

**Report On Organ Transplantation
Development in China
(2015–2018)**

Editorial Committee

Editor-in-chief: Huang Jiefu

Chief reviewer: Zhang Zongjiu

Executive editor: Guo Yanhong, Zhao Hongtao

Deputy editor-in-chief: Ma Xudong, Hu Shengshou,
Zheng Shusen, Shi Bingyi,
Wang Haibo, Chen Jingyu

Editorial board: Chen Junli, Chen Liping, Chen Sipeng
Chen Zhonghua, Du Bing, Hu Chunxiao
Huang Jie, Jin Hailong, Li Xiaoshan
Liu Sheng, Meng Lianguang, Shi Ying
Sun Yu, Xu Xiao, Zhang Tianyu, Zhang Wu
Zheng Zhe, Zhou Zhisheng, Zhou Zhiye



Preface

On December 3, 2014, at the Organ Procurement Organization (OPO) Alliance Conference held in Kunming, Yunan, Huang Jiefu, Director of China National Organ Donation and Transplantation Committee, announced that from January 1, 2015, voluntary organ donation from Chinese citizens would be the only legitimate source for organ transplantation in China. This reform signifies that China's organ transplantation has entered a new development stage that values rule of law, ethics and transparency. It also demonstrated China's commitments as a responsible political power and her resolution for reform.

Organ Transplantation is a great achievement of biomedical sciences in 20th century. Introduced to China from western developed countries, organ transplantation has gone through the stages of clinical trial and clinical application. It gradually becomes well-developed and grows into an effective medical procedure for the treatment of end-stage organ failure, which has not only saved thousands of lives, but also pushed forward the development of China's biomedical science. Because organ transplantation requires a transplantable organ, be it from a living or a deceased donor, this technology always involves profound issues related to the society, religion, ethics, politics, rule of law etc., and is closely related to a country's traditional culture and the development stage of its economy and society. For a long period of time, the source of organ transplantation in China relied mainly on judicial system. This severely hindered the development of our organ transplantation and was also not in line with Chinese people's interests, and therefore was widely criticized by international transplant community.

Reform starts from openness and transparency. At the World Health Organization High-level Meeting on Health for the Western Pacific Region

held in Manila, Philippines in 2005, China admitted to the world that organs from executed prisoners were used as the source of transplantation and made it clear that China would press ahead with reform. As a type of “imported goods”, organ transplantation needs to be developed in accordance with China’s national circumstances. Its development should be based on China’s traditional culture and social development stage and comply with codes of ethics recognized by the international community. On March 16th , 2006, the former Ministry of Health issued the “Interim Provisions on the Administration of Human Organ Transplantation in Clinical Application” (No.94 [2006] of the Ministry of Health), which required all the then transplantation hospitals to receive an accreditation through standardized technical inspection. In the same year, National Summit on the Regulation of Human Organ Transplantation in Clinical Application was held in Guangzhou, during which health professionals in the transplantation field reached a consensus on reform and published the “Guangzhou Declaration”, officially marked the start of regulation medical institutions of organ transplantation. In May, 2007, China’s first “Regulation on Human Organ Transplantation” (hereinafter referred to as Regulation) was officially issued by the State Council, which signified the institutionalization of China’s organ transplantation. In 2007, a “ban on organ transplantation tourism” was stipulated in China. In 2010, the former Ministry of Health launched the pilot program of deceased organ donation. Based on the principle of respecting our country’s social development stage and traditional culture, China entrusted the Red Cross as the third party with the responsibility to promote and witness organ donation in China. In accordance with international standard practice and the reality of public knowledge on organ donation , we creatively set three types of standard for deceased organ donation: Type I (donation after brain death); Type II (donation after cardiac death); and Type III (donation after brain death followed by cardiac death). This laid the theoretical foundation for the voluntary deceased organ donation in China. In 2011, China published Amendment (VIII) to the Criminal Law, which strictly prohibited the trading of organs, and categorized “organ trade” as a criminal offense. This further strengthened the legal framework for organ donation. In 2011, China Organ

Transplant Response System (COTRS) was put into service. The computer system automated allocates organs through national policies which are in compliance with internationally recognized principles for organ procurement and allocation, for example, regional geographic priority , priority based on disease severity, priority based on blood type and histocompatibility match, Priority on children, priority on the immediate family of the donors, priority on rare opportunity, and priority on waiting time, etc. Benefit from this system, we also formed a well-organized team of organ donation coordinators. From 2010 to 2012, the pilot program of voluntary donation after death had been advanced amid all difficulties and hardships. After three years' of hard work, the pilot achieved great success, as we established a well-developed working system, and set up a national organ donation center in the Red Cross. On February 25, 2013, deceased organ donation was officially carried out nationwide by the former Ministry of Health and Red Cross Society of China. All the transplant hospitals were required for the authorization from health administrative departments, which mandate the establishment of Organ Procurement Organization (OPO) and an organ donation office. In August of the same year, National Health and Family Planning Commission published the “Provisions on the Administration of the Human Organ Procurement and Allocation (Interim)”, which mandate that all transplant medical institutions strictly carry out organ allocation through COTRS. To create an open, fair and traceable organ sharing and allocation system, no institutions, organizations or individuals are allowed to allocate organ donations outside of the COTRS. “Hangzhou Resolution” was also published in the same year. On December 19th , 2013, the General Office of the CPC Central Committee and the General Office of the State Council issued “Opinions on Party Members and Cadres Taking the Lead in Promoting Funeral and Interment Reform”, which “encourages party members and cadres to donate their organs or bodies after death”. On December 3, 2014 , China Human Organ Donation and Transplantation Committee officially announced a ban on the use of organs from executed prisoners, which was strongly supported by the public and complimented by the international transplant community. “It takes ten years to grind a sword.” From admitting the use of the

executed prisoners' organs to promoting donation after death, after ten years' of arduous reform, we gradually establish an organ donation and transplantation system covering areas including organ donation, organ procurement and allocation, organ transplantation medical service, organ transplantation registries and organ transplantation regulation. As we promote the spread of love through organ donation, a climate of voluntary donation featuring fairness and transparency is gradually developing across the society.

China's reform is recognized and supported by the international community. Professor José Ramón Núñez, a medical officer in charge of transplantation at World Health Organization (WHO), once said that "China wasn't on the ship of world organ transplantation, and we had no idea where it headed. But after 2015, China has been standing in the center of the ship." It is known to all that due to the unethical source of organ transplantation, The Transplantation Society (TTS) adopted the "Three No" policy against China in 2006, namely no inclusion of China organ transplantation in The Transplantation Society, no permission of Chinese clinical transplantation scholars delivering speeches in transplant meetings, and no publication of Chinese clinical organ transplantation articles in international academic journals. Despite all this, the majority of international scholars still wished the best for China's reform. It is also from 2006 that many international organ transplantation scholars started to come to China to offer help and guidance. Together with Chinese scholars, they published many articles on reform in prestigious transplantation journals in the world. They took part in China's organ transplantation reform, and gradually recognized the progress made by China. As Professor Frank Delmonico mentioned in his speech at the 2017 China International Organ Donation Conference in Guangzhou, "Your bones are our bones, and your achievements are our achievements". China is now gradually integrated into the global community of organ transplantation. In August, 2016, the 26th International Conference of The Transplantation Society was held in Hong Kong, which was the first international transplantation conference held in China, and the first time for TTS to invite a large group of Chinese scholars to attend the conference. At this conference, Professor

Huang Jiefu introduced our ten years' of organ transplantation reform to the world for the first time. In October of the same year, China held the 1st China-International Organ Donation Conference in the Golden Hall of the Great Hall of the People in Beijing, and elaborated on the process of China's organ transplantation reform. Many experts from international transplantation societies also participated in the conference. Together all the attendees witnessed the integration of China's organ transplantation into the global community. In February, 2017, China attended the Pontifical Academy Summit on Organ Trafficking and Transplant Tourism upon invitation. Professor Huang Jiefu detailed the process of China's organ transplantation reform, and shared China's experience in this regard. It was highly recognized by transplantation leaders around the world, and "Chinese experience" in organ donation and transplantation was praised by WHO as "China's innovation and contribution to the world organ transplantation". China's experience also gained recognition and plaudits at a meeting of the Ethics in Action initiative co-hosted by the United Nations and the Pontifical Academy of Sciences in March, 2018. It was referred to as the "Chinese model", which could be used as a reference for other countries with similar social and cultural backgrounds and similar social and economic development stage. In May, 2018, China attended a side session on organ transplantation of the 71st World Health Assembly, at which Professor Huang Jiefu gave a speech about China's organ transplantation reform. Dr Tedros Adhanom Ghebreyesus, Director-General of WHO, highly praised and appreciated China's contribution to the world transplant community. In August of the same year, "WHO Task Force on Donation & Transplantation of Human Organs and Tissues" proposed by China was officially established during the 27th International Congress of The Transplantation Society in Madrid, Spain. Two Chinese scholars became members of the 31-member task force, and continued to contribute Chinese wisdom to the global governance of organ transplantation.

Over the past few years, China has issued laws and regulations and established mechanisms that are conducive to organ donation. For example in 2016, China's six sectors including transportation, aviation and railway jointly

established a green passage mechanism to guarantee the smooth transportation of human organs. In May, 2017, the Law of the People's Republic of China on Red Cross Society was revised to promote organ donation work, and to explore humanitarian assistance mechanisms such as charitable institutions. There has also been a rapid development in the quantity and quality of China's organ donation and transplantation. The annual growth rate of deceased organ donation were between 22% to 47.5% for three consecutive years from 2015 to 2018. The number of recorded after-death donation was 2766 in 2015, 4080 in 2016, 5146 in 2017, and 6302 in 2018, and in addition there were 2200 to 2500 cases of living organ donation among relatives. Therefore, 20201 organ transplant surgeries were performed in 2018, ranking second in the world. The medical quality of China's organ transplantation has also been continuously improved, as the one-year and five-year survival rate are comparable with international level. Many innovative organ transplantation technologies have also emerged. For example, we are the front-runner in liver transplantation technologies, including auto liver transplantation and ischemia-free liver transplantation. We made breakthroughs in the incompatible blood type kidney transplantation and excel in the pediatric liver transplantation in a single center and the clinical service of heart transplantation. We have established the Chinese Lung Transplant Alliance and made huge progress in the organ preservation and donor organ maintenance technologies. Our clinical experience in liver transplantation for patients with hepatocellular carcinoma and hepatitis B has been gradually recognized by the international community. China is heading towards the peak of the world organ transplantation technology.

In March, 2018, National Organ Donation and Transplantation Committee made it clear that the focus of China's organ donation and transplantation work would shift from high-speed growth to high-quality development. We will continue to pursue supply-side structural reform as our main task, and further improve the resource layout of organ transplantation clinical service while encouraging donation. We will strengthen regulation on organ donation, procurement and allocation, and standardize the procedures for brain death

determination. We will also enhance our ability to resolve systematic risks, and achieve effective increase in quantity amid significant improvement in quality so as to pursue a more efficient, fairer and more sustainable development with better quality. We are clearly aware that there is still a huge gap between what our transplant service can provide and what the public need, and the reform is only the first step of this long march. It has only been four years since we prohibited the use of organs from executed prisoners and made the voluntary organ donation from Chinese citizens the only legitimate source for organ transplantation. This process is a painstaking “hard landing”, and we are as strongly determined to carry the reform forward as a courageous man cutting his own wrist off to stop snake venom from diffusing. As a country with 1.4 billion people and imbalanced social and economic development, China needs to keep strengthening its legal system and fighting against crimes such as organ trade throughout the reform. Over the past few years, national health authorities and public security departments have cooperated in law enforcement to crack down on organ trade gangs, revoke the licenses of illegal hospitals and unqualified health professionals, and investigate their criminal responsibility in accordance with law. For example, hospitals and personnel involved in this year’s cross-regional illegal organ procurement in Huaiyuan, Anhui province are being seriously investigated and punished according to law. In order to further meet people’s requirements for the transplant service, we will continue to encourage deceased organ donation, and increase the number of new qualified transplant hospitals in an orderly manner through stronger administrative supervision and stricter qualification verification. At present, there have been 173 qualified transplant hospitals, including transplant centers for heart, liver and kidney, lung, and pancreas and small bowel transplantation. While we are increasing the number of hospitals able to provide transplant service, we are building the team of medical personnel excellent in both professional skills and integrity, to provide high-quality medical service to Chinese people.

At present, a lot of work still needs to be done to strengthen and improve our organ donation and transplantation system. For example,

the China Organ Transplantation Development Foundation is only at its initial stage, and our OPO system still needs to be improved. Also, the development and training system for organ transplantation has just been launched. The coordinator teams still need to be regulated and expanded. In addition, China Organ Transplant Response System (COTRS) still needs further improvement and strengthening, and there have to be transformation in social traditions before people can change their original beliefs about life and death. Civil administration, transportation, education, public security, justice department and many other government authorities need to strengthen their coordination to promote a more law-based organ transplantation system. Therefore, we need to revise the Regulation, turning them into an upgraded new Regulation which clearly defines the power and responsibility of all sides, so as to provide more authoritative, more comprehensive and more sufficient legal support for the regulation and adjustment of all parties involved in organ transplantation, thus promoting the healthy development of the whole sector.

At present, there are still hostile forces around the world spreading rumors and distorting the reality of China's rise. They keep smearing and dismissing China's progress. "A strong tree is hardly possible to be shaken by ants." We are convinced that hostile attacks can never hinder our advancement in organ transplantation. Nevertheless, "It takes a good blacksmith to make good steel." In October, 2019, the fourth plenary session of the 19th CPC Central Committee made it clear that we need to stick to and improve socialism with Chinese characteristics, and promote the modernization of China's governance system and governance capacity. We will actively respond to the call of the Party to further modernize the organ transplantation reform. We need to strengthen institution building, system building and capacity building, rise to the challenges with courage and resolution, and keep improving ourselves, so as to safeguard the hard-earned fruits of reform. We will make unremitting efforts to build a well-developed donation and transplantation system that conforms to ethical standards and WHO guidelines, and strive to reach the scientific and technological peak

of transplantation-related disciplines. We will actively conduct international cooperation on organ donation and transplantation under the Belt and Road Initiative, and present ourselves as a responsible political power in the global community, contributing our due share to the building of “a community with shared future for mankind”.

This report is written to record the achievements of China’s organ transplantation development at the new historical stage, and to share with the world what we have learned and gained from the organ transplantation reform. This year’s report is a summary of China’s organ transplantation development from 2015 to 2018. From 2019, the report will be written annually and be published officially in both Chinese and English. Your valuable comments and suggestions will be very much appreciated.

Editorial Committee
November, 2019



Table of Contents

Chapter I Organ Allocation and Sharing in China.....	1
I. Distribution of medical institutions for organ donation and transplantation.....	3
II. Organ donation	5
III. Patients waiting for organ transplantation	8
IV. Utilization of organs	10
V. Summary and prospects	11
Chapter II Liver Transplantation in China	13
I. Distribution of medical institutions for liver transplantation	13
II. Data of liver transplant recipients	16
III. Quality and safety analysis of liver transplantation	17
IV. Summary and prospects	21
Chapter III Kidney Transplantation in China	24
I. Distribution of medical institutions for kidney transplantation	24
II. Data of kidney transplant recipients	30
III. Quality and safety analysis of kidney transplantation	31
IV. Summary and prospects	33
Chapter IV Heart Transplantation in China	36
I. Distribution of medical institutions for heart transplantation	36
II. Data of heart donors and transplant recipients	38
III. Quality and safety analysis of heart transplantation	41
IV. Summary and prospects	44

Chapter V Lung Transplantation in China	46
I. Distribution of medical institutions for lung transplantation.....	46
II. Data of lung donors and transplant recipients	48
III. Quality and safety analysis of lung transplantation	51
IV. Summary and prospects	54

Chapter I Organ Allocation and Sharing in China

This chapter was generated based on the data of the China Organ Transplant Response System (COTRS). The data scope of statistics was from Mainland China, data of Hongkong, Macao and Taiwan was not included.

From January 1st, 2015 to December 31st, 2018, there were 18,294 donors of deceased donation (DD) in total.

In 2018, 6,302 DD donors recorded, and 20,201 patients received organ transplantation in China. The rate of donation rose from 2.01 pmp (donors per million population) in 2015 to 4.53 pmp in 2018.

China organ donation and transplant scheme (Figure 1-1) is consists of the organ donation system, organ procurement and allocation system, organ transplant service system, quality control system, regulatory system, to achieve an open, fair and transparent organ allocation.

