who have Brugada type (coved type) ECG (including findings during pharmacological stress testing and ECG findings documented in a first intercostal space) and meet at least two of the following three conditions:
   1) History of syncope.
   2) Family history of sudden death.
   3) Ventricular fibrillation induced during EPS.

Class IIb

1. Patients with Brugada type (coved type) ECG (Including findings during pharmacological stress testing and ECG findings documented in a first intercostal space.) and meet only one of the above three conditions.

It has been reported that the 3-year incidence of arrhythmic events in patients with symptomatic Brugada syndrome is about 30%, while the incidence of sudden death is low in asymptomatic patients. However, ICD therapy is considered even for patients in whom ventricular fibrillation has not been documented, when they have typical ECG findings of Brugada syndrome; a history of syncopal attacks; polymorphic ventricular tachycardia induced during programmed stimulation; or a family history of sudden death.

4. Congenital Long QT Syndrome

Class I

1. Patients with a history of ventricular fibrillation or cardiac arrest.

Class IIa

1. Patients with a history of torsade de pointes or syncope who do not respond to β-blockers.
2. Patients with a family history of sudden death who do not respond to β-blockers.

Class IIb

1. Patients with a history of torsade de pointes or syncope who respond to β-blockers.
2. Patients with a family history of sudden death who respond to β-blockers.

Note: The efficacy of β-blockers should be evaluated according to symptoms and severity of QT prolongation during stress testing. β-blockers are considered ineffective in patients diagnosed with LQTS type 3 (LQT3).

ICD therapy for the treatment of LQTS should be considered in 1) patients with recurrent syncope not responding to β-blockers or other drugs, or patients resuscitated from sudden death; 2) patients whose first manifestation was resuscitated from cardiac arrest; 3) patients with a family history of SCD; and 4) patients with non-adherence to pharmacotherapy or patients meet the criteria for intolerance. However, the ICD is not a curative therapy, and may cause mental disorder due to frequent ICD discharges after implantation. The indication for ICD implantation in children especially should be evaluated carefully.

Left Cervicothoracic Sympathetic Ganglionectomy for Congenital Long QT Syndrome

Class I

None.

Class IIb

1. Patients with frequent ICD discharges after implantation despite of treatment with β-blockers.
2. Patients with syncope associated with torsade de pointes despite of treatment with β-blockers.

Although few patients have undergone left cervicothoracic sympathetic ganglionectomy in Japan, this procedure has been used to treat drug-resistant patients in Europe and the United States, and favorable results have been reported in the treatment of drug-resistant congenital LQTS.

5. Implantable Cardioverter-Defibrillators in Children

Few children have undergone ICD implantation since the prevalence of fatal arrhythmia associated with structural heart disease such as ischemic heart disease is low among children, and the rate of resuscitation is lower in children than adults. Among other reasons. Since the most common causes of SCD in children include cardiomyopathy, congenital heart diseases and arrhythmias, and SCD due to arrhythmia is especially common, children receiving ICD implantation after resuscitation is expected to increase in the future. In fact, successful resuscitation of children has increased in Japan, since automated external defibrillator (AED) become widely available in Japan; public education was provided to emphasize the importance of basic life support (BLS); and the use of AED by emergency medical technicians and bystanders was allowed in 2003 and July 2007, respectively. In the schools, it is highly likely that children can survive without sequelae when teachers and nursing teachers try to resuscitate them using BLS and AED. The results of multicenter clinical studies of ICD therapy in children and patients with congenital heart disease have been published.

The following recommendations were prepared according to the guidelines for the diagnosis and treatment of arrhythmia in children proposed by the Japanese Society of Pediatric Cardiology and Cardiac Surgery and the AACC/AHA/Heart Rhythm Society (HRS) 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities.

1. Indications for ICD Implantation in Children and Patients With Congenital Heart Diseases

ICD implantation in children is quite rare in Japan, and in most cases ICD implantation is conducted for secondary prevention.

Class I

1. Patients resuscitated from cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes.
2. Patients with symptomatic sustained ventricular tachycardia associated with congenital heart disease (catheter ablation or surgical repair may offer possible alternatives in carefully selected patients).

Class IIa

1. Patients with congenital heart disease with recurrent syncope of unknown etiology in the presence of either ventricular dysfunction or inducible ventricular arrhythmias during EPS.
Class III
1. Patients whose life expectancy is less than 12 months.
2. Patients with frequent episodes of ventricular tachycardia/ fibrillation.
3. Patients with severe mental disorders which may exacerbate after ICD implantation or in whom follow-up after ICD implantation is expected to be difficult.
4. Patients with drug-resistant severe heart failure and NYHA Class IV symptoms who are not indicated for heart transplantation, CRT, or LVAD.
5. Patients with syncope of unknown etiology in the absence of both underlying heart disease and inducible ventricular tachycardia during EPS.
6. Patients with ventricular fibrillation/tachycardia who are amenable to catheter or surgical ablation (e.g., WPW syndrome or idiopathic sustained ventricular tachycardia).
7. Patients with tachycardia due to reversible causes (e.g., electrolyte abnormality, drugs) in whom recurrent ventricular tachycardia/fibrillation may be prevented by eliminating the cause.

