

Disorders of cardiac rhythm in China

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ABSTRACT The *Annual Report on Cardiovascular Health and Diseases in China* (2022) intricate landscape of cardiovascular health in China. In connection with the previous section, this seventh section of the report offers a comprehensive analysis of disorders of heart rhythm in China. In 2021, China has achieved significant development and gratifying results in many aspects of the field of arrhythmia. Left bundle branch pacing (LBBP), as an emerging pacing technique originating from China, has received widespread attention. New research results have emerged on its indications, surgical procedures, clinical evaluation, and comparison with other pacing techniques. Its feasibility, effectiveness, and safety have been basically verified, but its long-term prognosis still needs further confirmation from larger samples and longer follow-up time research results. Leadless pacemakers have begun to be used in a wider range of clinical applications, and related large sample cohort studies have been reported. In addition, there are also noteworthy new achievements in the fields of pacemaker remote programming, anticoagulation and radiofrequency catheter ablation (RFCA) therapy for atrial fibrillation, and implantable cardioverter defibrillator prevention of sudden cardiac death. In terms of clinical practice, due to COVID-19 pandemic, the number of RFCA procedures and other device implantations in China has fluctuated, but it has gradually recovered since 2020.

Cardiac arrhythmias are usually classified as bradyarrhythmias and tachyarrhythmias. Bradyarrhythmias mainly include sick sinus syndrome and atrioventricular block. Severe bradyarrhythmias require pacemaker implantation. Atrial fibrillation (AF) has become the most common tachyarrhythmia. In recent years, patients with AF usually receive anticoagulant therapy or catheter ablation. Malignant ventricular arrhythmias are likely to result in sudden cardiac death (SCD), which can be treated with implantable cardioverter defibrillator (ICD) or catheter ablation.

BRADYARRHYTHMIA

Pacemaker Implantation

In recent years, great progress has been made in the treatment of bradyarrhythmia in China. According to the data from online registration system of National Health Commission and the data of the provincial quality control centers in China, the number of cardiac pacemaker implantation in 2021 increased by 15.2% compared with the estimates in

2020, with 71 cases per million people (Figure 1). Among them, there were 72,891 cases of dual chamber pacemakers, accounting for 73%, slightly higher than the international level (70%) (Figure 2).

With the increase in the number of pacemaker implantation, related complications are also receiving increasing attention in clinical practice. After a one-year follow-up of 2125 patients with permanent pacemaker implantation, a study found that 34 patients were diagnosed as cardiovascular implantable electrical device (CIED) infection. Elevated body mass index (BMI), receiving anticoagulant therapy, and a hospital stay of ≥ 4 days are risk factors for CIED infection after pacemaker implantation in the early and middle stages.^[1] A study on the clinical characteristics and prognostic factors among 79 cases with CIED infection showed that the non-complicated pocket infection was dominant among the hospitalized patients with CIED infection. Debridement and removal of the generator and leads were still the main treatment measures.^[2] Some studies have also focused on subclinical CIED infection. Among 418 patients who underwent cardiovascular electronic device implantation, 12.0% showed positive bacterial culture in the pocket tis-

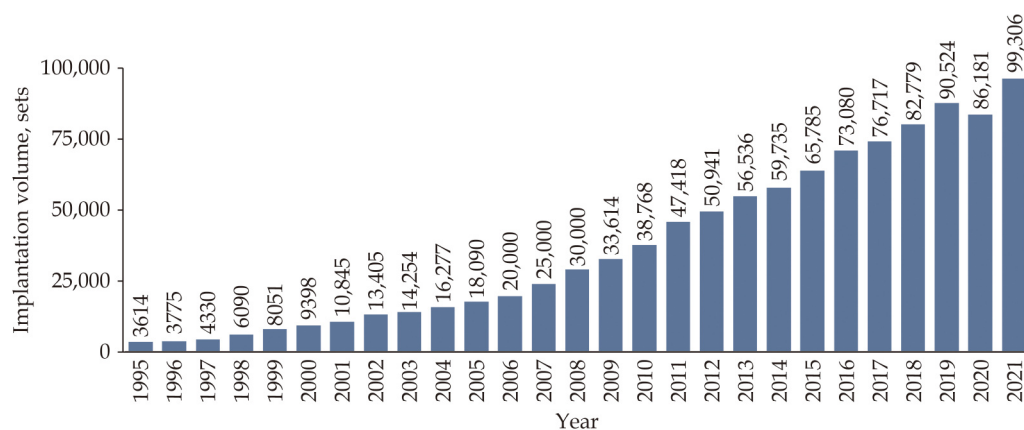


Figure 1 Numbers of annual pacemaker implantation in China (1995–2021).