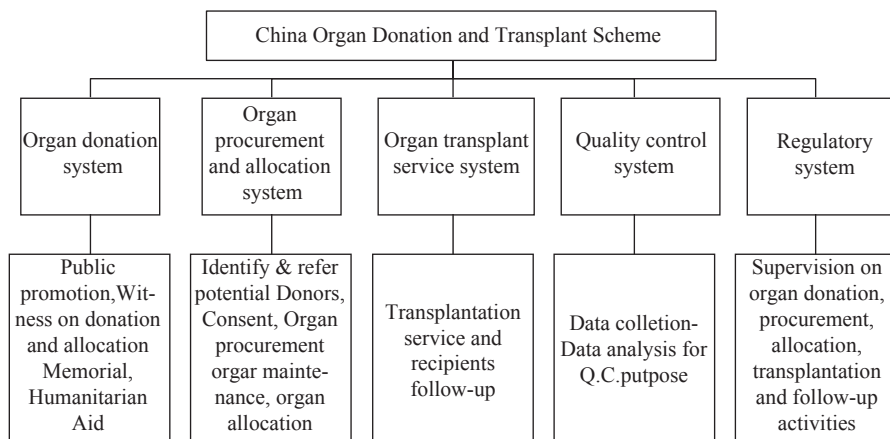


Figure 1-1 China organ donation and transplant scheme (Hongkong, Macao and Taiwan not included)

COTRS (Figure 1-2), an essential part of China’s organ donation and transplant system, is not only a significant embodiment and concrete implementation of Article 6 and Article 22 of the “Regulations on Human Organ Transplantation”, and the Amendment VIII to the “Criminal Law” of the People’s Republic of China, but also a highly specialized critical system for implementing the laws and regulations as well as scientific policies on organ allocation and sharing in China.



Figure 1-2 China organ transplant response system

In 2018, the National Health Commission issued the “Notice on Issuing the Basic Principles and Core Policies for China Organ Allocation and Sharing” (GWYF [2018] No. 24) revising the “Notice of the Ministry of Health on Issuing the Basic Principles for China Organ Allocation and Sharing and the Core Policies for Liver and Kidney Transplantation” (WYGF [2010] No. 113); developed the core policies for heart and lung allocation and sharing; and formulated the “Basic Principles and Core Policies for China Organ Allocation and Sharing”. COTRS was upgraded per the new core policies, and its Version 2.0 was officially launched on October 22, 2018.

COTRS implements the national scientific organ allocation policy by automatically allocating and sharing organs and providing full monitoring

for national and local regulators so as to establish the traceability of organ procurement and allocation, minimize human intervention and ensure a just, fair, and open allocation of organs. Moreover, it functions as an essential cornerstone for winning people's trust in the work of DD.

COTRS, certified by the China Information Technology Security Evaluation Center, guarantees the information security of donors and recipients during the organ allocation and protects patient privacy by controlling the access and monitoring the operations of relevant medical institutions. It consists of three subsystems, i.e., Potential Organ Donor Identification & referral System, Organ Donor Registry and Organ Matching System, Organ Transplant Waiting List System, with a supervision platform.

I. Distribution of medical institutions for organ donation and transplantation

1. Distribution of OPO in China

In China's organ donation and transplant system, the OPO, set up in a medical institution, is composed of medical personnel, organ donation coordinators and administrative staff. From an administrative perspective, China's OPO is not an independent legal entity, which is different from that of the United States and Spain's Organization National De Transplantz (ONT).

By December 31st, 2018, China had 122 OPO (Figure 1-3).

2. Distribution of transplant centers in China

By December 31st, 2018, there were 169 medical institutions qualified for organ transplantation in China (Figure 1-4), and the top five province were Guangdong (19), Beijing (16), Shandong (13), Shanghai (11), Hunan (9) and Zhejiang (9).

Report On Organ Transplantation Development in China (2015–2018)

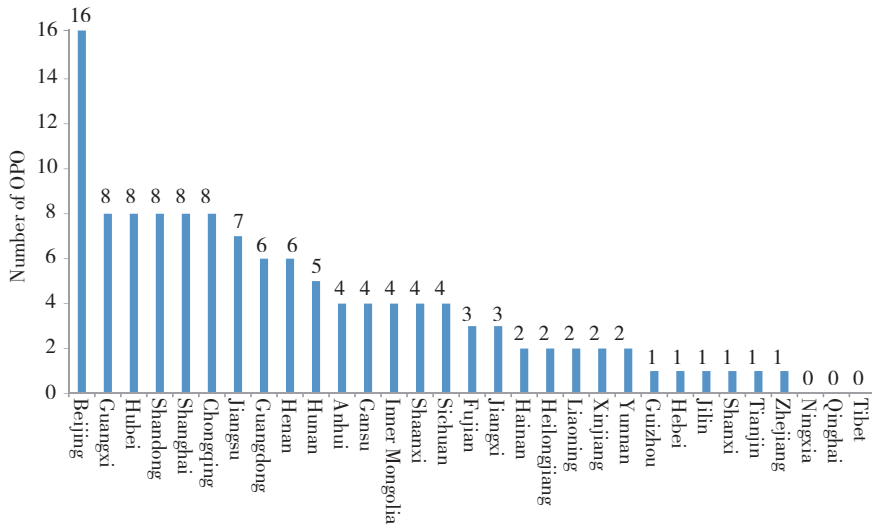


Figure 1-3 Distribution of OPO by province of China in 2018
(Data of Hongkong, Macao and Taiwan not included)

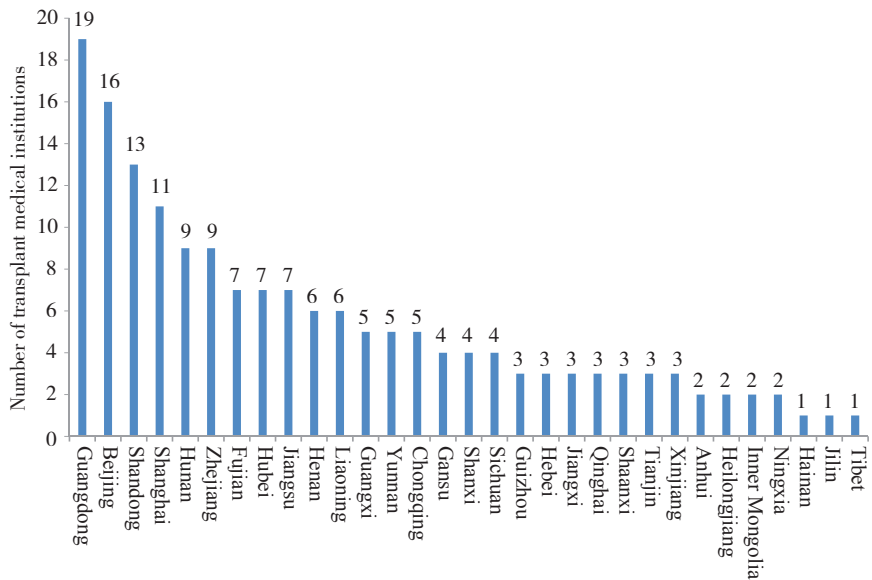


Figure 1-4 Distribution of transplant medical institutions in 2018 in China
(Data of Hongkong, Macao and Taiwan not included)

II. Organ donation

1. Organ donation in China

During 2015–2018, the number of DD was 2,766; 4,080; 5,146; and 6,302, and the PMP was 2.01, 2.98, 3.72, and 4.53 (Figure 1-5).

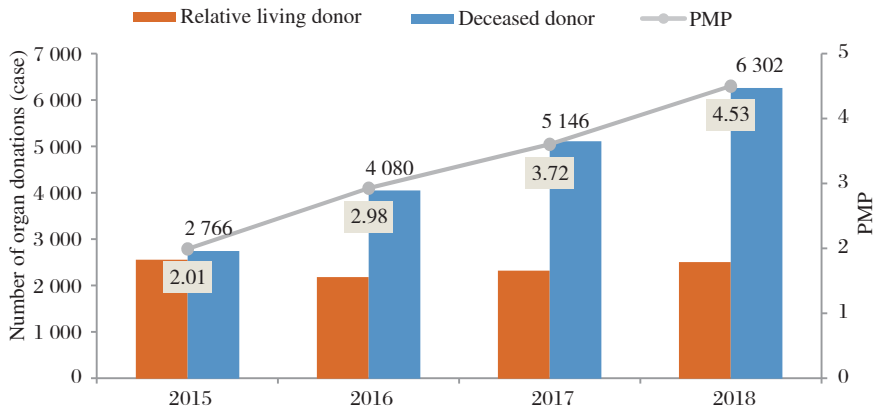


Figure 1-5 Number of DD in 2015–2018 in China
(Data of Hongkong, Macao and Taiwan not included)

During 2015–2018, the top five provinces of China based on the number of organ donations were (Figure 1-6) Guangdong (2,400), Shandong (1,933), Hubei (1,873), Hunan (1,697), and Beijing (1,601).

In 2018, the number of organ donations in China increased by 22.46% comparing with that in 2017; it increased in 21 of 31 provinces, and it increased by more than 100% in Guizhou, Hainan, and Jiangxi. The PMP exceeded the national level in nine provinces, and the top five provinces (Figure 1-7) were Beijing (29.16), Tianjin (18.88), Hubei (10.08), Guangxi (7.88), and Hunan (7.77).

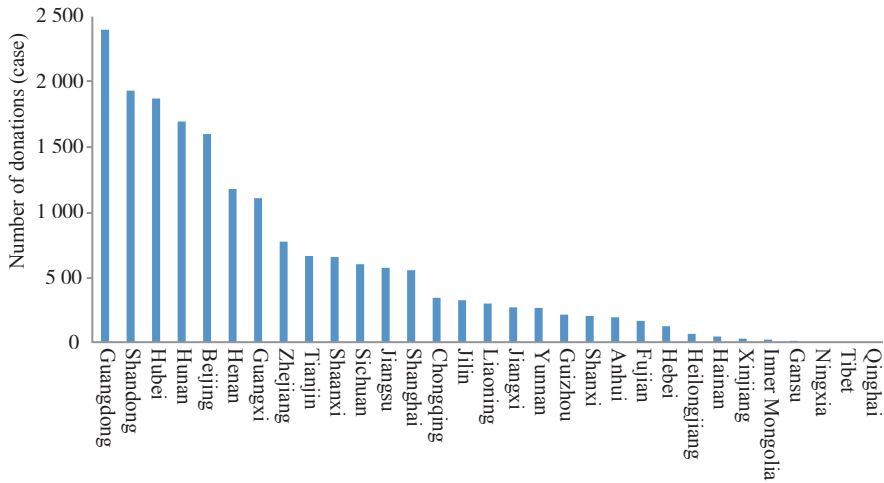


Figure 1-6 Number of DD in each province during 2015–2018
(Data of Hongkong, Macao and Taiwan not included)

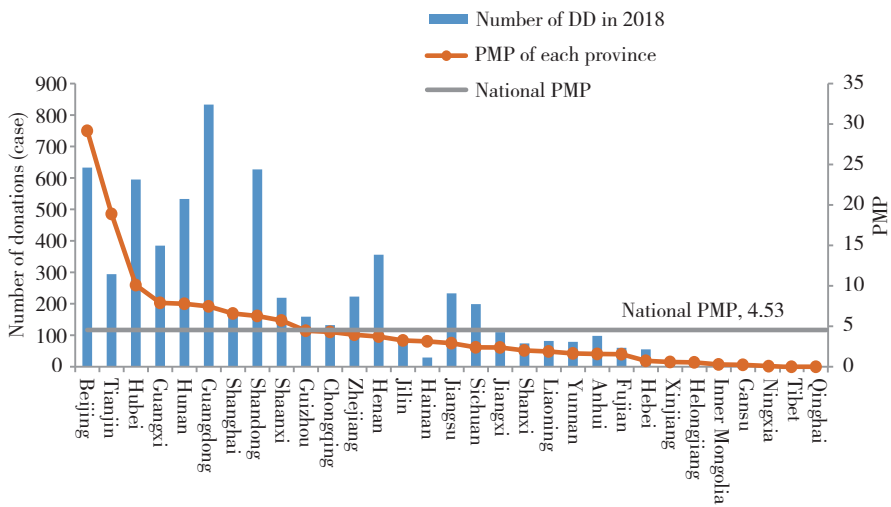


Figure 1-7 Number of DD and the PMP by province in 2018
(Data of Hongkong, Macao and Taiwan not included)

During 2015–2018 in China, 3 OPOs performed more than 600 DDs, 11 OPOs performed 300-600 DDs, 13 OPOs performed 200-299 DDs.

In 2018 in China, 4 OPOs performed more than 200 DDs, 12 OPOs were between 100-200 DDs and 22 OPOs were between 50-90 DDs.

2. Characteristics of DD donors

During 2015–2018, the median age of the donors was 44, and child donors (under the age of 18) accounted for 11.40%. 81.03% of the donors were males. Per the blood type, 37.38% of the donors were blood Type O, 28.25% were blood Type A, 26.73% were blood Type B, and 7.64% were blood Type AB (Figure 1-8). Notably, 23% of the donations were C-I (donation after brain death, DBD), 42% were C-II (donation after cardiac death, DCD), and 35% were C-III (donation after brain death followed by cardiac death, DBCD) (Figure 1-9).

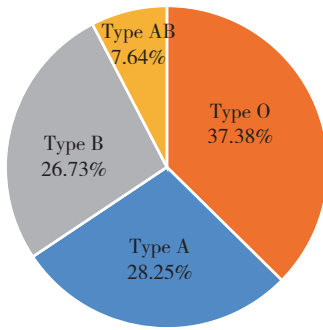


Figure 1-8 Blood type of DD donors (Data of Hongkong, Macao and Taiwan not included)

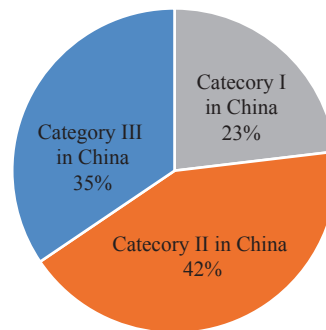


Figure 1-9 Category of DD donors (Data of Hongkong, Macao and Taiwan not included)

During 2015–2018, trauma and cerebrovascular accident were the two principal causes of DD donors' death (Figure 1-10), accounting for 86.57% of all deaths. The proportion of donors with cerebrovascular accident increased by year (Figure 1-11).

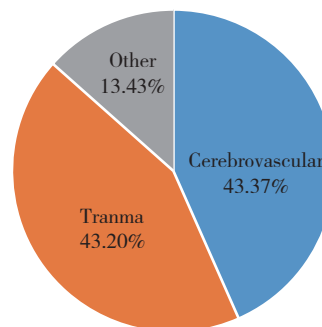


Figure 1-10 Causes of DD donor's death (Data of Hongkong, Macao and Taiwan not included)

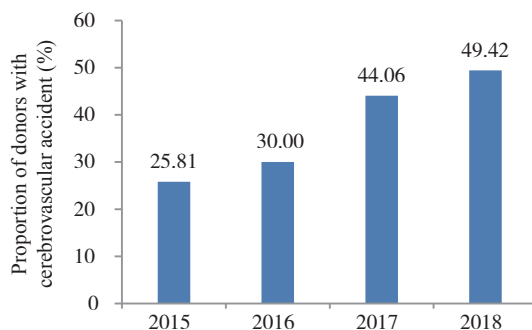


Figure 1-11 Proportion of donors with cerebro-vascular accident in 2015–2018 (Data of Hongkong, Macao and Taiwan not included)

III. Patients waiting for organ transplantation

During 2015–2018, the number of patients waiting for liver and kidney transplantations (Figure 1-12) increased by year. By the end of 2018, there were 34,567 patients awaiting kidney and 3,841 patients awaiting liver.

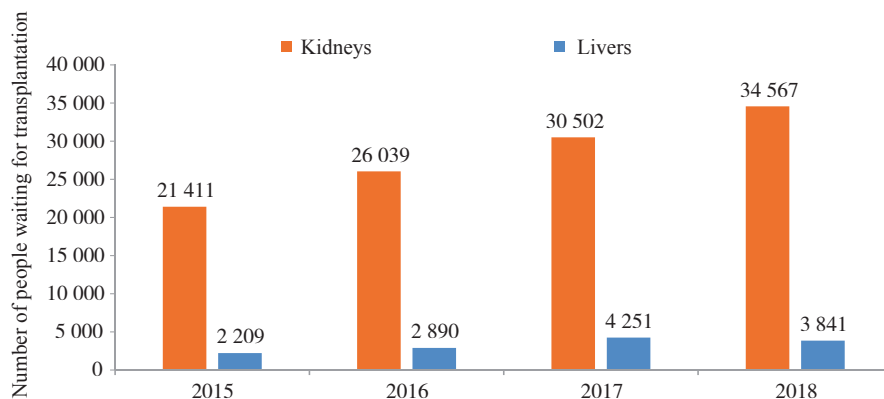


Figure 1-12 Number of patients awaiting liver and kidney transplantations in 2015–2018 (Data of Hongkong, Macao and Taiwan not included)

Note: The heart and lung transplants were not included, as their allocation system was not launched until October 22, 2018.

By the end of 2018, the top five provinces based on the number of patients waiting for kidney transplantation (Figure 1-13) were Guangdong (4,698),

Zhejiang (4,052), Hunan (3,725), Hubei (2,928), and Shanghai (2,872).