2. Hypertrophic Cardiomyopathy
A major cause of death among young patients with hypertrophic cardiomyopathy is sudden death. The risk of sudden death is high in patients with nonsustained ventricular tachycardia; those with ventricular tachycardia; those with a left ventricular wall thickness of 30 mm or more; those with increased interventricular septal thickness or left ventricular posterior wall thickness; those with increased QTc dispersion (20 ms or more) or myocardial bridge in the anterior descending branch of left coronary artery confirmed by coronary angiography; those with heart failure; and young children under 3 years of age with heart failure. Indications for ICD therapy in children with hypertrophic cardiomyopathy are similar to those in adult patients.

3. Long QT Syndrome
Among arrhythmias considered as the cause of sudden death of children in the schools, LQTS is the most common cause. Among patients with congenital LQTS diagnosed during the neonatal and infantile periods, the incidence of clinically significant symptoms is highest among those with LQTS type 2 (LQT2) and LQT3. Patients who developed symptoms related to drug-resistant LQTS receive pacemaker therapy or ICD implantation as secondary prevention. For detailed information regarding ICD therapy in children with LQTS, readers should refer to “Guidelines for Diagnosis and Management of Patients with Long QT Syndrome and Brugada Syndrome” (JCS 2007; 2005–2006 Joint Working Groups Report).

4. Adult Patients With Congenital Heart Disease
Tetralogy of Fallot and complete transposition of the great arteries are the most common underlying diseases associated with postoperative sudden death in adult patients with congenital heart diseases. Among patients with tetralogy of Fallot, sudden death has been related to the use of transannular patch; moderate or severe pulmonary regurgitation; a history of ventricular tachycardia; a QRS interval more than equal to 180 msec or more than 120 msec; a LVEF less than 40%; complete AV block lasting for 3 days or more after surgery; and longer duration after the surgery among other factors.

VI Cardiac Resynchronization Therapy and Cardiac Resynchronization Therapy Device That Incorporates Both Pacing and Defibrillation Capabilities
Patients with heart failure may often develop intraventricular conduction disturbance, AV dyssynchrony, intraventricular dyssynchrony, and interventricular dyssynchrony. CRT with biventricular pacing can reduce these dyssynchrony conditions. CRT may prevent the progression of heart failure and improve the prognosis in patients with moderate or severe chronic heart failure who have cardiac contractile dysfunction and cardiac dyssynchrony. However, CRT may not be effective in all patients with heart failure. Important factors predicting the efficacy of CRT include low LVEF and wide QRS complex on the ECG. Many clinical studies have been conducted in patients with a QRS interval of 120 to 150 msec. In the present guidelines, a wide QRS complex is defined as a QRS interval of 120 msec or more. CRT is highly effective in patients with a wide QRS complex of 150 msec or more (see below). Further studies are required to consider the indications of CRT in patients with mild heart failure. Although diagnostic imaging techniques such as echocardiography are expected to detect left ventricular contraction dyssynchrony, no standard criteria have been developed to detect the presence of dyssynchrony and evaluate responses to and effectiveness of CRT.

On the other hand, it is believed that CRT may decrease the total mortality of patients with heart failure but does not affect the incidence of SCD. It has been reported that CRT with ICD backup may further decrease total mortality by preventing SCD. CRT-D is recommended for patients who are indicated for both CRT and ICD (Class I or IIb).

Cardiac Resynchronization Therapy (CRT-P [CRT Device That Provides Pacing But Not Defibrillation Capability])

Class I
1. Patients with NYHA Class III or ambulatory Class IV symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, a QRS interval of 120 msec or more, and sinus rhythm.

Class IIa
1. Patients with NYHA Class III or ambulatory Class IV symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, and who have received or are planned to receive permanent pacemaker implantation, and have depended on or are expected to require frequent ventricular pacing.

Class IIb
1. Patients with NYHA Class II symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, and who are selected to receive permanent pacemaker implantation and are expected to require frequent ventricular pacing.
Class III
1. Asymptomatic patients with low LVEF who are not indicated for pacemaker therapy.
2. Patients whose physical function is limited by chronic conditions other than heart failure, or patients whose life expectancy is less than 12 months.

**Cardiac Resynchronization Therapy Device That Incorporates Both Pacing and Defibrillation Capabilities**

*Class I*
1. Patients with NYHA Class III or ambulatory Class IV symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, a QRS interval of 120msec or more, and sinus rhythm, and who are indicated for ICD therapy.

*Class IIa*
1. Patients with NYHA Class III or ambulatory Class IV symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, a QRS interval of 120msec or more, and AF, and who are indicated for ICD therapy.
2. Patients with NYHA Class II symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 30% or less, a QRS interval of 150msec or more, and sinus rhythm, and who are indicated for ICD therapy.
3. Patients with chronic heart failure NYHA Class III or ambulator Class IV symptoms with optimal pharmacotherapy, a LVEF of 35% or less, and who have received or are planned to receive ICD therapy, and have depended on or are expected to require frequent ventricular pacing.