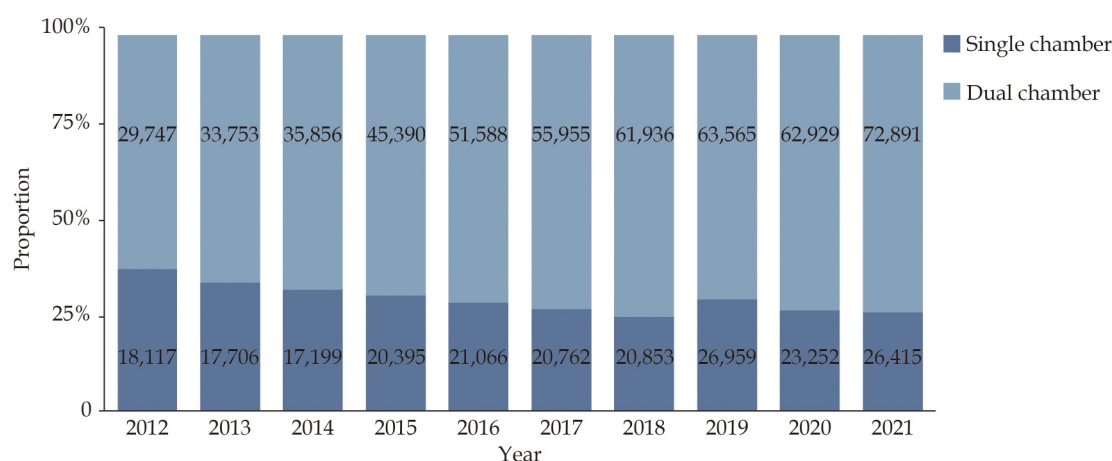


Figure 2 Proportion of single/dual chamber pacemaker implantation in China (2012–2021).

sue, with coagulase negative staphylococcus predominating and associated with a higher risk of readmission.^[3] Analysis and research on venous occlusion related to cardiac pacing leads in China showed that among 106 patients with cardiac pacemaker implantation, 26 cases (24.5%) experienced severe stenosis or occlusion of the subclavian vein and superior vena cava. Renal insufficiency was associated with the occurrence of venous complications,^[4] while antiplatelet drugs (aspirin, clopidogrel) have been found to be potential risk factors for bleeding events.^[5]

Patients undergoing pacemaker implantation need regular follow-up and programming to ensure the safety of pacemaker operation. At present, there are teams in China that have carried out remote real-time programming based on 5G cloud technology support platforms, aiming to provide new technical solution to solve the predicament of routine in-office visits in China.^[6,7]

The results indicate that conducting a 3.0T mag-

netic resonance examination under a standardized process has good feasibility and safety. A study investigated the safety and practical concerns of magnetic resonance imaging (MRI) at 3.0T for patients with MRI compatible pacemakers in China for the first time. The results indicated that 3.0T magnetic resonance examination under a standardized process has good feasibility and safety.^[8]

His-Purkinje System Pacing in China

Clinical research on the feasibility, safety and effectiveness of His-Purkinje system (HPS) pacing, including His bundle pacing (HBP) or left bundle branch pacing (LBBP), in patients with bradyarrhythmia is progressing rapidly in China.