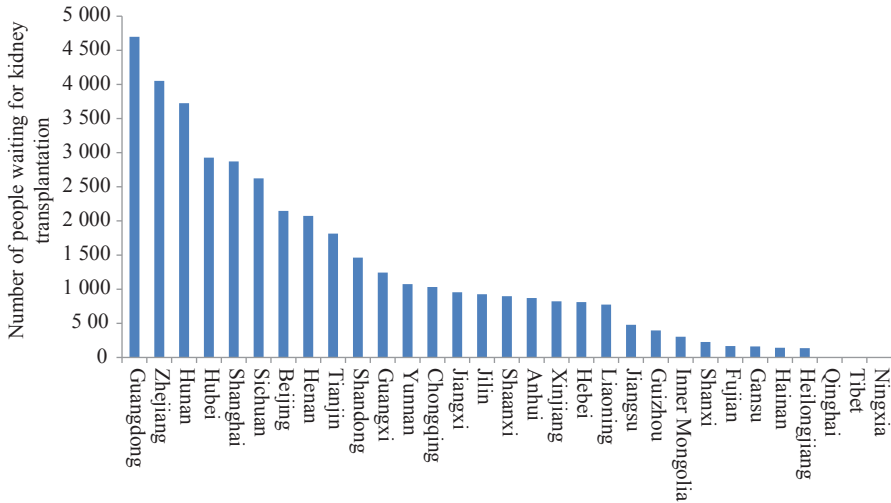


Figure 1-13 Number of people awaiting kidney transplantation by the end of 2018 by province (Data of Hongkong, Macao and Taiwan not included)

By the end of 2018, the top five provinces based on the number of patients waiting for liver transplantation (Figure 1-14) were Sichuan (987), Tianjin (687), Guangdong (687), Shanghai (343), and Beijing (325).

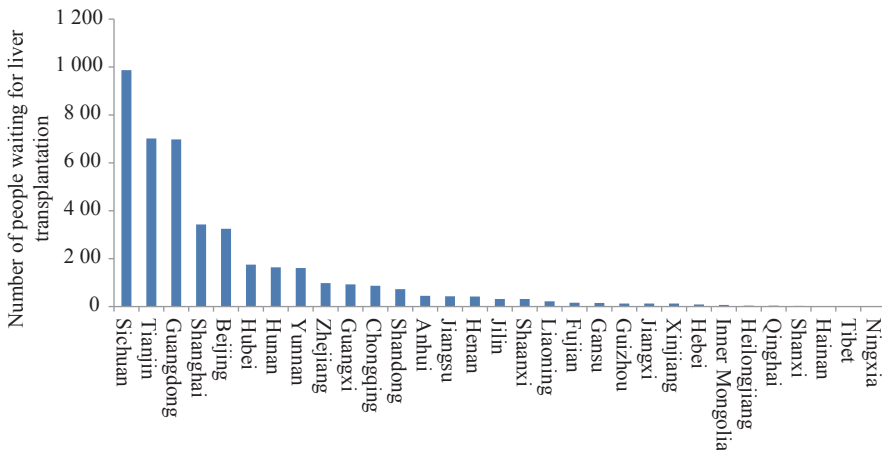


Figure 1-14 Number of people awaiting liver transplantation by province by the end of 2018 (Data of Hongkong, Macao and Taiwan not included)

IV. Utilization of organs

1. The yield of donated organs per donor

During 2015–2018, the yield of donated kidney organs per donor by year was 1.92, 1.87, 1.89, and 1.91, and that of liver was 0.88, 0.87, 0.90, and 0.91 (Figure 1-15).

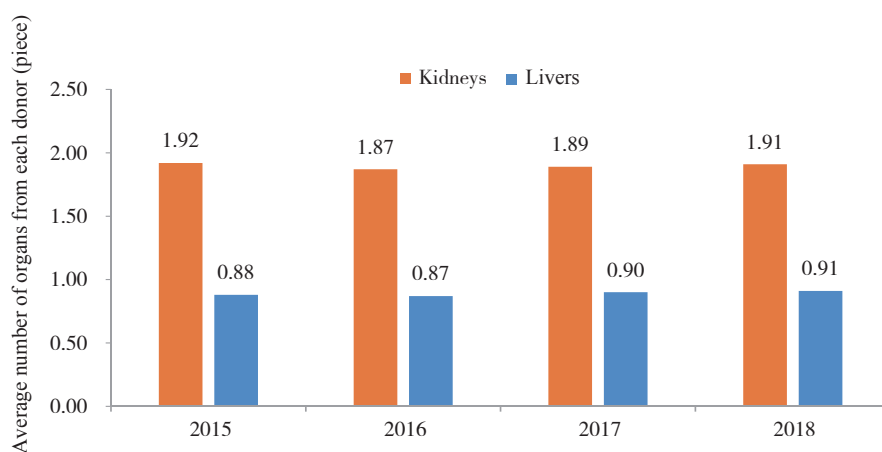


Figure 1-15 The yield of donated organs per donor in 2015–2018
(Data of Hongkong, Macao and Taiwan not included)

2. Comparison of organ sharing before and after the implementation of the green channel policy

On May 6th, 2016, the then National Health and Family Planning Commission, the Ministry of Public Security, the Ministry of Transportation, the Civil Aviation Administration of China, China Railway, and the Red Cross Society of China jointly issued the “Notice on Establishing a Green channel for organ Transportation” (here in after referred to as the “Notice”) to establish a green channel for donated organ transportation. In the “Notice”, responsibilities of all parties were specified, aiming to ensure smooth transportation of organs and minimize the impact of organ transportation time on the quality and safety of organ transplant patients.

In the “Notice”, organ transportation was divided into general and emergency processes based on the transportation type to achieve a fast track and priority transportation of organs, to improve the efficiency and guarantee the safety of the transportation, and to reduce the organ wastage owing to transportation.

Comparison of organ sharing in China before and after the implementation of the green channel policy for organ transportation reveals that after the implementation of the policy, the sharing of livers and kidneys (Table 1-1) in China has increased by 7.3%, of which the sharing of kidneys increased by 6.5%, and the sharing of livers increased by 8.4%.

Table 1-1 Sharing of livers and kidneys in China before and after the implementation of the Green Channel Policy (Data of Hongkong, Macao and Taiwan not included)

Period	Overall (%)			Kidney (%)			Liver (%)		
	Before	After	Change	Before	After	Change	Before	After	Change
For center level use	75.0	68.1	-6.9	84.6	78.1	-6.5	53.2	46.2	-7.0
Shared within the province	12.6	12.2	-0.4	10.5	10.5	0	17.3	15.9	-1.4
national sharing	12.4	19.7	7.3	4.9	11.4	6.5	29.5	37.9	8.4

V. Summary and prospects

Organ transplantation is a significant achievement in the development of human medicine, and it has saved the lives of countless patients with end-stage diseases. In 2018, China ranked second worldwide, both in the number of DD and in the number of transplantation.

1. Improving the utilization of donated organs

China has a large population and a large number of patients. Organ shortage is still one of the main factors in the development of organ transplantation. With the shortage of donated organs, it is necessary to improve the maintenance of donated organs, expand the supply of organs, improve the utilization of heart and lung for transplantations, and increase the overall

utilization of organs.

In addition, publicity and education on organ donation should be strengthened to raise public awareness.

2. Strengthening the role of green channel to reduce organ wastage during transportation

With the increase of organ donation in China, more and more organs are being matched and shared. The green channel policy for organ transportation helps to achieve a fast track and priority transportation of organs, to improve the efficiency and guarantee the safety of transportation, and to reduce the organ wastage owing to transportation.

3. Strengthening the supervision to promote the quality and capacity of organ transplantation

In recent years, organ donation and transplantation have been significantly improved in China, both in quantity and quality. With the improved medical and health conditions and people's higher expectations of health, there should be more supporting policies and measures, as well as stringent supervision for organ donation and transplantation in China, to improve the quality and capacity of organ transplantation in China.

Chapter II Liver Transplantation in China

This chapter mainly analyzes the cases collected by the China Liver Transplant Registry (CLTR). These data are from Mainland China, excluding those from Hongkong, Macao and Taiwan. The statistics are obtained from the DD liver transplantations and the living-related donor liver transplantations performed during 2015–2018, including the distribution of medical institutions for liver transplantation, demographic characteristics of recipients, safety quality analysis, and annual trend.

CLTR is China's official liver transplant registry system established under the supervision of the National Health Commission, and it requires the medical institutions qualified to perform liver transplantation to report regarding the transplantation timely and entirely. CLTR describes the medical quality status of liver transplantation through the dynamic and scientific analysis of liver transplantation in Mainland China, provides a basis for national regulatory authorities to formulate relevant transplantation policies and regulations, and provides scientific management tools of liver transplant recipients to all transplant centers. Moreover, it has become one of the most significant information systems in organ transplantation and one of the academic exchange platforms for liver transplantation in China.

I. Distribution of medical institutions for liver transplantation

By December 31, 2018, there were 92 medical institutions qualified for liver transplantation in China, and they were mainly distributed in Beijing (11), Shandong (8), Shanghai (8), and Guangdong (8) (Figure 2-1).

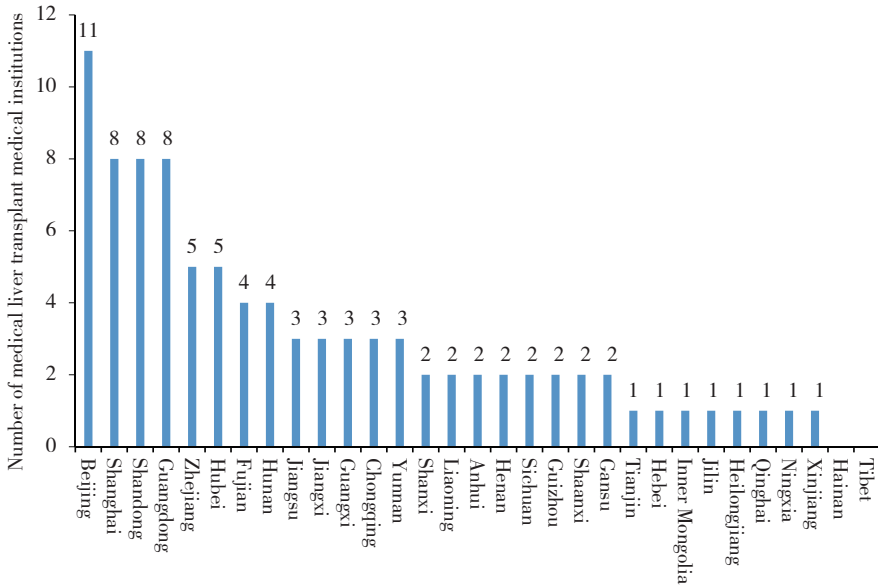


Figure 2-1 Distribution of medical institutions qualified for liver transplantation in China by the end of 2018 (excluding Hongkong, Macao and Taiwan)

From January 1, 2015 to December 31, 2018, liver transplantation was performed on 17,724 cases in China, including 15,302 (86.3%) cases of DD liver transplantation and 2,422 (13.7%) cases of living-related donor liver transplantation (Figure 2-2). The number of Pediatric liver transplantations

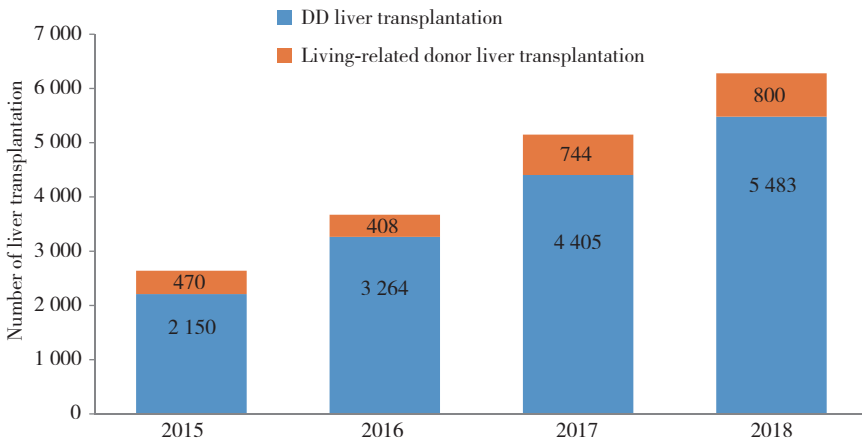


Figure 2-2 Number of liver transplantation in China during 2015–2018 (excluding Hongkong, Macao and Taiwan)

increased from 529 in 2015 to 1055 in 2018 (Figure 2-3). The top five provinces based on the number of liver transplantation in 2018 were Shanghai (1,515), Beijing (848), Guangdong (626), Zhejiang (511), and Hunan (303) (Figure 2-4).

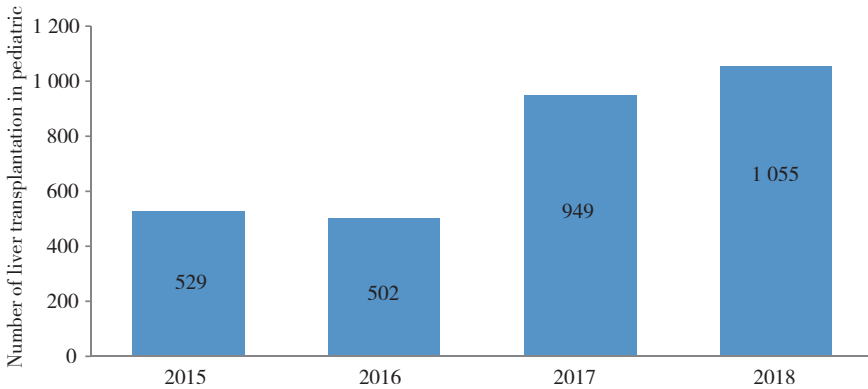


Figure 2-3 Number of liver transplantation in pediatric in 2015–2018 (excluding Hongkong, Macao and Taiwan)

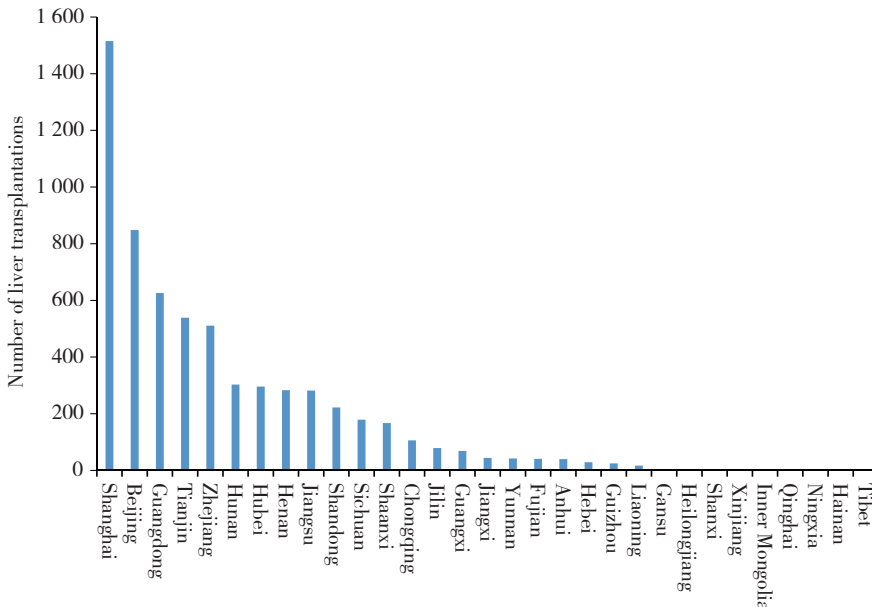


Figure 2-4 Distribution of liver transplantation in different provinces of China in 2018 (excluding Hongkong, Macao and Taiwan)

II. Data of liver transplant recipients

In China, most of the liver transplant recipients are males and ages mainly range from 35 to 65. (Table 2-1).

Table 2-1 Demographic characteristics of Chinese liver transplant recipients during 2015–2018 (excluding Hongkong, Macao and Taiwan)

Variable	Mean±SD	Proportion (%)
Sex		
Male		76.1
Female		23.9
Age (years)		
	42.3±20.0	
< 18		16.2
18–35		7.2
35–50		32.7
50–65		38.6
≥65		5.4
Blood type		
O		30.4
A		31.0
B		28.6
AB		10.0
Body Mass Index (BMI) (kg/m²)		
	22.1±4.4	
< 18.5		18.4
18.5~24.0		48.6
24.0~30.0		30.0
≥30		3.0

III. Quality and safety analysis of liver transplantation

1. Variation trend of important clinical indexes of liver transplantation

During 2015–2018, an apparent decline (from Figure 2-5 to Figure 2-16) was noted in the mean cold ischemia time, mean warm ischemia time, mean anhepatic phase, mean operative time of liver transplantation, the mean blood loss, and mean volume of transfused red blood cells (RBC) during the operation. This observation indicates that the transportation efficiency and liver transplantation technique have improved each year steadily in China.

