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English translation of Japanese newsletter

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Inaugural Greetings from New Chairman

Introduction

My name is Kosuke Kato and I was appointed as the 4th Chairman of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) on August 1. I have been the Managing Director of Edwards Lifesciences Limited since 2013.

Established in 2009, the AMDD is now comprised of 66 Japanese subsidiaries that provide advanced medical technologies, such as medical devices and in vitro diagnostics (IVD), with its headquarters in the US (as of the end of September 2015). While many companies known to be foreign-affiliated are members of the AMDD, the AMDD is an organization that is always considering medical care and patients in Japan, the medical device industry in Japan, and how we can contribute to Japan. We, the AMDD, aim to become a true partner for medical care in Japan by making full use of the characteristics of the Japanese subsidiaries of foreign-affiliated companies, and by providing global knowledge and experience of our medical devices and IVD.

Our Initiatives

It is important for patients in Japan to have access to innovative medical devices used around the world. In a sense, the products provided by the AMDD member companies actually function as a lifeline that is essential for medical care in Japan. In order to deliver such products to Japanese patients, it is important for the AMDD to create a stable

environment for its member companies to do business in Japan. For this reason, the AMDD has taken initiatives focusing on three key tasks; 1) to resolve the device lag and gap, 2) to establish a regulatory system that takes into consideration the characteristics of medical devices, and 3) to realize a medical care system that fairly evaluates the value of innovative medical technologies.

As a result, it was very good news for us when the Act for Ensuring the Quality, Effectiveness, and Safety of Pharmaceutical Products, Medical Devices, etc. was enacted in November 2013, and we are impressed that medical devices are now handled in an independent chapter separate from pharmaceuticals. About one year after the enactment of this new Act, various companies commented that the flow from application to approval was smoother than before.

The AMDD will further work to expedite the review of medical devices through the collaborative plan for expediting the review of medical devices, etc. by promoting collaboration between makers on the applicant side and the PMDA, etc. on the government side.

Our Next Goals

Recently, the medical device industry has been attracting attention as a growth industry and the government is also stepping up to promote innovation. In order for innovation to accelerate, a mechanism to nurture it is essential. A system to properly evaluate innovation is also necessary. To establish a clear and disciplined evaluation system, it is required to provide patients with valuable medical technology at a limited medical cost. The AMDD will continue to make policy proposals toward the establishment of a better healthcare system. We, the AMDD, are built on the voluntary and proactive participation of its member companies. We are disseminating the thoughts of our member companies through numerous committees. In order to further promote various activities of the AMDD, we are now discussing turning the AMDD into a general incorporated association. The AMDD will continue to promote our activities to contribute to the development of medical care in Japan in cooperation with the Japanese government, scientific societies, and related industry associations, while maintaining close relationships with patients and healthcare professionals as before and continuing to collaborate with the US government and the Advanced Medical Technology Association (AdvaMed). Your continued guidance and encouragement of the AMDD is greatly appreciated.



Kosuke Kato
American Medical Devices and Diagnostics Manufacturers' Association (AMDD)
Managing Director,
Edwards Lifesciences Corporation

Japan and the Development of Medical Devices

Toyota Motor Corporation is the world's No. 1 automaker. Not only in the automobile industry but also in other industries, such as precision equipment and robotics, our country's engineering industries are at the top level globally. There is no doubt that Japan is the world's leading superpower in science and technology. On the other hand, we can say that the level of medical care in this country, that has led post-war Japan to having the longest longevity in the world, is also world-class. Thus, it is no wonder that Japan is leading the world in the medical device industry that applies science and technology to medical care. However, as you know, we actually have a trade deficit of about 700 billion yen per year in medical devices.

Why has the Development of Medical Devices not Progressed in Japan?

It is said that manpower, capital, and goods are necessary to activate an industry. I feel that each one of them is lacking in the medical device industry in Japan. In medical education in Japan, which emphasizes clinical medicine, education on the development of medical devices is rarely provided. The jobs of medical professionals are primarily clinical in medical settings and there are almost no medical institutions that promote medical innovation. For this reason, we can say that the interest of medical professionals in medical innovation is low.

While medical care and engineering must be closely linked for the development of medical devices, the collaboration between medical care and engineering has not been successfully nurtured in Japan. Although the academic area of biomedical engineering, which integrates medicine with engineering, has been well established in Europe and the US, Japan is lagging in this area. More than anything, I do not think that there are many people who can discern and judge medical devices because there are few successful experiences of developing them. If we liken this to the chicken-and-egg story, Japan is in a situation where there is neither a chicken nor an egg. In other words, there is no industrial base or cycle (the ecosystem), for the development of medical devices.

Issues in the Development of Medical Devices

So what should we do about this situation?