LBBP technology was initially originated in China. More than 70 studies have been published in international cardiovascular journals since 2019, exploring the indications, pacing approach, feasibility, safety, effectiveness, and comparison results with



other pacing technologies of LBBP. Results from clinical studies indicated that LBBP yielded a narrow QRS duration and preserved left ventricular synchrony.^[9] The procedure can be accomplished with a simplified “nine partition method”.^[10] Successful LBBP with a well-defined lead tip location by visualization of the tricuspid valve annulus was reported recently.^[11] Compared with His bundle pacing, multiple meta-analyses have shown that LBBP has similar pacing QRS intervals, but significantly better success rates, shorter procedure and radiographic exposure times, and more satisfactory pacing parameters such as lower pacing thresholds and higher R-wave amplitudes.^[12–15] Compared with traditional RVP, LBBP’s pacing parameters, the incidence of surgical related complications including tricuspid valve regurgitation and clinical outcomes have no significant difference,^[16,17] which can achieve better left ventricular mechanical synchronization, thus significantly reducing the incidence of pacing induced left ventricular dysfunction.^[18] In patients with persistent atrial fibrillation who require high burden of ventricular pacing, LBBP can significantly improve left ventricular ejection fraction (LVEF) and left atrial diameter compared to RVP, suggesting that it may have a role in reversing left atrial remodeling.^[19] Hypertrophic cardiomyopathy (HCM) may pose a substantial challenge to LBBP due to thick interventricular septum and heavy burden of myocardial fibrosis. Pacing modalities should be cautiously considered in this special population.^[20] LBBP was tentatively used in patients after transcatheter aortic valve implantation (TAVI). A study involving 12 patients revealed that LBBP yielded shorter QRS intervals, higher LVEF and lower N-terminal pro-B-type natriuretic peptide (NT-proBNP) values when compared with right ventricular apex pacing (RVAP).^[21] LBBP was regarded as a therapeutic option for these patients.^[22,23]

In summary, compared to other pacing methods, LBBP has its advantages in different aspects, but its long-term prognosis still needs further investigation with larger sample and longer time span studies. At present, two cohort studies of LBBP revealed that the pacing parameters were stable. In addition, domestic researchers also paid attention to the left ventricular septal pacing, and proposed a method to distinguish it from LBBP.^[24,25]

Leadless Pacemaker Implantation in China

Leadless pacemakers can reduce complications related to leads and pockets compared to traditional transvenous pacemakers. The first leadless pacemaker implantation in China was accomplished at the Cardiac Arrhythmia Center of Fuwai Hospital on February 10, 2015. Leadless pacemaker came on the Chinese market in December 2019, and more than 10 medical centers in China have been able to perform this procedure since then. A domestic study reviewed 68 patients with leadless pacemaker implantation, with a success rate of 100% and no instrument related complications or serious adverse events. The main cardiac function indicators improved significantly 3 months after procedure, and the threshold values, impedance parameters were within the ideal range and had a stable trend within one year. However, the perception gradually increased, and the long-term prognosis needs to be further observed.^[26] Some staff in China have attempted to extract an infected pacemaker device followed by the immediate implantation of a leadless pacemaker.^[27] In addition, there were some reports of cases of leadless pacemaker implantation in patients with right atrial enlargement and tricuspid valve stenosis,^[28] biovalve replacement of tricuspid valve for Ebstein malformation,^[29] indicating a broader range of indications of leadless pacemakers.

TACHYARRHYTHMIA

Atrial Fibrillation

Epidemiology

One multistage stratified sampling study in 2020–2021 estimated the prevalence of AF in adults aged ≥ 18 years in China.^[30] A total of 114,039 participants from 22 provincial administrative units in China were included in the final analysis. The overall age-standardized prevalence of AF was 1.6%. It was higher in men (1.7%) than in women (1.4%), higher in rural areas (1.7%) than in urban areas (1.6%), and higher in Central regions (2.5%) than in Western (1.5%) and Eastern regions (1.1%). The associated factors for AF included older age (OR = 1.41, 95% CI: 1.38–1.46; $P < 0.001$), male sex (OR = 1.34, 95% CI: 1.24–1.45; $P < 0.001$), hypertension (OR = 1.22, 95% CI: 1.12–1.33; $P < 0.001$), CAD (OR = 1.44,



95% CI: 1.28–1.62; $P < 0.001$), chronic heart failure (OR = 3.70, 95% CI: 3.22–4.26; $P < 0.001$), valvular heart disease (OR = 2.13, 95% CI: 1.72–2.63; $P < 0.001$), and TIA/stroke (OR = 1.22, 95% CI: 1.04–1.43; $P = 0.013$). Compared with those who had obstructive sleep apnea syndrome (OSAHS) and were without obesity, the risk of persistent AF increased by 2.34-fold in those with OSAHS and obesity. Obesity is significantly associated with the risk of persistent AF. Obesity and OSAHS play an interactive role in the pathogenesis of persistent AF.^[31]