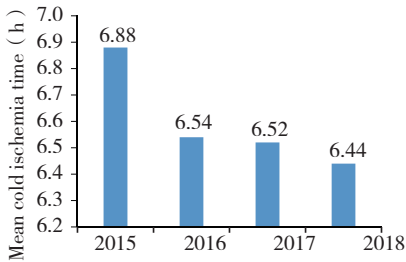


Figure 2-5 Mean cold ischemia time of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

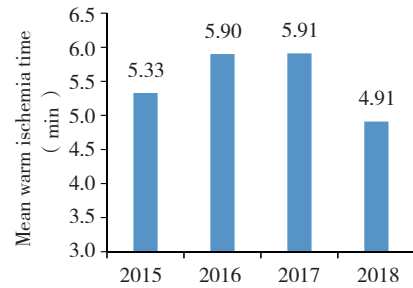


Figure 2-6 Mean warm ischemia time of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

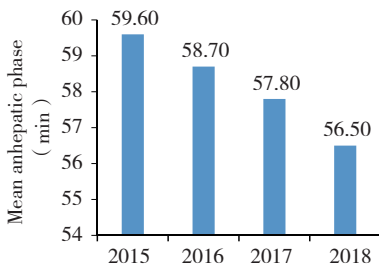


Figure 2-7 Mean anhepatic phase of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

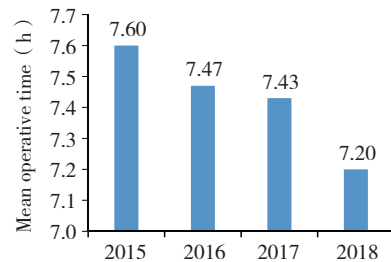


Figure 2-8 Mean operative time of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

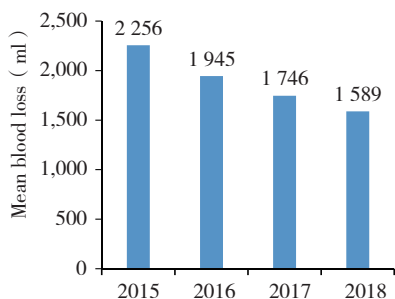


Figure 2-9 Mean blood loss during the operation of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

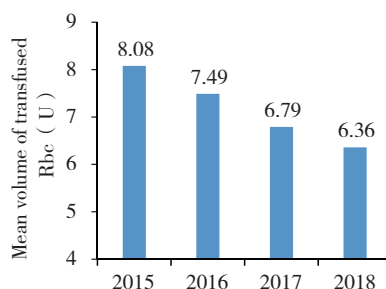


Figure 2-10 Mean volume of transfused RBC during the operation of DD liver transplantation (excluding Hongkong, Macao and Taiwan)

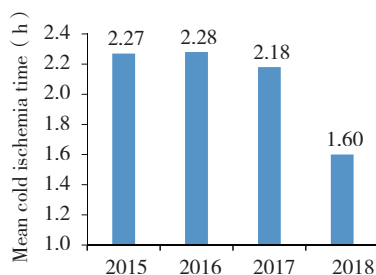


Figure 2-11 Mean cold ischemia time of living-related donor liver transplantation (excluding Hongkong, Macao and Taiwan)

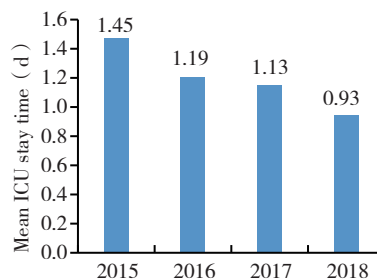


Figure 2-12 Mean ICU stay time of living donor after operation (excluding Hongkong, Macao and Taiwan)

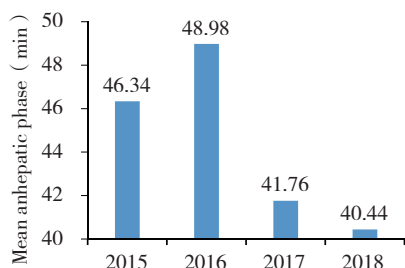


Figure 2-13 Mean anhepatic phase of living-related donor liver transplantation (excluding Hongkong, Macao and Taiwan)

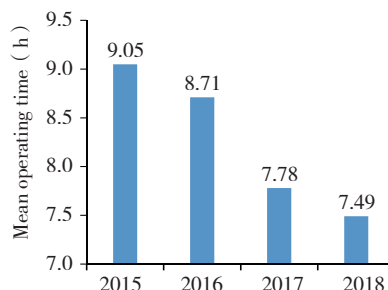


Figure 2-14 Mean operating time of living-related donor liver transplantation (excluding Hongkong, Macao and Taiwan)

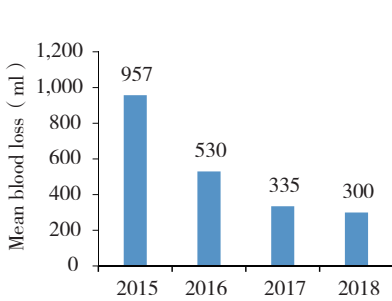


Figure 2-15 Mean blood loss during the operation of living-related donor liver transplantation (excluding Hongkong, Macao and Taiwan)

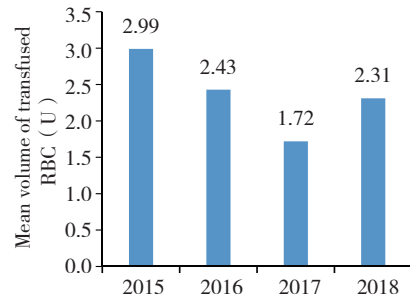


Figure 2-16 Mean volume of transfused RBC during the operation of living-related donor liver transplantation (excluding Hongkong, Macao and Taiwan)

2. Outcomes of liver transplant recipient after liver transplantation

2.1. Complications within 30 days after transplant

The incidence of complications within 30 days after transplant of DD liver transplantation is 38.1%, including pleural effusion (22.7%), postoperative infection (15.1%), and intra-abdominal effusion or abscess (13.8%). The incidence of complications within 30 days after transplant of living-related donor liver transplantation is 19.3%, including postoperative infection (9.7%), intra-abdominal effusion or abscess (7.2%) and pleural effusion (6.4%).

2.2. Mortality within 30 days after transplant

The mortality of liver transplant recipients within 30 days after transplant has declined each year (Figure 2-17), which indicates the improvement of the liver transplantation technique and post-transplantation management in China.

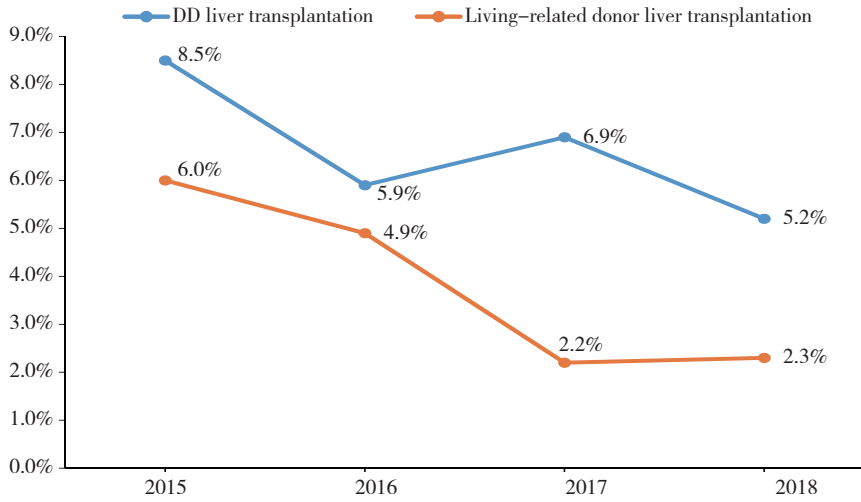


Figure 2-17 Mortality of liver transplant recipients within 30 days after transplant

2.3. Survival of recipients after liver transplantation

In China, during 2015–2018, the 1-year and 3-year survival rates of DD liver transplant recipients after transplant were 83.0% and 73.5%, respectively. The 1-year and 3-year survival rates of living-related donor liver transplant recipients after transplant were 92.5% and 89.8%, respectively.

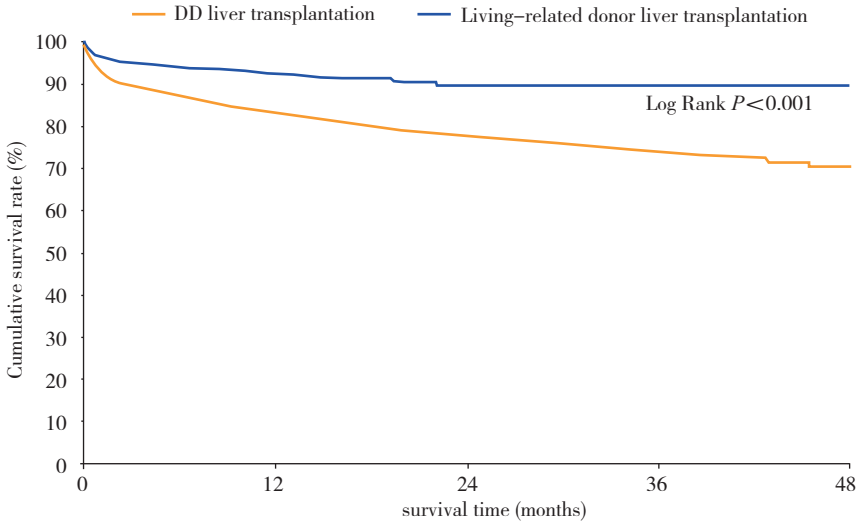


Figure 2-18 Survival curve of recipients after liver transplantation during 2015–2018 in China

2.4. Disease-free survival of recipients after liver transplantation for hepatocellular carcinoma (HCC)

During 2015–2018, the 1-year and 3-year disease-free survival rates of recipients after liver transplantation for HCC were 76.7% and 59.4%, respectively in China (Figure 2-19).

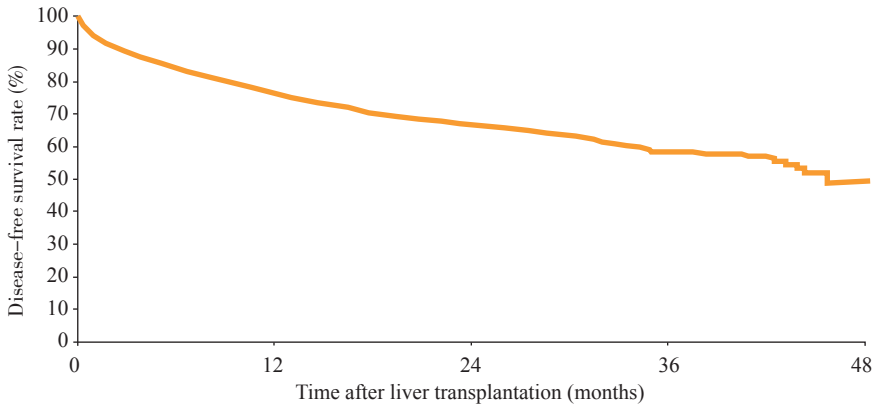


Figure 2-19 Disease-free survival curve of recipients after liver transplantation for HCC during 2015–2018 in China

IV. Summary and prospects

1. Characteristics and innovations of liver transplantation in China

In recent years, liver transplantation in China has steadily improved in quantity and quality. In 2018, there were more than 6,000 cases of liver transplantation in China, with an increase of nearly 140% compared to 2015. The characteristics of liver transplantation include the following three aspects.

1.1 Liver transplantation develops rapidly in pediatric. From 2015 to the end of 2018, the proportion of liver transplantation in pediatric was 17.1%, and the 1-year survival rate of recipients in China was 92.5%. Renji hospital SJTU school of Medicine which has the largest number of pediatric liver transplantation, performed 427 cases of pediatric liver transplantation in 2018,

among which 366 were living-related donor liver transplantation.

1.2 The proportion of living-related donor liver transplantation was high. From 2015 to the end of 2018, the proportion of living-related donor liver transplantation was 13.7% in China. In 2018, 71.8% of the liver allograft came from living-related donors among pediatric liver transplantation, which indicates a close relationship between relatives in China.

1.3 Notably, China had a high incidence of liver cancer and a high proportion of liver transplant was performed in recipients with malignancy. Among the DD liver transplant recipients, the proportion of recipients with malignancy in China was about 40%. In recent years, the Hangzhou criteria for liver transplantation of HCC has been widely recognized by the academic community and clinically applied. The 3-year survival rate within Hangzhou criteria (77.3%) is significantly higher than that of the recipients exceeding Hangzhou criteria (48.9%).

Methods and techniques of liver transplantation have been innovated continuously. For example, the kind of anastomosis for liver transplantation has been transformed from the continuous anastomosis to the intermittent anastomosis of anterior and posterior walls, greatly reducing the incidence of postoperative anastomotic stenosis; the anastomosis site has been changed from the gastroduodenal artery to the splenic artery, significantly improving the postoperative blood flow of the liver graft and reduces the incidence of biliary complications; a non-ischemic liver transplantation has been performed; the world's first auxiliary Domino liver transplantation has been performed by exchanging half of the liver of two individuals with different genetic metabolic defects to achieve organ transplantation without additional organ donation.

2. The work plan and prospect for liver transplantation in China

2.1 Informatization needs to be strengthened to achieve the automatic collection and intelligent feedback of data.

2.2 The standards and systems for quality management and control of liver transplantation need to be established and implemented. The evaluation

and preservation system of donated livers need to be further improved to improve the quality of donated livers, reduce the incidence of complications, and raise the survival rate of recipients. Furthermore, significant postoperative complications need to be extensively monitored, such as early allograft dysfunction, acute kidney injury, and new-onset diabetes. In addition, a more scientific and refined quality control system needs to be established to improve the clinical quality, service, and curative effect of liver transplantation in China.

2.3 Data on liver transplantation needs to be scientifically monitored to find valuable information. Clinical research needs to be conducted using big data design and refined management, and clinical decisions have to be guided by evidence-based medicine. Therefore, superior clinical resources need to be gathered to innovate the multi-center, high-quality clinical research that focuses on the liver transplantation to facilitate the transformation from scientific findings to clinical application and promote the development of liver transplantation.

Chapter III Kidney Transplantation in China

This chapter is mainly based on the data from the Chinese Scientific Registry of Kidney Transplantation (CSRKT). Statistical limits are data from mainland of China, not including Hongkong, Macao and Taiwan.

CSRKT is China's official kidney transplant registry system established under the supervision of the National Health Commission, and it requires the medical institutions qualified to perform kidney transplantation to provide information regarding the transplantation timely and entirely. Being the unique scientific registry system of kidney transplant recipients in China, CSRKT provides bases for national regulatory authorities to formulate relevant transplantation policies and regulations through the dynamic and scientific analysis of kidney transplantation in China, and it provides scientific management tools of kidney transplant recipients to all transplant centers. Nowadays, it has become one of the most critical information systems in organ transplantation and academic exchange platforms for kidney transplantation in China.

I. Distribution of medical institutions for kidney transplantation

By December 31, 2018, there were total 126 medical institutions qualified for kidney transplantation in China, and they were mainly distributed in Guangdong (15), Beijing (11), Shandong (11), Hunan (9), and Shanghai (7) (Figure 3-1).

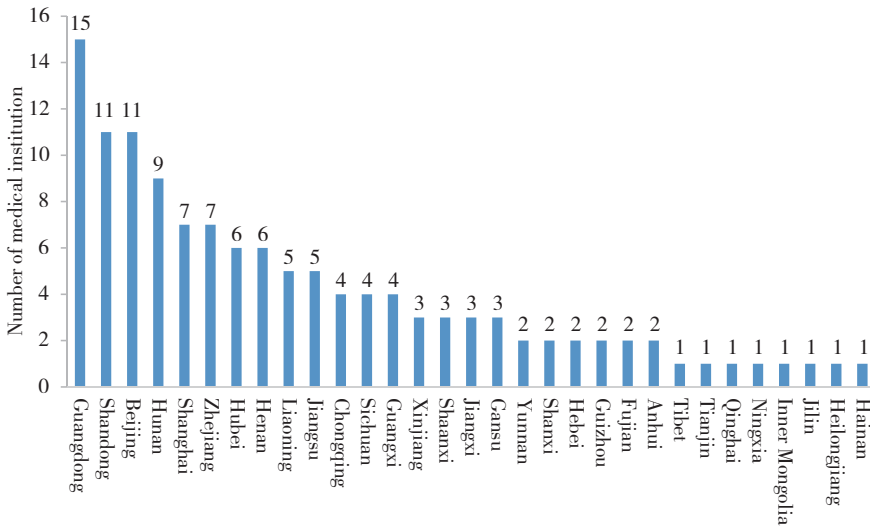


Figure 3-1 Geographical distribution of medical institutions qualified for kidney transplantation in China (excluding Hongkong, Macao and Taiwan)

From January 1, 2015 to December 31, 2018, overall 39,881 patients underwent kidney transplantation (Figure 3-2) in China, of which 32,497 underwent DD kidney transplantation and 7,384 underwent living-related donor kidney transplantation.

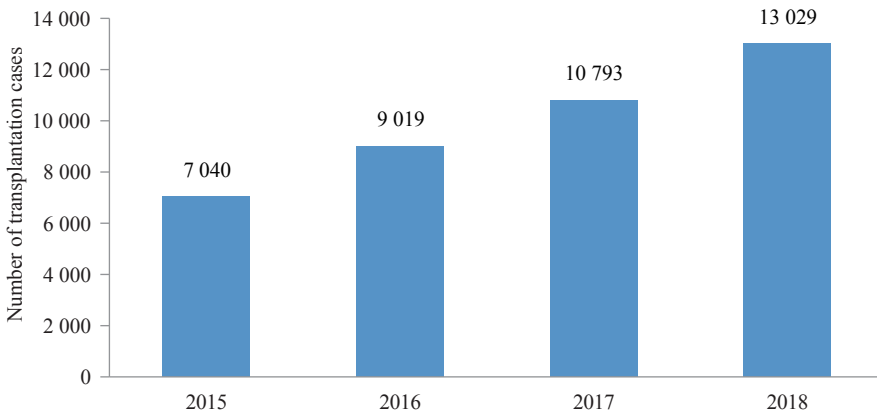


Figure 3-2 Number of kidney transplantation cases during 2015–2018 in China (excluding Hongkong, Macao and Taiwan)

Since 2015, DD kidney transplantation has developed rapidly in China, with significant increase yearly. Thus far, it has become the main type of kidney transplantation in Mainland China (Figure 3-3). However, the number and proportion of living-related donor kidney transplantation cases have decreased each year (Figure 3-4).