In the past, the electronics and automobile industries in Japan tried to learn from the rest of the world. Through studying and modifying foreign product industries in Japan, they could utilize them to Japan's advantage. I think that there should also be something of an attitude in the medical device industry toward actively learning from foreign products. In today's Japan, it seems to me that there is a feeling that we can do it on our own; our pride as a technological powerhouse has become an obstacle.

And what is essential when pushing forward the development of medical devices is the knowledge of medical care, engineering, and pharmaceutical affairs that can fully manage the entire development, from the early stages to after the start of sales. Unless these are well linked, it is impossible to create a medical device. In addition, knowledge of the business of the development of medical devices is necessary to succeed. For example, even if something appears to be a good medical device, there may be hurdles when obtaining the patent or pharmaceutical approval, it may not be possible to raise the development cost, or if in competition with other therapeutic methods, it may not be successful.

I often hear many people in Japan say that medical devices developed in Japan do not move forward because pharmaceutical regulations in Japan are too strict. However, I do not think that such statements are necessarily appropriate. If this statement is true, the number of medical devices approved and used in Japan should be small. In other words, the foreign-affiliated companies are expanding their medical devices globally, while responding to pharmaceutical regulations in Japan. I think that people who say this have this attitude because they only see the market in Japan.

Toward Further Development

Does this mean that we cannot do anything about the medical devices developed in Japan? I have discovered several excellent seeds for medical devices that could be expanded globally. Some of them are very high-level. Thus, I think that it is possible to develop a relatively large number of medical devices in Japan if we can successfully nurture them. However, we do not have the soil to nurture such medical devices.

That is why I established and now operate a medical device incubator called the Japanese Organization for Medical Device Development, Inc. (JOMDD). The business model of this company is to receive seeds for medical devices from researchers at universities, etc., commercialize them, and forward them on to medical device makers. In Japan, there is not an environment that supports entrepreneurs and there is a culture that failure will not be excused. As a result, not many people are willing to develop medical devices in venture companies. Therefore, at JOMDD, we receive ideas from researchers, etc. and commercialize them on our own.

I think that people working at foreign-affiliated medical device makers have a high level of skill in developing medical devices since they are involved in the development of innovative medical devices. What kind of job you select is up to you. I am sure that there are quite a few people who are willing to use their skills for the medical device industry in Japan, which is generating a trade deficit of 700 billion yen every year despite its high potential.

As I said earlier, manpower, capital, and goods are all lacking in the medical device industry in Japan. We need to work together to boost the development of medical devices from Japan. Please feel free to contact us if you are interested in the efforts of the Japanese Organization for Medical Device Development, Inc.



Takahiro Uchida
Chief Executive Officer,
Japanese Organization for Medical Device Development, Inc.

Specialist in General Medicine/Cardiovascular Medicine. Graduated from Harvard School of Public Health and Harvard Business School. Served as the first Japanese Medical Officer at the Center for Devices and Radiological Health, US Food and Drug Administration. Specialist in the development of medical devices with working experience at foreign-affiliated medical device makers. Involved in the development of products, always taking into account clinical needs and commercialization of a wide range of global products from the design of clinical studies to marketing. Has experience in public projects serving as a practical manager of the research project to promote clinical trials in Japan, which is funded by a Health Labour Sciences Research Grant. Part-time Instructor at the Graduate School of Pharmaceutical Sciences, The University of Tokyo, in 2015.

Patient's Voice

Aiming to Establish a Treatment Method and Improve QOL



Kunitoshi Kanai

President,
Japanese Retinitis Pigmentosa Society (JRPS)

A disease (retinitis pigmentosa or RP) in which visual cells of the retina are affected. All of us have experienced the desperate feeling of having nowhere to go when we were told that we would lose our sight sooner or later, or that there was no treatment for this disease. We continue to look for ways to live our lives while fighting the fear of losing our vision and part of our visual field every day.

The JRPS (Japanese Retinitis Pigmentosa Society) was established in 1994 as the Japanese chapter of Retina International (RI) as advocated by Professor Emiko Adachi, then of the Chiba University Department of Ophthalmology. Currently, approximately 4,000 members are voluntarily workers, aiming to establish a treatment method for this disease and improve the QOL of patients with RP.

With the desire to keep the light on the research of this rare disease, we award research grants every year, though they are not sufficient, to researchers and research institutes involved in studies on retinitis pigmentosa, retinoblastoma, retinopathy of prematurity, low vision, etc. This year marks the 19th “JRPS Research Grant Project.” This project is our pride and joy since it not only provides simple and temporary grants, but from keeping in touch with researchers who received grants, we can also see that it has produced many researchers who play active roles on the world stage.

As a result of the efforts of these researchers, research on RP has made significant progress in the past several years and we feel as if we can finally see a ray of light at the end of a long tunnel. The therapeutic approaches for this disease vary, including artificial retinas, neuroprotective treatment, gene therapy, and retinal regeneration by iPS cells, which has been in the news recently. RP patients are motivated to actively participate in clinical trials and clinical studies.