The overall prevalence of stroke in Chinese patients with AF was 24.8%. It was 26.9% in those with rheumatic valvular AF, and 24.2% in those with non-valvular AF. In patients with non-valvular AF, age ≥ 75 years, hypertension, diabetes mellitus and left atrial thrombus were independently associated with stroke.^[32] Left atrial appendage (LAA) morphology is believed to be associated with ischemic stroke, and non-chicken wing LAA morphology increases the risk of thromboembolic events. However, the existing classification of LAA morphology is not accurate, especially when explaining the relationship between LAA morphology and stroke.^[33]

Prevention of thrombosis in atrial fibrillation

Chinese Atrial Fibrillation Registry (CAFR) study analyzed 7977 patients with non-valvular AF in 32 hospitals from 2011 to 2014.^[34] Significant improvements in oral anticoagulation treatment were observed in Chinese patients with AF. The proportions of oral anticoagulant (OAC) use were 36.5%, 28.5%, and 21.4% for patients with CHA2DS2-VASc scores ≥ 2 , 1, and 0, respectively. Rates of OAC use varied widely among different hospitals, from 9.6% to 68.4% in tertiary hospitals and from 4.0% to 28.2% among non-tertiary hospitals. A study on the pre-admission medication history of patients diagnosed with AF at 3 tertiary hospitals showed that only 24.41% of patients diagnosed with AF after admission received anticoagulant therapy that met the guidelines.^[35]

Data from Optimal Thrombophylaxis in the Chinese Elderly patients with Atrial Fibrillation (ChiOTEAF) Registry indicated that in patients with high-risk CHA2DS2-VASc and HAS-BLED, or HAS-BLED ≥ 3 , high fall risk, CKD/liver disease, and age ≥ 85 years, treating with anticoagulation had a lower incidence of composite endpoints (AMI, ischemic stroke, intracranial hemorrhage and all-cause death) than those treating with antiplatelet therapy (all $P < 0.05$).^[36]

The use of novel oral anticoagulants, including direct thrombin inhibitor and direct factor Xa inhibitor, is increasing in China. Based on the results of AUGUSTUS trial and the expert consensus of Chinese Society of Cardiology, it is suggested that apixaban should be used in combination with a P2Y12 receptor antagonist for antithrombotic management of patients with AF and CAD.^[37] However, this has to be further investigated due to short time and limited experience of clinical use.

As for the compliance of antithrombotic treatment, ChiOTEAF study demonstrated that the prevalence of recommended anticoagulation was only 44.7% in senile AF patients.^[36] Education background, place of residence, complications, CHA2DS2-VASc score, and HAS-BLED score were independent influencing factors for novel oral anticoagulant compliance in non-valvular AF patients.^[38]

Left atrial appendage closure (LAAC) is a new method to prevent left atrial thrombosis in patients with AF. This technique was started in China in 2013, and has been popularized rapidly in recent years. Analysis of the database of China AF Center from November 2018 to November 2019 indicated that there was a high success rate and low incidence of severe complications in the use of LAAC in patients with AF. LAAC combined with catheter ablation was safe and effective due to lower complications and higher proportion of sinus rhythm.^[39]

Catheter ablation of atrial fibrillation

Circumferential pulmonary vein isolation is still the main procedure of radiofrequency catheter ablation (RFCA) at present, accounting for 60.2% of the total ablations.^[40] The incidence of procedure-related cerebrovascular complications following AF ablation is 0.4% per procedure for ischemic stroke and 0.1% per procedure for hemorrhagic stroke.^[41] The strategy of empiric superior vena cava isolation plus pulmonary vein isolation as a second procedure for paroxysmal AF improved atrial tachyarrhythmia recurrence-free rate without increasing procedural time or complications.^[42] Catheter ablation vs. pharmacotherapy in the management of persistent and long-standing persistent atrial fibrillation (CAPA study) revealed that in patients with persistent and long-standing persistent AF, RFCA-based treatment was superior to pharmacotherapy in decreasing stroke/TIA and new onset congestive heart fail-



ure. More patients had sinus rhythm in the ablation group than in the pharmacotherapy group, but fewer patients were on antiarrhythmic drugs and anti-coagulant drugs.^[43]