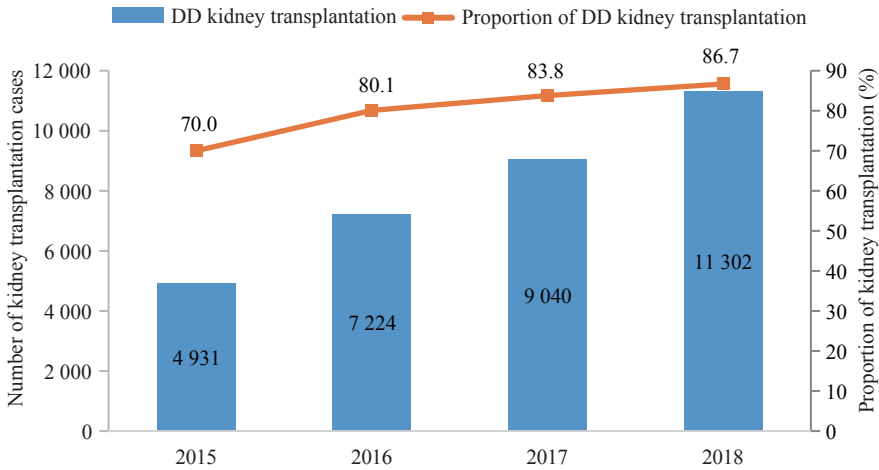


Figure 3-3 Number and proportion of DD kidney transplantation cases during 2015–2018 in China (excluding Hongkong, Macao and Taiwan)

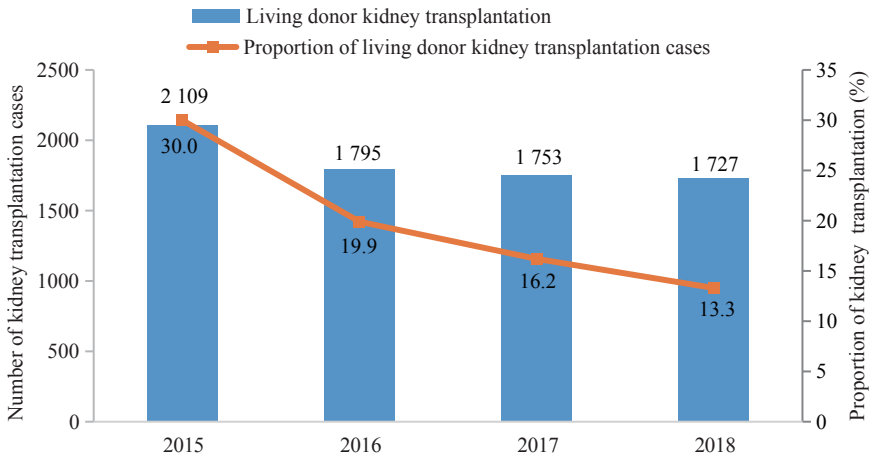


Figure 3-4 Number and proportion of living-related donor kidney transplantation cases during 2015–2018 in China (excluding Hongkong, Macao and Taiwan)

Recently, kidney transplantation in children (<18 years) has garnered attention. The number of kidney transplantations in children accounts for about 2% of overall kidney transplantation cases each year from 2015–2018 (Figure 3-5) in China.

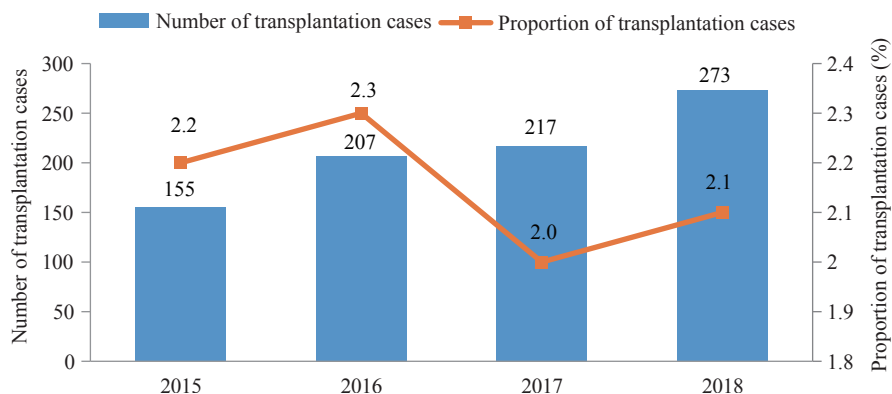


Figure 3-5 Number and proportion of kidney transplantation cases during 2015–2018 in China (excluding Hongkong, Macao and Taiwan)

The top five provinces based on the number of kidney transplantation cases in 2018 were Guangdong, Hubei, Hunan, Beijing, and Shandong. The distribution of kidney transplantation cases in each province is shown below in Figure 3-6.

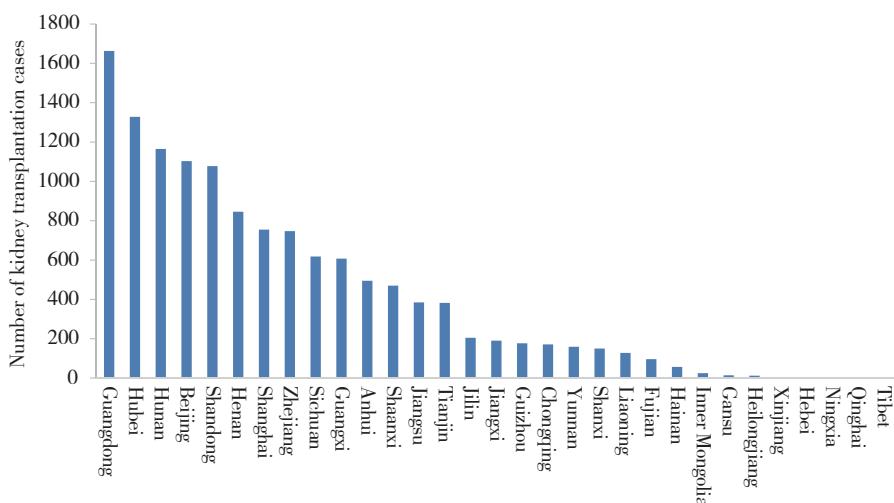


Figure 3-6 Distribution of kidney transplantation cases in each province of China in 2018 (excluding Hongkong, Macao and Taiwan)

In 2018, no less than 250 cases of kidney transplantation were performed at 14 medical institutions, 200–249 cases were performed in 8 medical institutions, 100–199 were performed in 21 medical institutions, 50–99 were performed in 19 medical institutions, 10–49 were performed in 38 medical institutions, 1–9 were performed in 11 medical institutions, and 0 was performed in 15 medical institutions (10 of which had never performed a kidney transplantation for 3 consecutive years, from 2016 to 2018). The number and proportion of kidney transplantation cases in each range in 2018 are shown below in Figure3-7.

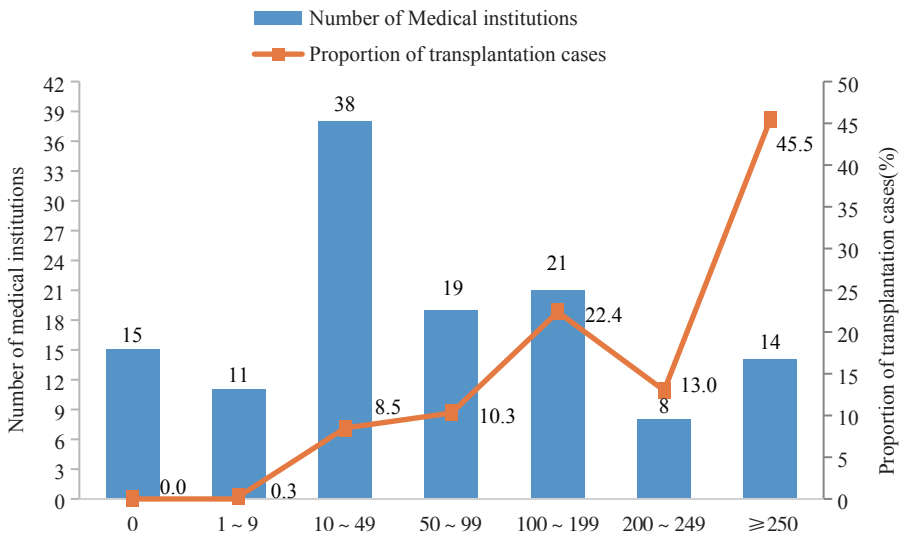


Figure 3-7 Number and proportion of kidney transplantation cases in each range in 2018 (excluding Hongkong, Macao and Taiwan)

In 2018, kidney transplantation demonstrated obvious regional advantages, and no less than 600 (76.1% of the total cases) cases of kidney transplantation were performed in 10 provinces of China (Figure 3-8).

In 2018, the top 10 provinces based on the number of DD kidney transplantation cases were Guangdong, Hubei, Hunan, Beijing, Shandong, Henan, Shanghai, Guangxi, Zhejiang, and Shaanxi, accounting for 78.8% of the overall cases that year (Figure 3-9).

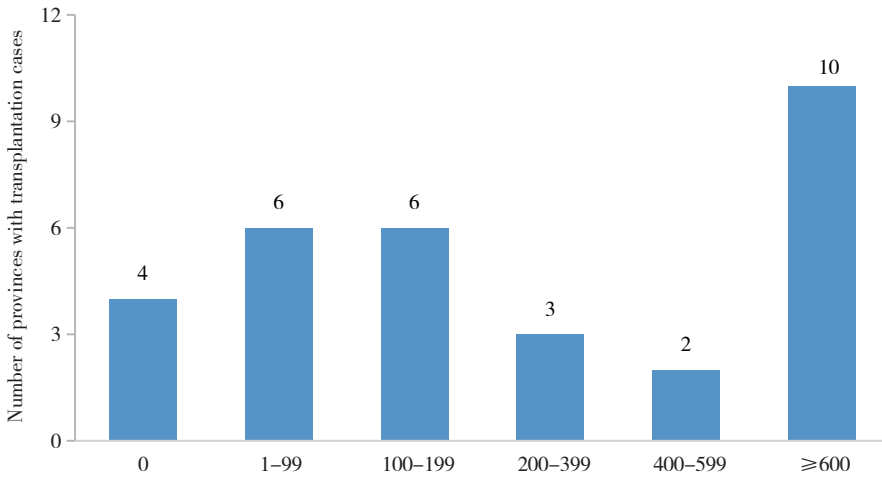


Figure 3-8 Distribution of kidney transplantation cases in each province of China in 2018 (excluding Hongkong, Macao and Taiwan)

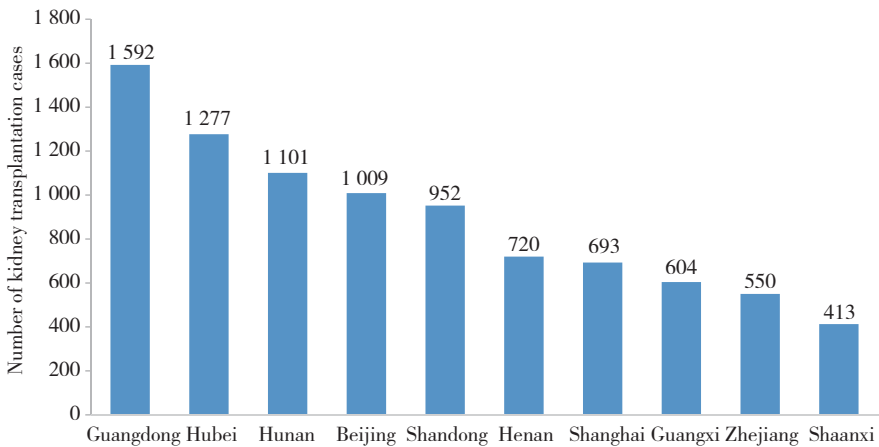


Figure 3-9 Top 10 provinces based on the number of DD kidney transplantation cases in 2018 (excluding Hongkong, Macao and Taiwan)

In 2018, the top provinces according to the number of living-related donor kidney transplantation cases were Anhui, Sichuan, Zhejiang, Henan, and Shandong (Figure 3-10).

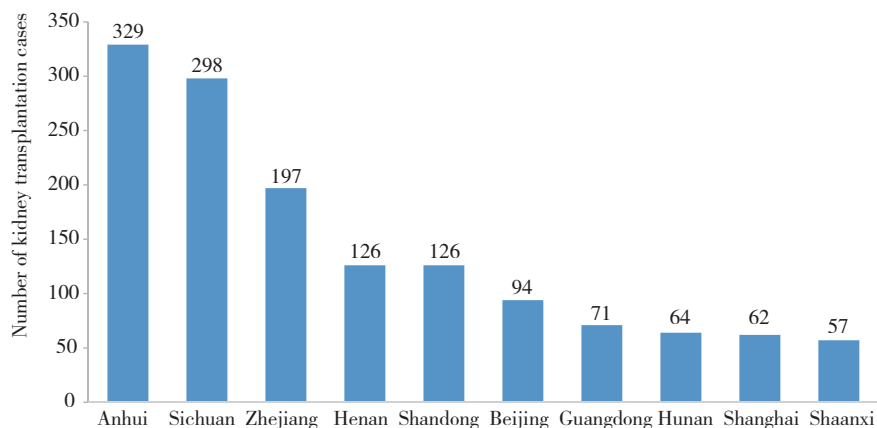


Figure 3-10 Top 10 provinces based on the number of Living donor kidney transplantation cases in 2018 (excluding Hongkong, Macao and Taiwan)

II. Data of kidney transplant recipients

The demographic analysis of the kidney transplantation cases performed in China from January 1, 2015 to December 31, 2018 revealed that the recipient age was 39.2 ± 11.7 years. In addition, the analysis revealed that the value of BMI was $21.9 \pm 3.4 \text{ kg/m}^2$, and the duration of pretransplant dialysis was 759 ± 820 days. In total, 70.4% of the transplant recipients were males, and the ones with AB blood type had the smallest proportion (Table 3-1).

Table 3-1 Basic information of kidney transplant recipients during 2015–2018 (excluding Hongkong, Macao and Taiwan)

Variable	Mean \pm SD
Age (years)	39.2 \pm 11.7
BMI (kg/m ²)	21.9 \pm 3.4
Duration of pretransplant dialysis (days)	759 \pm 820
Blood type	Proportion (%)
O	33.1
A	29.9
B	27.6
AB	9.4
Sex (Male/female)	70.4/29.6

III. Quality and safety analysis of kidney transplantation

1. Ischemia time of donor kidney for DD kidney transplantation

The cases of DD kidney transplantation in 2018 and during 2015–2018 in China are analyzed in this report. The mean cold ischemia time of donor kidney is no more than 6 hours (Table 3-2 and Figure 3-11).

Table 3-2 Ischemia time of donor kidney for DD kidney transplantation (mean ± SD) (excluding Hongkong, Macao and Taiwan)

parameter	2018	2015–2018
Cold ischemia time of donor kidney (hours)	5.5±3.5	5.9±4.1
Warm ischemia time of donor kidney (minutes)	5.4±6.6	6.3±6.2

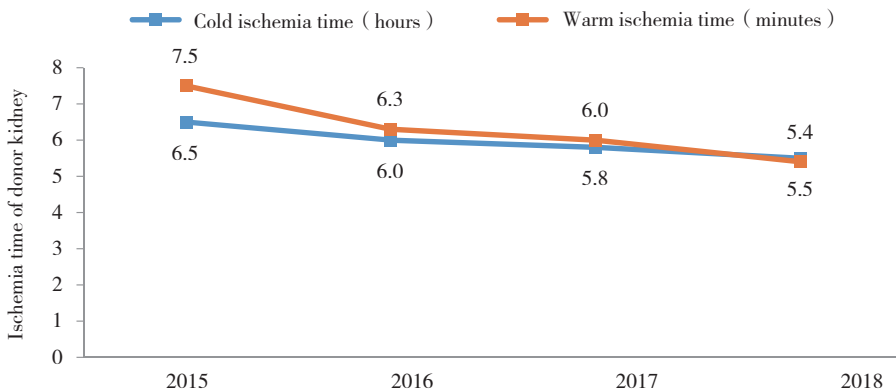


Figure 3-11 Mean ischemia time of donor kidney for DD kidney transplantation in 2015–2018 (excluding Hongkong, Macao and Taiwan)

2. Change in serum creatinine values before and after kidney transplantation

In 2018, there were 13,029 cases of kidney transplantations in China. According to the requirement of CSRKT, the mean values of serum creatinine in recipients of living kidney transplantation between relatives and DD kidney transplantation at four follow-up time points (pre-operation, postoperative 30, 180, and 360 days) were analyzed (Figure 3-12).