**Class IIb**
1. Patients with NYHA Class II symptoms of chronic heart failure despite optimal pharmacotherapy, a LVEF of 35% or less, and who are planned to receive ICD therapy and are expected to require frequent ventricular pacing.

**Class III**
1. Asymptomatic patients with low LVEF who are not indicated for ICD therapy.
2. Patients whose physical function is limited by chronic conditions other than heart failure, or patients whose life expectancy is less than 12 months.

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**VII Surgery**

Surgeries for cardiac arrhythmias were developed as curative techniques, and have significantly contributed to the understanding of anatomy and electrophysiology of arrhythmias as well as the advancement of non-pharmacological procedures such as catheter ablation. The first surgical procedure for arrhythmias, ventricular aneurysmectomy developed for patients with ventricular tachycardia, was reported in 1959. Electrophysiological procedures such as surgical interruption of the accessory pathway was then established as a surgical procedure for patients with WPW syndrome, and Cox et al. developed the Maze procedure for patients with AF. As catheter ablation techniques for WPW syndrome become more sophisticated and widespread, the Maze procedure and surgical treatment of ventricular tachycardia become the most common surgical procedures for arrhythmias. The results of long-term follow-up of patients after arrhythmia surgeries should be examined and the development of more curative and minimally invasive surgical procedures are awaited.

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1. **Atrial Fibrillation**

**Indications for Surgical Treatment of Atrial Fibrillation**

*Class I*
1. Patients with AF associated with mitral valve disease who undergo cardiac surgery for the treatment of mitral valve disease.

*Class IIa*
1. Patients with AF who undergo cardiac surgery for the treatment of structural heart disease other than mitral valve disease.
2. Patients with AF who are complicated by left atrial thrombus resistant to thrombolytic and/or anticoagulation therapy, or have a history of embolism caused by left atrial thrombus despite appropriate anticoagulation therapy.
3. Patients with AF in whom catheter ablation failed or AF recurred.

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2. **Other Supraventricular Tachycardia**

**Indications for Surgical Treatment of Other Supraventricular Tachycardia**

*Class I*
1. Patients with typical atrial flutter or intra-atrial reentrant tachycardia who undergo cardiac surgery for the treatment
of structural heart disease.

2. Patients with supraventricular tachycardia that developed after the Fontan-type operation (total cavopulmonary connection, TCPC) with extracardiac conduit or other techniques and in whom catheter ablation is impossible or difficult due to their unique hemodynamics.

3. Patients with drug-resistant supraventricular tachycardia associated with WPW syndrome or other conditions with serious symptoms or a significant deterioration of QOL, and in whom catheter ablation was unsuccessful or tachycardia recurred.

### Class IIa

1. Patients with supraventricular tachycardia that developed after surgery of congenital heart disease who have hemodynamic instability during tachycardia, and in whom catheter ablation was unsuccessful or tachycardia recurred.

Surgical treatment of arrhythmias is indicated in patients who have typical atrial flutter or intra-atrial reentrant tachycardia who need surgical treatment of structural heart disease and patients who have ischemia-dependent atrial flutter or incisional atrial reentry that developed in the long-term period after the operation requiring complex atrial incisions such as the Fontan-type, Mustard and Senning operations during infancy or early childhood. Surgical treatment of arrhythmias is also indicated in patients in whom catheter ablation is impossible or was unsuccessful or tachycardia recurred after catheter ablation.

### 3. Ventricular Tachycardia

#### Indications for Surgical Treatment of Ventricular Tachycardia

**Class I**

1. Patients with sustained monomorphic ventricular tachycardia due to underlying heart disease in whom pharmacotherapy, catheter ablation and ICD therapy are ineffective or cannot be used, and ventricular tachycardia can be induced repeatedly.

2. Patients with idiopathic sustained ventricular tachycardia, severe symptoms and a significant deterioration of QOL, in whom pharmacotherapy is ineffective or cannot be used, in whom catheter ablation was unsuccessful or tachycardia recurred, and in whom repeated catheter ablation is not expected to be successful.

3. Patients with frequent episodes of ventricular tachycardia or frequent ICD discharges that cannot be suppressed by pharmacotherapy and/or catheter ablation.

**Class IIa**

1. Patients with sustained monomorphic ventricular tachycardia associated with myocardial infarction and who have heart failure or thromboembolism due to ventricular aneurysm or left ventricular akinesis.

Surgical treatment of ventricular tachycardia is indicated for patients with ventricular tachycardia associated with underlying heart disease in whom conventional antiarrhythmic treatment is ineffective or cannot be used. Patients with sustained monomorphic ventricular tachycardia should undergo surgery directed by preoperative or intraoperative mapping.

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**Appendix**

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