Ventricular Arrhythmia

Non-sustained ventricular tachycardia (NSVT) is a common asymptomatic arrhythmia in clinical practice. Its clinical significance depends on potential heart disease or structural heart disease. Within 48 h of AMI, 45% of patients develop NSVT, but it does not increase the risk of long-term death. The incidence of NSVT ranges from 5% to 10% from 48 hours after myocardial infarction to the first month. Multivariate analysis showed that NSVT doubled the overall mortality and the risk of sudden death. NSVT associated risk is higher in patients with decreased left ventricular function.^[44]

The incidence of NSVT in patients with HCM ranges from 20% to 30%. The annual sudden death rate in HCM patients combined with NSVT is 8% to 10%, while the annual sudden death rate in patients without NSVT is 1%. Obstructive sleep apnea (OSA) is independently associated with NSVT in patients with hypertrophic obstructive cardiomyopathy. NSVT is a risk factor for sudden cardiac death (SCD) and CVD death, and the prevalence of NSVT increases with the severity of OSA.^[45]

The incidence of asymptomatic NSVT in patients with dilated cardiomyopathy (DCM) is as high as 40%–70%. DCM patients with left ventricular dysfunction are likely to develop NSVT and the risk of

SCD is also high. But for DCM patients with compensatory cardiac function, NSVT is detected in only 5% of them and there is no adverse prognosis. Both the incidence of NSVT and the risk of SCD increase with the progressive decline of LVEF.^[44]

Frequent ventricular premature complex (VPC) is a key factor for significant left ventricular dilatation and dysfunction. Right bundle branch block (OR = 143.9, $P < 0.001$) and VPC burden $> 20\%$ (OR = 132.6, $P < 0.001$) are risk factors for left ventricular enlargement. Left ventricular enlargement is reversible after catheter ablation or medication.^[46]

RADIOFREQUENCY CATHETER ABLATION

RFCA has been widely used in more than 600 hospitals in China. According to the data from National Arrhythmia Intervention Quality Control Center, the procedures of RFCA had been increasing rapidly from 2009 to 2021 (Figure 3), with an annual growth rate between 13.2% and 17.5%. Based on the data from Direct Re-reporting System for Interventional Treatment of Arrhythmia in China, the procedures of RFCA in 2021 were 210,609, which increased by 34% in comparison with the estimates in 2019 and reached 154 procedures per million population. According to the data from national AF registry research network platform, the proportion of RFCA for treatment of AF increased annually in China, accounting for 31.9%, 33.0%, 32.2% and 46.4% of the total ablations from 2018 to 2021, respectively (Figure 4).

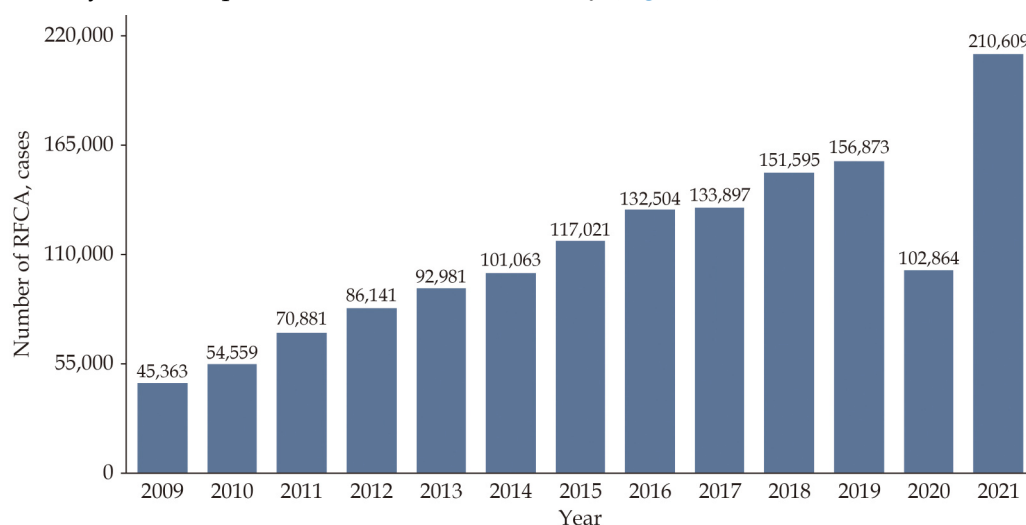


Figure 3 Annual procedures of RFCA in China (2009–2021).