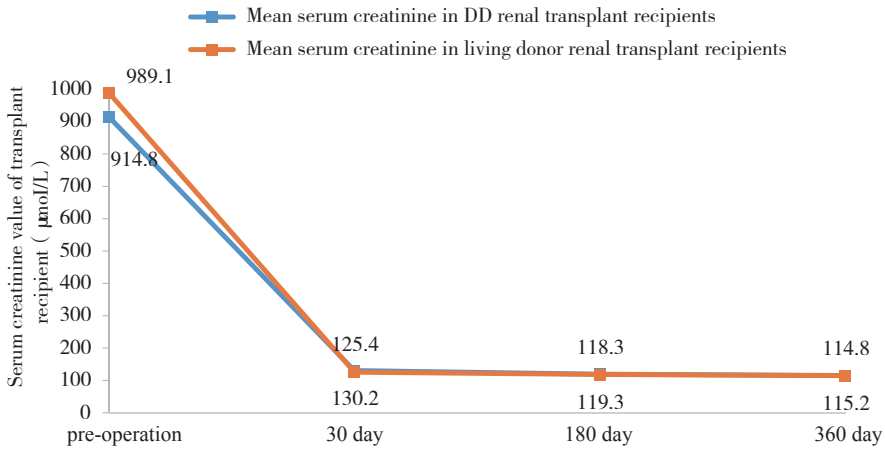


Figure 3-12 Mean value of recipients' serum creatinine before and after kidney transplantation (excluding Hongkong, Macao and Taiwan)

3. Overview of adverse events after kidney transplantation

Significant adverse events after kidney transplantation usually include delayed function of allograft, acute rejection, death of recipient, and renal allograft loss. According to the retrospective analysis of cases during 2015–2018, the incidence of significant adverse events is presented in Table3-3.

Table 3-3 Incidence of adverse events within postoperative one year (excluding Hongkong, Macao and Taiwan)

Adverse event	Living donor kidney transplantation (%)	DD kidney transplantation (%)
Delayed ograft function	2.1	14.6
Acute rejection	3.6	4.5
Recipient death	1.0	3.0
All-cause graft loss	2.0	5.8

4. Survival analysis of kidney transplant recipient and graft

In 2018, the Kidney Transplantation Quality Control Center. The results were as follows: randomly selected 6719 kidney transplant cases from 41 large transplant centers in CSRKT and analyzed the survival of recipient and graft.

(1) One-year survival probability after transplantation: the 1-year survival

probability of recipient/allograft was 96.7%/93.8%, whereas the survival probabilities of recipient and graft were 98.8% and 97.7%, respectively (Table3-4).

(2) Three-year survival probability after transplantation: the 3-year survival probability of recipient/allograft after DD kidney transplantation was 95.6%/91.3%, whereas the 3-year survival probability of recipient/allograft after living relative donor kidney transplantation was 98.2%/95.8% (Table3-4).

Table 3-4 Survival probabilities of kidney transplant recipient and graft after kidney transplantation in China (excluding Hongkong, Macao and Taiwan)

Donortype	1 year		3 years	
	Recipient (%)	Allograft (%)	Recipient (%)	Allograft (%)
Living donor	98.8	97.7	98.2	95.8
DD	96.7	93.8	95.6	91.3

IV. Summary and prospects

1. DD kidney transplantation has become a mainstream, with promising clinical effects

Since 2015, DD kidney transplantation has played a dominant role in kidney transplantation, and the number of DD kidney transplantations accounts for 86.7% of total number of kidney transplantations in China in 2018 with Guangdong, Hubei, Hunan, Beijing, and Shandong in the top of the list, showing obvious regional advantage. Considering the survival probabilities of living kidney transplantations between relatives and DD kidney transplantation from 1 and 3 years, the clinical outcome is promising. The cold ischemic time of DD kidney transplantation cold ischemia time of graft is short on death donors, which might be because that donated organs are usually procured and allocated regionally and the Chinese government has established the green channel for human organs transport since May 2016 to shorten the cold ischemia time and avoid unnecessary organ damage or waste. The number of kidney transplantations in children has increased over the years, with more

significant progresses and satisfactory clinical outcomes in provinces like Henan, Guangdong, Shanghai, etc. With cumulated clinical experience in kidney transplantation in children, it has become an outstanding feature of medical care in these provinces.

2. Quality control and improvement project of kidney transplantation has been conducted

The quality control of kidney transplantation aims to narrow the gap of all transplant centers in the curative effect and fully improve the quality of kidney transplantation. Therefore, a series of quality control standards and technical specifications have been issued. In addition to the quality control indicators for corresponding medical evaluation, the quality improvement project of kidney transplantation is developed, and prospective studies are carried out according to these technical specifications in order to achieve the virtuous circle from medical quality evaluation (quality control) to medical quality improvement, and continuously boost the development of kidney transplantation in China.

3. Attention has been paid to the hot issues in kidney transplantation and breakthroughs have been made

The shortage of donors and allograft rejection in organ transplantation will still be the key constrained factors of the development of kidney transplantation for a long period to come. Over the years, domestic scholars have been committed to linking the research results in immunology, stem cell, and genetic engineering with the organ transplantation, and carrying out basic and clinical research works, in order to provide the theoretical and practical basis for improving the medical quality of kidney transplantation. There have been several breakthroughs, such as donor-specific antibody, antibody-mediated rejection, clinical immune tolerance, organ function maintenance for potential organ donor, preservation and full utilization of donated organ, and transplantation-related virus infections, in research hotspots.

4. CSRKT-based large sample study is carried out to promote academic exchanges

CSRKT is the precious wealth of China in organ transplantation. In order to make the CSRKT more scientific and modernized, the Kidney Transplantation Quality Control Center has also mined the data of the CSRKT and performed a large sample, real-world study of the clinical outcomes of Chinese kidney transplant recipients. The research report, which was presented at International Congress of the Transplantation Society, revealed the characteristics, achievements, shortcomings, and prospects of kidney transplantation in the Mainland China. It has not only raised the voice of China in transplantation in the big data atmosphere, but also strengthened the academic exchanges in the international transplantation, thereby laying a scientific foundation for the sustainable and healthy development of kidney transplantation in China.

Chapter IV Heart Transplantation in China

This chapter is mainly based on the data of China Heart Transplant Registry (CHTR).

CHTR is established under the supervision of the National Health Commission as an official heart transplant registry system, and it requires the medical institutions with heart transplantation qualifications to submit heart transplantation data.

As the only scientific registry system for heart transplantation in China, the data of CHTR included characteristics of recipient, donor and transplant, immunosuppressants, in-hospital and long-term outcomes.

As an important part of the organ transplantation information system in China as well as the academic platforms for heart transplantation specialty, CHTR releases regular reports regarding the national, regional, and center-specific heart transplantation volumes, results of data audit, and patient outcomes via comprehensive analysis of collected data. Based on those analyses and reports, CHTR summarizes results and experience on heart donor acquisition and preservation, donor-recipients matching and clinical transplantation management. Furthermore, CHTR provides vital information for the constitution of relative regulations, laws and guidelines for the relative national administrative.

I. Distribution of medical institutions for heart transplantation

By December 31, 2018, a total of 46 medical institutions were qualified for heart transplantation in China, which were mainly distributed in Guangdong

(5), Beijing (4), and Hubei (4) (Figure 4-1).

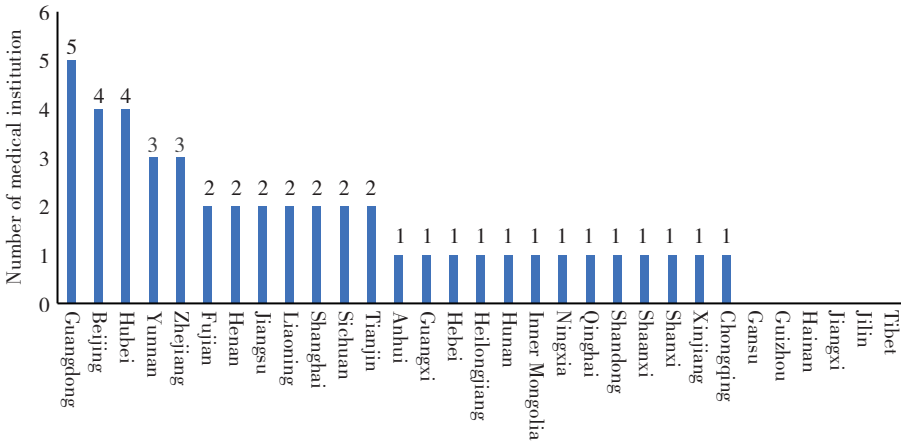


Figure 4-1 Distribution of medical institutions qualified for heart transplantation in 2018 in China (excluding Hongkong, Macao and Taiwan)

As revealed by CHTR, 1,583 heart transplantation cases were performed during 2015–2018 in China, including 19 cases of heart-lung transplantation. In 2018, 490 cases of heart transplantation were completed in 30 medical institutions qualified for heart transplantation (Figure 4-2). The distribution of total heart transplantation cases in each province is presented in Figure 4-3.

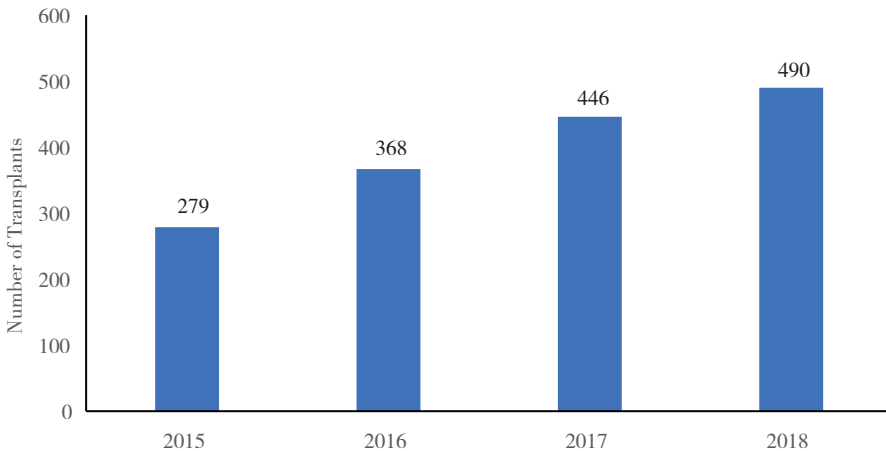


Figure 4-2 Number of heart transplantation cases in China over the years of 2015–2018 (excluding Hongkong, Macao and Taiwan)

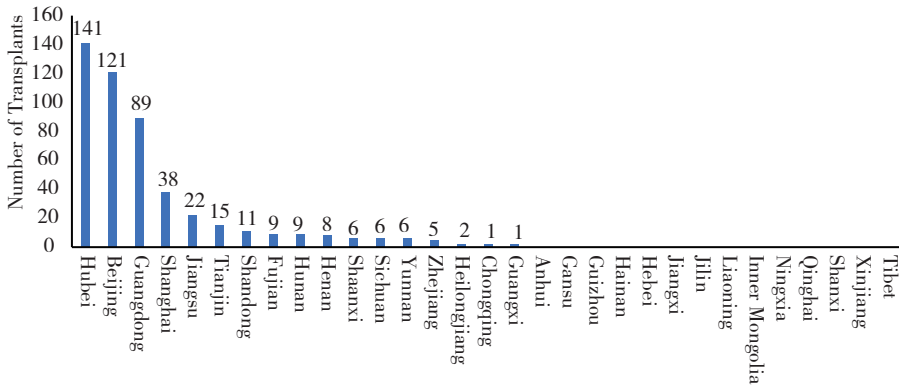


Figure 4-3 Distribution of heart transplantation cases in each province of China in 2018 (excluding Hongkong, Macao and Taiwan)

The top 10 medical institutions ranked by the total number of transplantation cases in 2018 are shown in Figure 4-4.

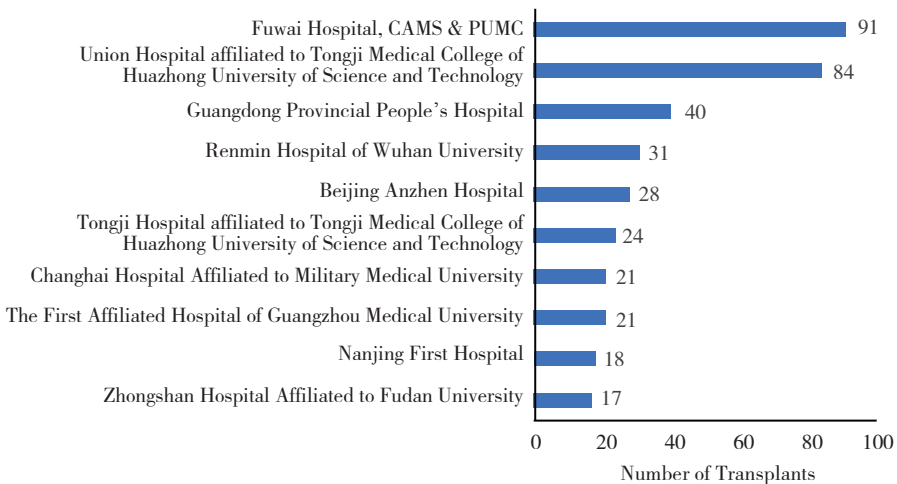


Figure 4-4 Top 10 medical institutions by the number of transplantation cases in 2018 (excluding Hongkong, Macao and Taiwan)

II. Data of heart donors and transplant recipients

From 2015 to 2018, the male heart donors accounted for 88.9% of total donors in China, which was higher than the corresponding proportion reported by

International Society of Heart and Lung Transplantation (ISHLT) (68.3%). The median age of donors was 35 years, which was same as that reported by ISHLT. In total, 25.3% of donors had blood type A, 24.8% had blood type B, 5.4% had blood type AB, and 44.5% had blood type O. The median weight of donors was 65 kg, which was lower than the median weight of 80 kg reported by ISHLT (Table 4-1).

Table 4-1 Basic information of Chinese heart transplant recipients and donors during 2015–2018 (excluding Hongkong, Macao and Taiwan)

	CHTR 2015–2018	ISHLT 2009–2016
Recipient age	50.0 (16.0–66.0)	55.0 (25.0–68.0)
Recipient sex/male	77.7%	79.0%
Recipient weight	62.0 (41.0–85.0)	80.0 (54.0–109.0)
Recipient height	169.0 (153.0–180.0)	175.0 (157.5–188.0)
Recipient BMI	22.1 (16.0–28.7)	26.3 (19.5–34.8)
Donor age	35.0 (16.0–52.0)	35.0 (17.0–58.0)
Donor weight	65.0 (50.0–80.0)	80.0 (56.8–114.5)
Donor sex/male	88.9%	68.3%
Ischemic time	195.0 (60.0–420.0)	192.0 (90.0–300.0)

From 2015 to 2018, the median age of Chinese heart transplant recipients was 50 years; however, ISHLT reported it to be 55 years. The proportion of male heart transplant recipients was 77.7%, similar to the proportion of 79.0% reported by ISHLT. In total, 30.5% of transplant recipients had blood Type A, 28.3% had blood Type B, 10.4% had blood Type AB, and 30.8% had blood Type O. The median BMI of recipients was 22.1 kg/m² (5% and 95% quantiles were 16.0 and 28.7 kg/m², respectively), lower than the 26.3 kg/m² (5% and 95% quantiles were 19.5 and 34.8 kg/m², respectively) reported by ISHLT.

The median age of children heart recipients (< 18 years) was 13.5 years; ISHLT reported that age to be 7 years. The proportion of recipients in each age group during 2015–2018 is compared with the data reported by ISHLT, as shown in Figure 4-5. The age matching of Chinese heart recipients and donors in 2015–2018 is presented in Figure 4-6.

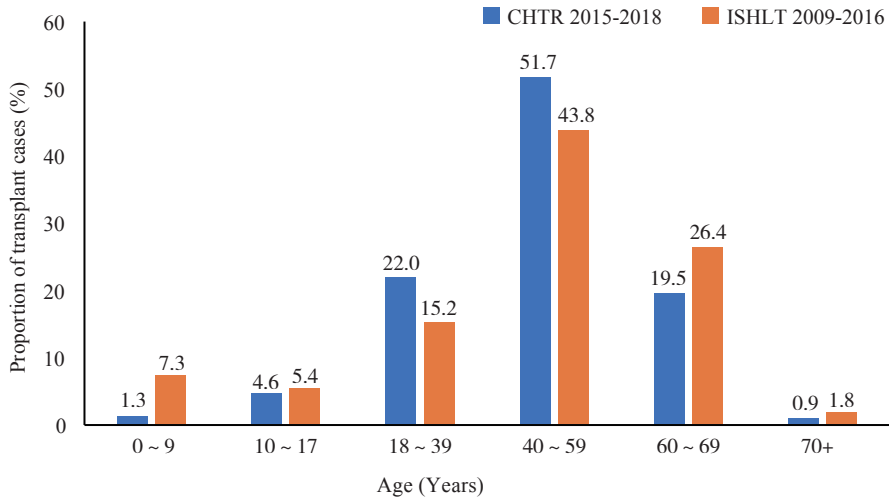


Figure 4-5 Comparison of age composition of recipients reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

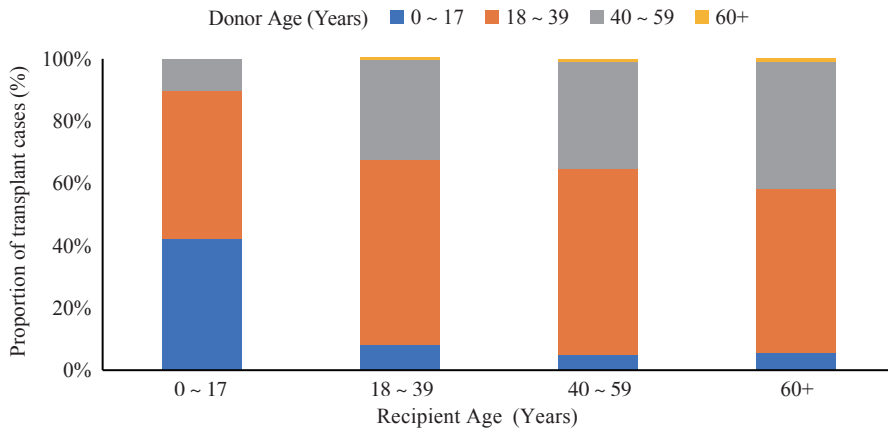


Figure 4-6 Age matching of Chinese heart transplant recipients and donors during 2015–2018 (excluding Hongkong, Macao and Taiwan)

The causes of heart transplantation were non-ischemic cardiomyopathy (73.5%), coronary heart disease (15.7%), congenital heart disease (2.1%), heart valve disease (5.3%), and other (3.4%) (Figure 4-7). The proportion of recipients with cardiomyopathy was higher than that reported by ISHLT (73.5 VS 50.5%), whereas the proportion of recipients with coronary heart disease was lower (15.7% VS 33.1%).

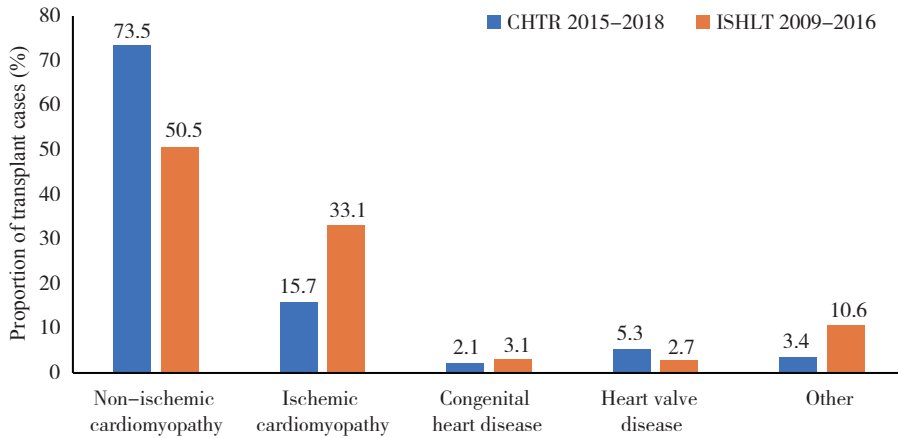


Figure 4-7 Comparison of preoperative causes of adult recipients reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

III. Quality and safety analysis of heart transplantation

1. Ischemia time of heart donor

From 2015 to 2018, the median time of heart ischemia in Chinese heart donors was 3.2 hours, which is similar to the 3.3 hours reported by ISHLT. Figure 4-8 shows the distribution of ischemia time of heart donors in China as compared with ISHLT. The proportion of recipients with heart transplantation ischemia time longer than 6 hours is 22.1%, which was about only 3% reported by ISHLT. The in-hospital survival rate is 91.4%, which was higher than the 30-day survival rate of 89.9% published by ISHLT.

2. Postoperative in-hospital outcomes

2.1 In-hospital survival rate

The in-hospital survival rate of heart transplant recipients in China was 92.3% during 2015–2018, which was similar to the 30-day survival rate of 92.6% after heart transplantation during 2009–2016 presented in the annual report of ISHLT. This indicates that the outcomes of Chinese heart transplantation is comparable to other countries.

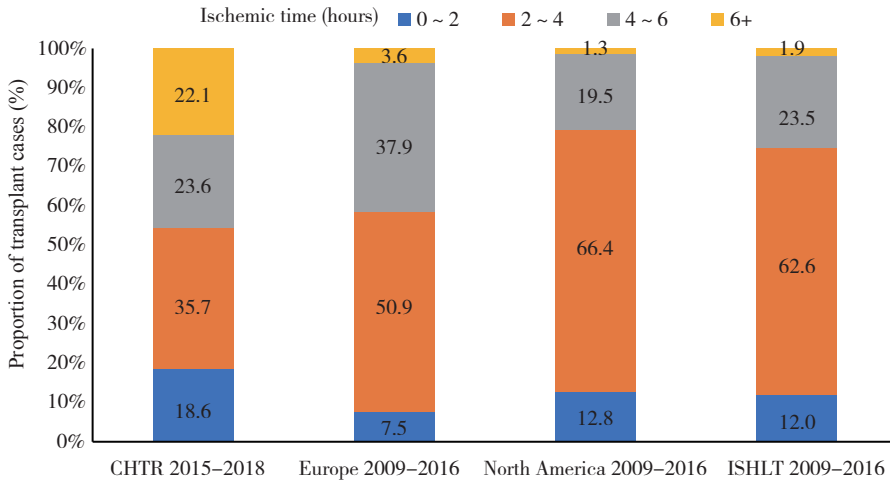


Figure 4-8 Comparison of ischemia time of heart donors reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

2.2 Primary disease and in-hospital death

During 2015–2018, primary diseases of the heart transplant recipients who died in hospital included the coronary heart disease (11.8%) and cardiomyopathy (60.5%). The proportion of in-hospital deaths in patients with coronary artery disease receiving heart transplantation has decreased year by year, and it is lower than that reported by ISHLT (Figure 4-9).

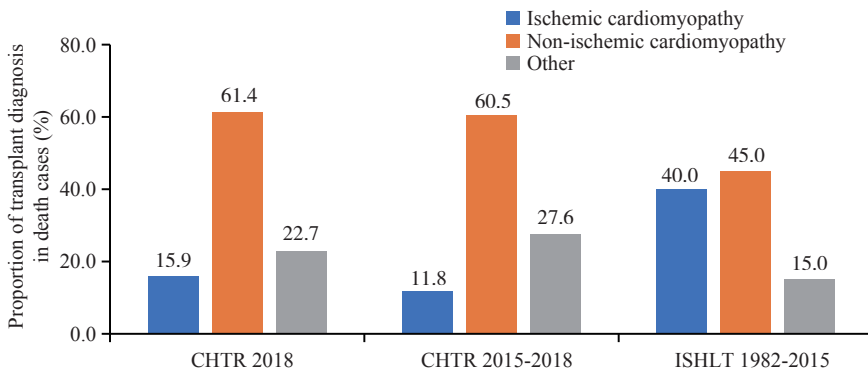


Figure 4-9 Proportions of causes of in-hospital deaths reported by China during 2015–2018 and 30-day postoperative deaths reported by ISHLT (excluding Hongkong, Macao and Taiwan)

2.3 Major early postoperative complications and causes of death

During 2015–2018, early postoperative complications in Chinese heart transplant recipients were mainly infections (20.2%), cardiac arrest, rethoracotomy, tracheotomy, and re-intubation (Figure 4-10). Figure 4-11 presents the causes of in-hospital deaths of heart transplant recipients. Multiple organ failure and transplant heart failure account for more than 50% of early death, similar to that reported by ISHLT. the early postoperative transplant heart failure was mainly treated with extracorporeal membrane oxygenation (ECMO) and intra-aortic balloon pump (IABP), However, parts of recipients died from the kidney, liver, or gastrointestinal failures after the functional recovery of the heart allograft.

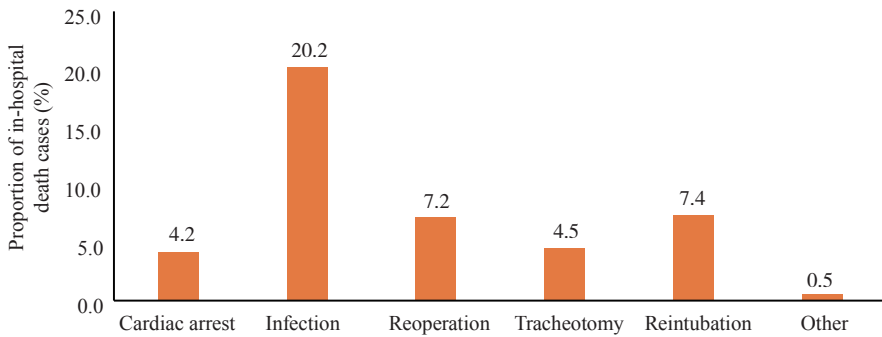


Figure 4-10 Incidence of early postoperative complications in heart transplant recipients during 2015–2018 (excluding Hongkong, Macao and Taiwan)

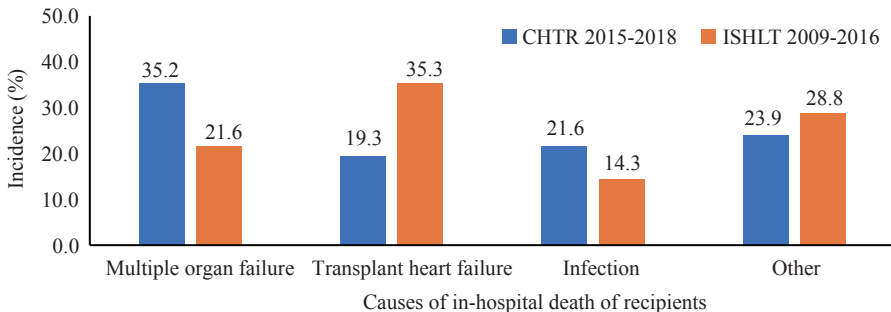


Figure 4-11 Comparison of causes of in-hospital death of heart transplant recipients during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

4. Long-term survival analysis

In 2018, the one-year survival rate after heart transplantation was 90.8% in China, which was higher than the rate of 85.4% reported by ISHLT. (Figure 4-12)

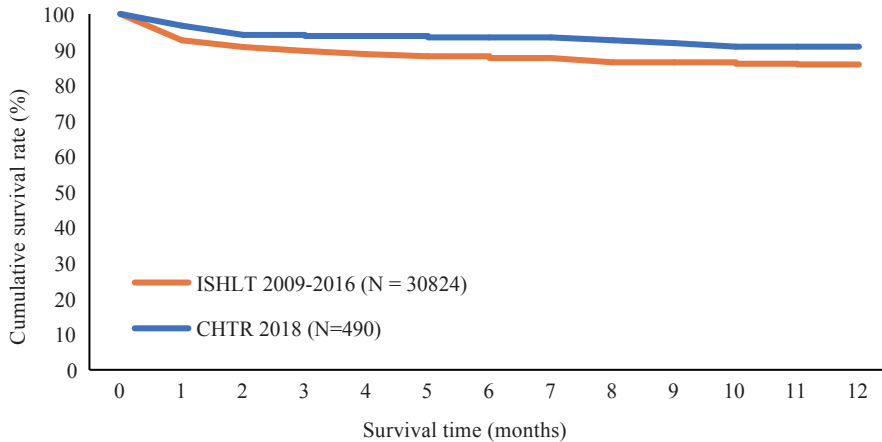


Figure 4-12 One-year survival rate after heart transplantation in 2018 in China (excluding Hongkong, Macao and Taiwan)

IV. Summary and prospects

From 2015 to 2018, heart transplant have gradually increased in China. The annual heart transplantation number exceeded to 75 in two heart transplant centers in the past four years. According to data of the ISHLT, there are only five heart transplant centers with the annual average number of transplantation cases exceeding 75 in the world, which indicated that the large centers in China have among the first-class heart transplant centers all over the world.

From 2015 to 2018, the in-hospital and long-term survival rate of heart transplantation in China have reached the international level. The long-term survival rate in the large medical institutions is even higher than the international institutions. With long ischemia time of heart donors, the large heart transplant centers can still achieve a higher in-hospital and long-term survival rate than the international level. China has accumulated successful experience in the heart donors selection and preservation, and also the

perioperative and long-term management of transplantations.

In the future, China Heart Transplantation Quality Control Center will focus on further optimization of the CHTR, establishment of a efficient system for international cooperation and exchange, and also organize an expert committee to propose the quality measures for heart transplantation, strengthen specialty training and narrow regional disparity.

Chapter V Lung Transplantation in China

The data analyzed in this chapter are of those patients registered by each lung transplantation center in China Lung Transplantation Registry (CLuTR) from January 1, 2015 to December 31, 2018. As the unique scientific registry system of lung transplant data in China, CLuTR has comprehensively and timely collected the preoperative information of recipients, donor information, transplantation information of recipients, postoperative information, and follow-up information. By dynamic and scientific analysis of the lung transplantation in Mainland China, CLuTR provides a basis for national regulatory authorities to formulate the relevant transplantation policies and regulations.

I. Distribution of medical institutions for lung transplantation

By the end of 2018, 32 medical institutions in China have obtained qualifications for lung transplantation. These institutions cover 20 provinces and are mainly distributed in the east and north of China (Figure 5-1).

From January 1, 2015 to December 31, 2018, 1,024 cases of lung transplantation were reported by CLuTR, including 118 cases in 2015, 204 cases in 2016, 299 cases in 2017, and 403 cases in 2018 (Figure 5-2), showing an upward trend year by year.

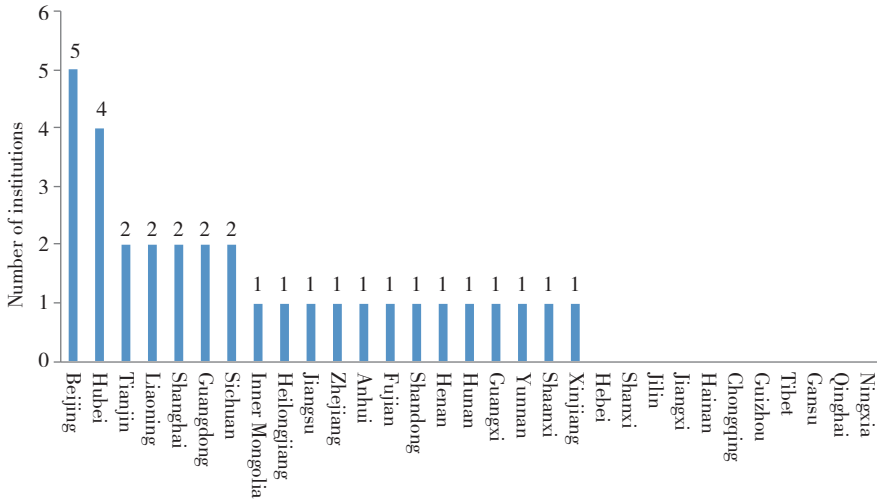


Figure 5-1 Distribution of medical institutions qualified for lung transplantation in each province of China by 2018 (excluding Hongkong, Macao and Taiwan)

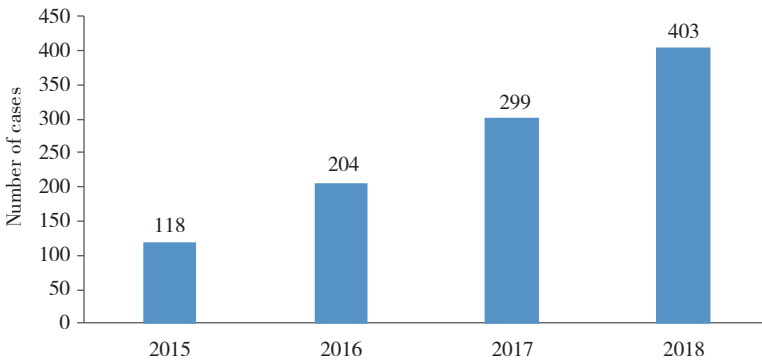


Figure 5-2 Number of lung transplantations in 2015–2018 in China (excluding Hongkong, Macao and Taiwan)

In 2018, lung transplantation was performed in 15 centers. The top three centers by the number of operations were Wuxi People’s Hospital (37.2%), China-Japan Friendship Hospital (26.5%), and the First Affiliated Hospital of Guangzhou Medical University (16.1%) (Figure 5-3).

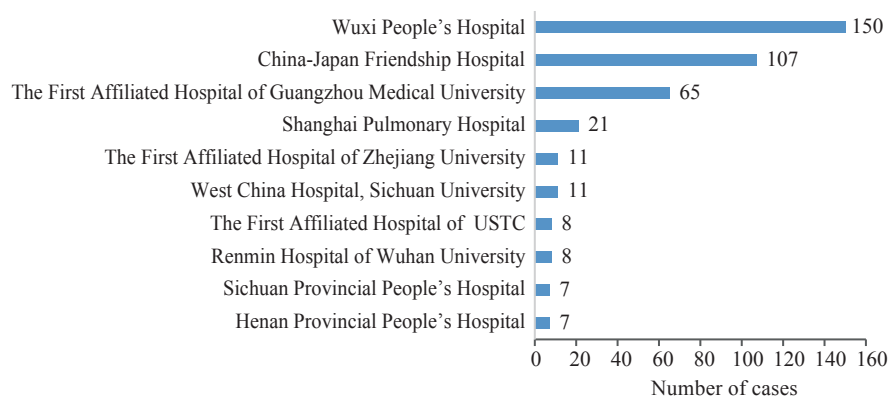


Figure 5-3 Top 10 medical institutions by the number of lung transplantation cases in 2018 in China (excluding Hongkong, Macao and Taiwan)

II. Data of lung donors and transplant recipients

During 2015–2018, lung donors in China were mainly aged 18–49 years (83.8%), and no donor was aged above 60 years. The proportion of donors aged 18–49 years was significantly higher than that reported by ISHLT (Figure 5-4). The proportion of male donors was 88.7%, which is significantly higher than the 56.2% reported by ISHLT.