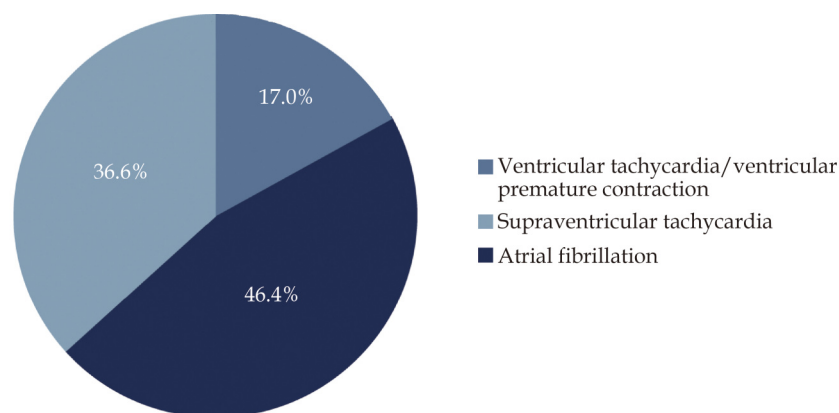


Figure 4 Proportion of diseases treated by RFCA in China, 2021. RFCA: radiofrequency catheter ablation.

SUDDEN CARDIAC DEATH

Incidence

A retrospective study reviewed medical records from 11 regions in Xinjiang with different ethnicities (Han, Uygur, Kazakh and Hui).^[47] Among 3,224,103 residents, there were 1244 events of SCD. The overall incidence of SCD was 38.6 per 100,000 residents. Men had an increased risk of SCD compared with women (age-adjusted standardized risk ratio [SRR] = 1.75, 95% CI: 1.10–2.79). SCD was associated with age. The risk of SCD was highest in residents of the Uygur (SRR = 1.59, 95% CI: 1.05–2.42) and Kazakh (SRR = 1.92, 95% CI: 1.29–2.87) compared with that of the Han. Poor economic development was associated with elevated risk of SCD (SRR = 1.55, 95% CI: 1.02–2.38).

Prevention of Sudden Cardiac Death

Chinese society of cardiology guidelines 2019 for the diagnosis and management of patients with STEMI proposed that the cardiac function and risk of SCD in patients with STEMI should be re-evaluated at 40 days (for those without complete revascularization) or 90 days (for those with revascularization) after MI. Primary prevention for SCD is recommended for patients 40 days after STEMI who have been on the optimal medications but still have clinical HF [New York Heart Association (NYHA) cardiac function grade II–III], LVEF $\leq$ 35% and a life expectancy of more than 1 year, or who have been on the optimal medications but still have mild symptoms of HF (NYHA cardiac function grade I), LVEF $\leq$ 30% and a life expectancy of more than one

year.^[48] A prospective, multi-center trial in China included 2618 primary prevention (PP) patients who were followed for a mean of 20.8 months. The study results revealed that PP patients who received cardiac resynchronization therapy-defibrillator (CRT-D) therapy had a 58% risk reduction in mortality compared with those without implantation. PP patients with an ICD indication had a 43% risk reduction in mortality with an ICD implantation compared with no implantation.^[49]

The term of “1.5 PP” was proposed by Chinese scholars and have been recognized internationally in recent years. Patients with one or more of the following risk factors: syncope or presyncope, LVEF $<$ 25%, NSVT, and frequent premature ventricular contractions (PVC, $\geq$ 10/h) were identified as “1.5 PP” patients. They are at a high risk of SCD and should be prioritized for implantation of ICD. A prospective study indicated that the “1.5 PP” patients with an ICD had a statistically significant 49% adjusted relative risk reduction in all-cause mortality when compared with 1.5 PP patients without an ICD.^[50]

Prevention of Sudden Cardiac Death by ICD

According to the data from Direct Reporting System for Interventional Treatment of Arrhythmia in China, 6547 patients were treated with ICD in 2021, which increased by 36% compared with the estimates in 2020 and reached 4 procedures per million population (Figure 5). The procedures of dual-chamber ICD were 2876, accounting for 44% of the total ICD implantations in 2021 (Figure 6).