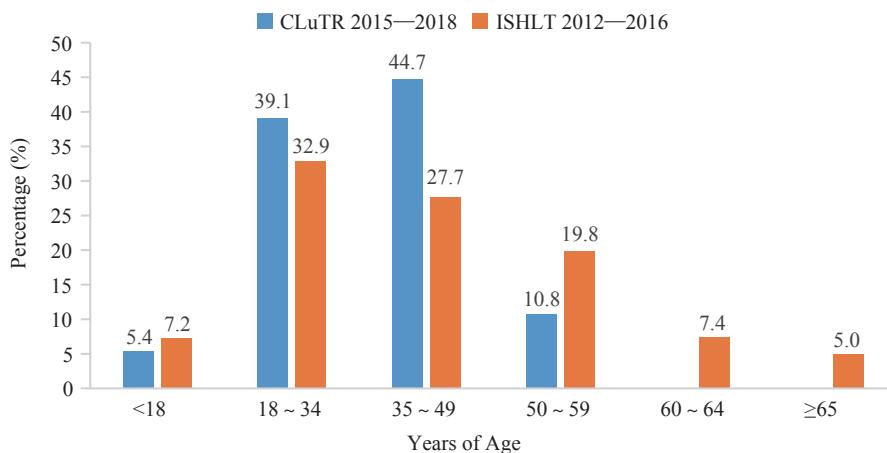


Figure 5-4 Comparison of age distribution of lung donors reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

In 2018, the proportions of Chinese lung transplant donors aged <18 years, 18–34 years, 35–49 years and ≥ 50 years were 4.0%, 38.9%, 45.5%, and 11.6%, respectively. Male donors constituted 82.9% of all the donors.

The average age of lung transplant recipients in China was 54.9 ± 12.8 years during 2015–2018, and the proportion of recipients aged above 60 years was significantly higher than that reported by ISHLT (46.6% versus 38.8%) (Figure 5-5). The proportion of male recipients was 83.2%, which is higher than the proportion of 57.5% reported by ISHLT. In total, 58.6% of the recipients had normal BMI ($18.5\text{--}24.0 \text{ kg/m}^2$), 25.7% were lean ($<18.5 \text{ kg/m}^2$), and 15.7% were overweight ($\geq 24.0 \text{ kg/m}^2$). In total, 31.6% of recipients had blood type O, 28.1% had type A, 29.8% had type B, and 10.5% had type AB.

In 2018, the average age of lung transplant recipients in China was 55.0 ± 12.6 years, and the proportion of recipients aged above 60 years was 42.5%. In total, 83.3% of the recipients were male, 25.8% had normal BMI, 58.6% were thin, and 15.6% were overweight. In total, 30.8% of the recipients had blood Type O, 29.7% had Type A, 28.1% had Type B, and 11.4% had Type AB.

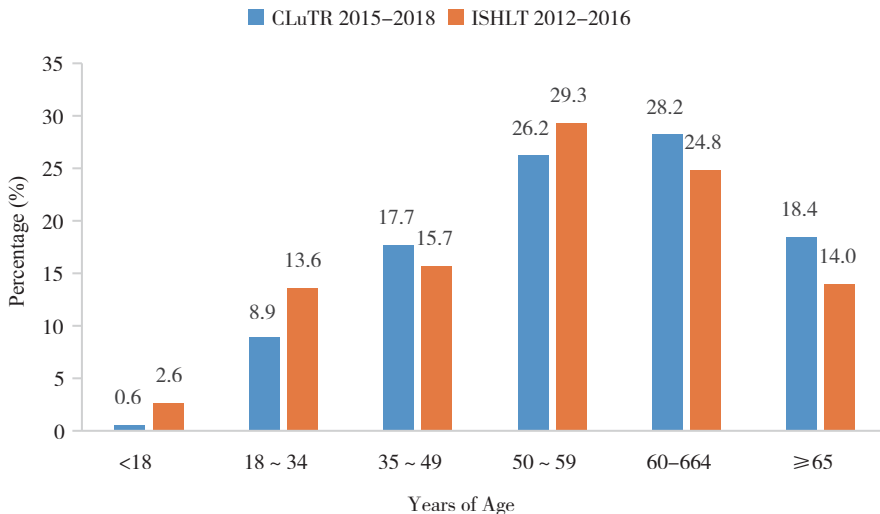


Figure 5-5 Comparison of age composition of lung transplant recipient reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

During 2015–2018, the primary diseases in lung transplant recipients in China mainly included idiopathic interstitial pneumonia (39.0%), chronic obstructive pulmonary disease (23.0%), non-idiopathic interstitial pneumonia (13.2%), and pneumoconiosis (9.2%). Deficiency of α -antitrypsin (4.9%) and vesicular fibrosis (15.4%) have certain proportions in foreign countries, but they constitute a low proportion of lung transplantations in China. The proportion of chronic obstructive pulmonary disease is also lower in China than that in foreign countries (23.0% versus 30.6%). However, the proportion of idiopathic and non-idiopathic interstitial pneumonias is significantly higher in China than that in foreign countries (39.0% versus 25.7%), especially the patients with pneumoconiosis have a higher proportion in lung transplant recipients in China (Figure 5-6).

In 2018, the primary diseases in lung transplant recipients in China mainly included idiopathic interstitial pneumonia (38.7%), chronic obstructive pulmonary disease (21.3%) non-idiopathic interstitial pneumonia (15.6%), and pneumoconiosis (9.2%).

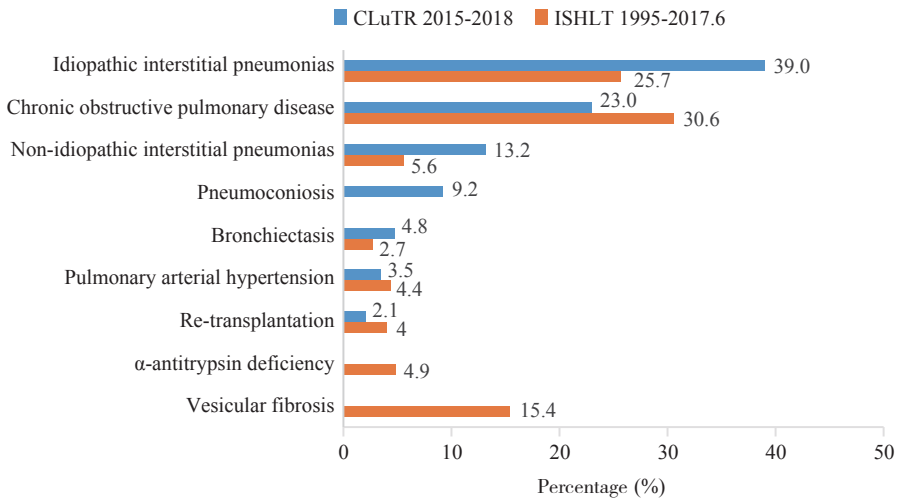


Figure 5-6 Comparison of the primary disease distribution in lung transplant recipients reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

III. Quality and safety analysis of lung transplantation

1. Operation method

There were relatively large differences between the single-lung and double-lung transplantations reported by China during 2015–2018 (57.6% and 42.4%) and the data reported by ISHLT (23.0% and 77.0%). The proportions of single-lung and double-lung transplantations in 2015, 2016, 2017, and 2018 were 34.0% and 66.0%, 59.8% and 40.2%, 65.0% and 35.0%, and 60.0% and 40.0%, respectively.

2. Cold ischemia time

The median cold ischemia times of single-lung transplantation and double-lung transplantation in China were 360.0 (247.5–430.0) min and 480.0 (360.0–570.0) min, significantly higher than the data (252 min and 330 min) reported by ISHLT. The proportion of cold ischemia time (>360 min) of lung transplantation in China was significantly higher than that reported by ISHLT (Figure 5-7). After comparison and analysis of the time trend, the median cold ischemia

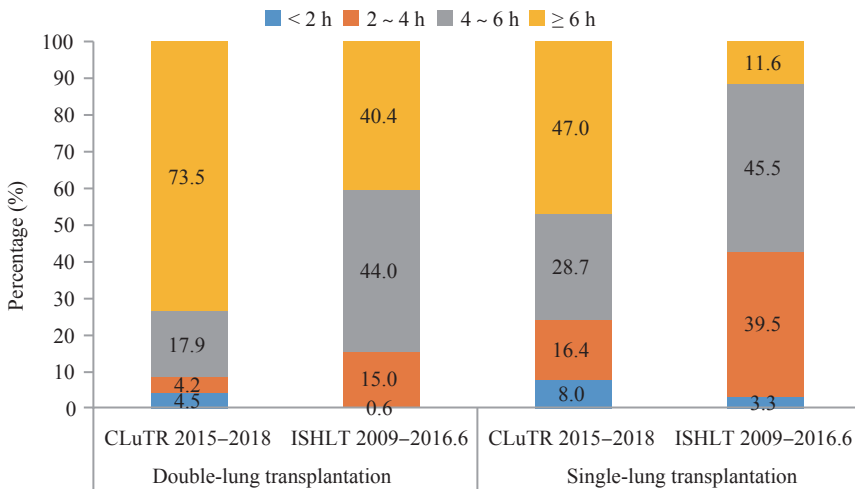


Figure 5-7 Comparison of ischemia time of lung donors reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

times of double-lung transplantation in China were 500.0 (365.0–602.0) min, 532.0(423.8–570.0) min, 480 (360.0–567.5) min, and 445.0 (340.0–545.0) min, respectively, in 2015–2018, whereas the median cold ischemia times of single-lung transplantation were 300.0 (207.5–450.0) min, 380.0 (300.0–447.5) min, 343.0 (241.3–425.0) min, and 360.0 (240.00–425.0) min, respectively.

3. Early postoperative complications

Infection (68.2%), acute rejection (17.4%), renal insufficiency (16.0%), primary lung graft failure (15.6%), diabetes (9.2%), bronchopleural fistula (6.4%), and bronchial anastomotic lesions (5.9%) are the main early complications reported after lung transplantation in China. In ISHLT, primary lung graft failure (24.3%), infection (19.2%), multiple organ failure (12.3%), and cardiovascular events (12.0%) were the main early complications reported after transplantation.

4. Status at discharge

In China, the survival rate of lung transplant recipients before discharge was 73.1%, whereas the survival rates at discharge in 2015, 2016, 2017 and 2018 were 76.0%, 76.5%, 72.8%, and 70.4%, respectively, thereby showing a downward trend over the years. The causes of perioperative death in lung transplant recipients in China are significantly different from the data reported by ISHLT (Figure 5-8). According to the data reported by ISHLT, primary lung graft failure (24.0%), pulmonary infection (18.7%), multiple organ failure (12.6%), and cardiovascular disease (12.0%) are the main causes of perioperative death.

5. Postoperative survival

During 2015–2018, the perioperative (<30 days), three-month, six-month, one-year and three-year survival rates of patients receiving double-lung transplantation were 78.5%, 72.5%, 66.8%, 64.5%, and 48.9%, respectively, whereas the perioperative (<30 days), three-month, six-month, one-year and three-year survival rates for patients receiving single-lung transplantation were 83.0%, 79.6%, 73.4%, 69.9%, and 46.8%, respectively. The single-lung transplant

recipients have a higher short-term survival rate than the double-lung transplant recipients. However, there is still a difference in the survival rate of lung transplant recipients as compared with the data reported by ISHLT (Figure 5-9).

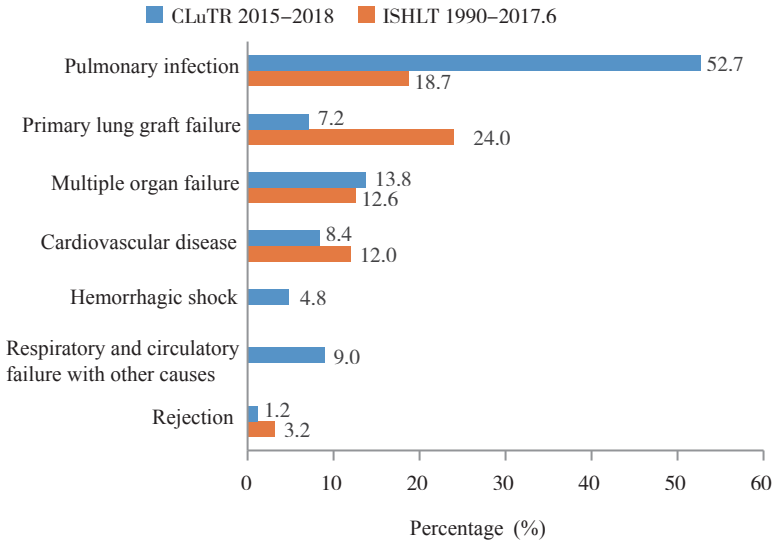


Figure 5-8 Comparison of causes of perioperative death in lung transplant recipients reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

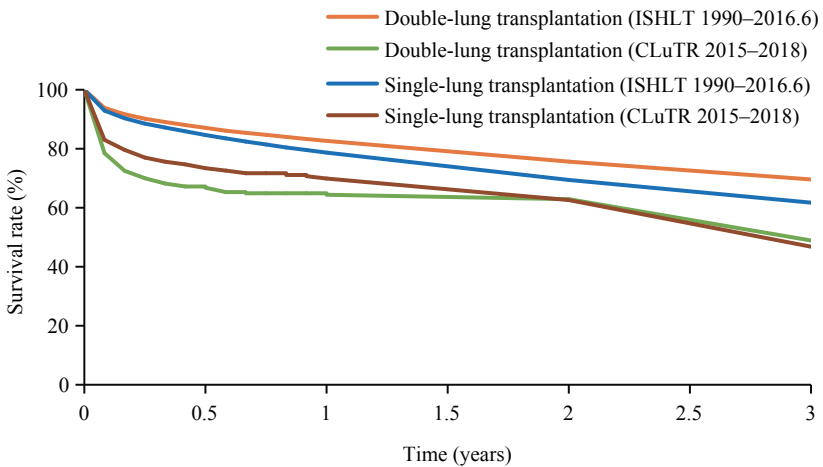


Figure 5-9 Comparison of postoperative survival time of lung transplant recipients reported by China during 2015–2018 with the data reported by ISHLT (excluding Hongkong, Macao and Taiwan)

IV. Summary and prospects

As compared with the international cases, the cases of lung transplantation in China have the features of many old recipients with critical illness, pulmonary fibrosis or occupational pneumoconiosis, difficult operation, and long cold ischemia time of deceased donor lungs. In recent years, with the establishment of the National Quality Management and Control Center for Lung Transplantation and the “Green Channel of Human Organ Transport”, as well as the formulation of the “Technical Specifications for Lung Transplantation” and the “Standard Procedures and Specifications for Lung Transplantation”, the quality and quantity of lung transplantation have been rising steadily in China. However, as compared with the international level, lung transplantation techniques in China still have a lot of room for improvement.

1. Further improve the multi-team collaboration mechanism

Lung transplantation requires the perfect cooperation of multiple professional teams, such as physicians, thoracic surgeons, intensive care specialists, rehabilitation physicians, anesthesiologists, and nurses. Up to now, surgery has become increasingly mature so it is not the bottleneck for the development of lung transplantation in China. The domestic lung transplantation team is evolved from the thoracic surgery group. Thoracic surgeons are versatile as they seek the assistance from relevant specialty only when it is necessary. However, this does not mean that we are worse than other countries in other specialties. On the contrary, our thoracic surgery, respiratory medicine, intensive care medicine, and other specialties on lung transplantation have approached or reached the advanced international level. Most of the existing lung transplant centers in China fail to transit the team building from the thoracic surgery, thereby leading to the multi-team collaboration. Although physicians of other specialties participate in the work in some transplant centers, the division of labor and degree of participation are far less refined

than those in the foreign countries. Therefore, if multi-specialty collaboration mechanism can be built, the procedure lung transplantation in China will be vastly improved in both quantity and quality.

2. Control infection at multiple stages

Infection is the leading cause of death in recipients after lung transplantation in China. The whole-process and multi-link infection control mechanism should be established for lung transplantation: ① Before the operation, high attention should be paid to evaluate the infection. For the documented infection, the suitability of transplantation should be discussed and evaluated, and the recipient infection control should be observed dynamically to determine the transplantation time. In terms of donor, the cold ischemia time of donor lung should be minimized to reduce the chances of infection. In addition, the full multi-specialty discussion should be made on the use of ECMO and type of transplant, and close communication should be kept with the medical institution of the donor lung to timely obtain the basic information of donor, such as serology and sputum culture, to further assess whether the donor lung can be used or not. ② During the operation, the operation procedures should be standardized, and the aseptic operation system should be strictly implemented. ③ After the operation, a personalized infection control plan should be developed according to conditions of the recipient to reduce the iatrogenic infection, and interventional procedures, such as catheter and bronchoscopy, should be minimized. The examination should be standardized to avoid the damages to the mucosa. Catheter should be timely removed. High-throughput sequencing of pathogenic microorganism can be performed on some patients to achieve the early discovery, diagnosis, and treatment.

3. Future directions of development

Later, the lung transplantation quality control center will establish the scientific quality control indicators for the clinical application of lung transplantation techniques, formulate the standard procedures and technical specifications, establish a standardized training base, build a multi-specialty

team, and create a complete database for lung transplantation to mine the data resources and continue to improve the quality of lung transplantation, especially the combined heart-lung transplantation, lung transplantation in children, and living relative donor lung transplantation.