A multi-center, prospective study enrolled 798



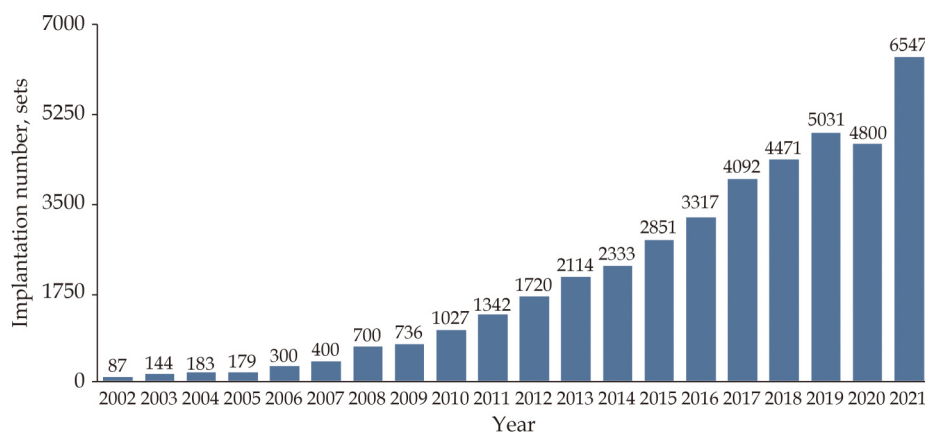


Figure 5 Annual ICD implantation in China (2002–2021). ICD: implantable cardioverter defibrillator.

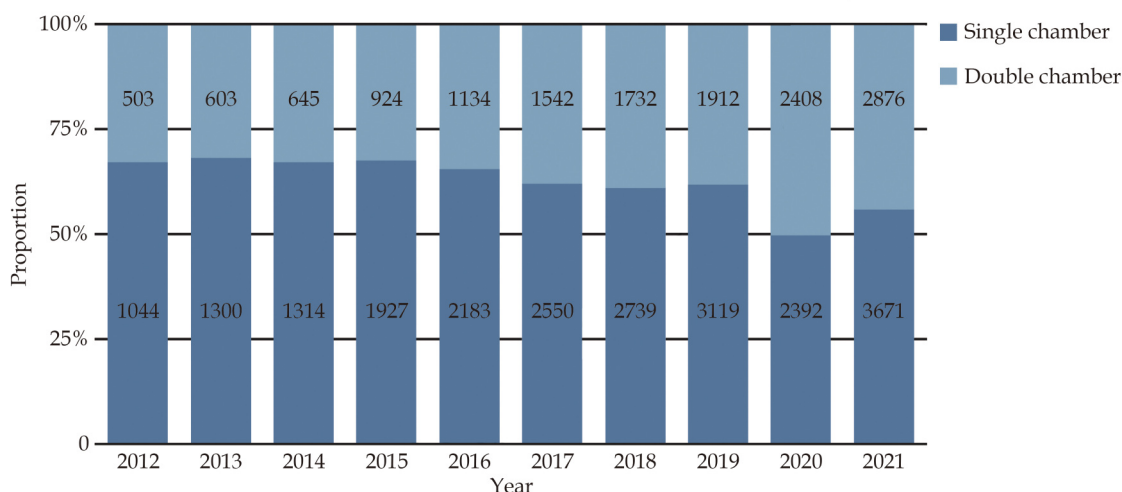


Figure 6 Proportion of single/dual chamber ICD implantation in China (2012–2021). ICD: implantable cardioverter defibrillator.

patients with ICD, CRT-P and CRT-D implantation. The mean follow-up time was 27.7 months. No differences in all-cause death were observed between the CRT-D and CRT-P groups, but the CRT-P group had a much higher SCD rate (8.0%) than the CRT-D group (3.3%) and ICD group (2.0%).^[51]

HEREDITARY ARRHYTHMIA

Long QT syndrome

Mutations in more than 15 genes have been identified to cause long QT syndrome (LQTS). Among 230 patients with a clinical diagnosis of LQTS from 10 hospitals in China, the main subtypes LQT1 (KCNQ1 mutation), LQT2 (KCNH2 mutation) and LQT3 (SCN5A mutation) accounted for 37%, 48% and 2%, respectively.^[52] A total of 59 patients diagnosed

with LQTS (56% males) were included in a retrospective review in Hong Kong, with a mean age of 8.2 years at presentation. Concomitant congenital heart disease was present in 8.5% of these patients. The 1-, 5-, and 10-year breakthrough cardiac event-free rates were 93.0%, 80.7%, and 72.6%, respectively.^[53]

Short QT Syndrome

Short QT syndrome (SQTS) is a rare inherited ion channelopathy in clinical practice. It is likely to trigger AF, ventricular tachyarrhythmia, and SCD. Five pathogenic genes have been reported in patients with SQTS. Study in a Chinese family indicated that among 14 family members, 4 were diagnosed as SQTS and 4 died of SCD at young ages.^[54]

Brugada Syndrome

Brugada syndrome is an acquired or inherited ion



channelopathy characterized by persistent ST-segment elevation in the precordial leads (V1-V3), right bundle branch block, and susceptibility to ventricular arrhythmias and SCD. It is associated with mutations in at least 12 ion channel related genes. A study reviewed the data of 182 patients with Brugada syndrome published in domestic journals from January 1998 to June 2013. Age of Brugada syndrome involved broadly, with a high prevalence in the middle-aged and young adults, with male predominance and syncope as its main clinical manifestation. The positive rates of drug provocation test and electrophysiological examination were high. Therapy status was poor and the rate of ICD implantation was low, and the sudden death rate was high.^[55]

Catecholaminergic Polymorphic Ventricular Tachycardia

Catecholaminergic polymorphic ventricular tachycardia (CPVT) is a ventricular arrhythmia induced by epinephrine with hereditary features. It is characterized by syncope or sudden death. One of the typical clinical manifestations is bidirectional ventricular tachycardia induced by exercise or catecholamine (such as emotional stress or isoproterenol and the like). The pathogenic mutations of CPVT include the most common RYR2 (CPVT1), less common CASQ2 (CPVT2), and others, such as KCNJ2 (CPVT3), TRDN, ANK2 and CALM1. A total of 12 CPVT cases were involved in a study in China. The mean age at the onset of CPVT symptoms was (8.4 ± 3.2) years, and two thirds of the patients were male. Genetic test was performed in 11 cases and RYR2 gene mutation was identified in 9 patients (82%). During the follow-up period of (0.92 ± 0.80) years, 1 patient died suddenly.^[56]

Early Repolarization Syndrome

Early repolarization syndrome (ERS) is characterized by an early repolarization pattern in the inferior and/or lateral leads on the 12-lead ECG. It is associated with an increased risk of sudden cardiac arrest or ventricular tachycardia/ventricular fibrillation. Analysis was performed on the ECG pattern of 1,215 college athletes from competitive sports major. The prevalence of ERS was 35.9%. It was higher in males than in females. The pattern was

mostly present in inferior leads, and the QRS complex was mostly manifested as a notching morphology.^[57]

NEW TECHNOLOGIES IN THE FIELD OF ARRHYTHMIAS

Cardiac contractility modulation (CCM) is primarily used in patients with heart failure and normal QRS interval (< 120 ms) to improve exercise tolerance and quality of life. The first CCM in China was successfully implanted in Fuwai Hospital on December 30, 2014. As of May 2016, a total of 8 CCM had been implanted at 5 centers in China. Results of 6-month follow-up showed that the safety of CCM implantation was reliable. Compared with baseline, the NYHA cardiac function grade, 6-min hall walk test (6MHW), and Minnesota Living with Heart Failure (MLWHF) quality of life scores were significantly improved.^[58]

A subcutaneous implantable cardioverter defibrillator (S-ICD) was successfully implanted in Fuwai Hospital for the first time in China on December 23, 2014. This device is mainly used for the patients with indications of ICD implantation but without appropriate venous access or with high risk of infection. In addition, S-ICD should be considered as an alternative to transvenous ICD for patients with indications of ICD implantation but without the need for cardiac pacing, cardiac resynchronization therapy (CRT), or anti-tachycardia pacing (ATP).

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