RP is not a common disease and public awareness of our organization, JRPS, is still low. However, we would like to tell potential patients who are distressed about this disease and feel unnoticed that they are not alone. The members of JRPS correctly understand their own disease and are waiting for the establishment of a treatment method as they battle this disease. We are hoping that the day when we can tell our grandchildren that RP is a curable disease is just around the corner.

Japanese Retinitis Pigmentosa Society (JRPS) <http://jrps.org/> (Japanese)

Voice from the Local Government

Development of Medical Devices in Kobe Biomedical Innovation Cluster (Part 1)



Masao Imanishi
Chief Operating Officer,
Kobe City
(in charge of Kobe Biomedical Innovation Center and Kobe
Enterprise Promotion Bureau)

1. Introduction

The City of Kobe started the “Kobe Biomedical Innovation Cluster Project” as a creative reconstruction effort following the Great Hanshin-Awaji Earthquake in 1998. They set 3 objectives: 1) to secure employment and activate the economy in Kobe, 2) to improve the welfare of Kobe residents by providing advanced medical technologies, and 3) to make international contributions by enhancing the healthcare standards in Asian countries.

Although the medical industry in Kobe began at zero, many companies that agree with the objectives of this project have continued to set up base in Kobe every year. In recent years, blue-chip companies with a global operational presence such as Sony, Teijin, Kaneka, Fuji Film, and Zeon Medical have moved to Kobe. On July 15, 2015, we welcomed the entrance of the 300th company.

The Kobe Biomedical Innovation Cluster has achieved a highly workable industry-academia-government collaboration in; 1) basic research industry-academia collaboration bases such as RIKEN and various universities, 2) highly specialized hospital clusters centering on Kobe City Medical Center General Hospital, and 3) clusters of over 300 medical-related companies, and grown to be one of the largest biomedical clusters in Japan.

2. State of Improvement in Infrastructure

Six universities, including Kobe University, Konan University, and Kobe Gakuin University in addition to RIKEN and Biomedical Research and Innovation, comprise the infrastructure necessary for the development of medical devices and are located in the collaboration bases for industry-academia basic research. Furthermore, this spring, the “Integrated Innovation Building (IIB)” opened as the fourth facility of RIKEN in Kobe. In addition, the manufacturing technology base and development facility for next-generation biologics opened as a GMP facility to develop advanced and highly efficient next-generation manufacturing technologies which manufacture antibody drugs in compliance with international standards.

Also, in the advanced specialized hospital cluster which is a clinical setting and source of medical device needs, not only Kobe City Medical Center General Hospital, a core hospital, and Biomedical Research and Innovation, which successfully transplanted iPS cells for the first time in the world, but also other highly specialized hospital clusters which specialize in cancer (minimally invasive therapy such as radiotherapy), as well as the rehabilitation, cardiovascular, and pediatric areas, have been already accumulated as core facilities of the

Kobe Biomedical Innovation Cluster. In Fiscal 2016, Hyogo Prefectural Kobe Children's Hospital (with a complex of new particle radiotherapy focusing on pediatric cancer) is scheduled to relocate and open in the Cluster.

In this way, the City of Kobe will further improve and expand the infrastructure and facilities necessary for the development of medical devices every year based on company needs, so that we can continue to offer a more attractive environment.
(Part 2 will be published in Vol. 21 to be issued in January 2016)

7th Annual Meeting of the AMDD

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held its 7th Annual Meeting on September 17. Chairman Kosuke Kato, Managing Director of Edwards Lifesciences Corporation stated his goals as the new Chairman during his opening remarks and said that he would become actively involved in the issues that the AMDD is tackling. He also stated that he would work towards receiving the cooperation of various stakeholders, such as governments both in Japan and the US, medical device industry associations, and local governments.

We welcomed Dr. Kunihiro Suzuki, Executive Director of the Japan Medical Association, as a special lecturer. Under the title of "The Current Situation of Cost-effectiveness Evaluation in the UK, France, and Germany and the Concept of Japanese-style Evaluation," Dr. Suzuki talked about how based on his experience at the Central Social Insurance Medical Council, we should review the introduction of HTA in the future by comparing the situation in these four countries.



Left: Mr. Kosuke Kato, Chairman, AMDD

Right: Dr. Kunihiro Suzuki, Executive Director of the Japan Medical Association

AMDD Takes Part in Summer Vacation Event, Children's Kasumigaseki Tour Day, in Kasumigaseki

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) took part in the Children's Kasumigaseki Tour Day, which was held July 29-30, and exhibited various medical devices in the booth of the Ministry of Health, Labour and Welfare entitled "Touching Cutting-edge Medical Devices that Save Human Lives."

This event aims to give children the opportunity to learn about jobs at different government ministries in Kasumigaseki which they cannot usually access through tours and hands-on experience. It has been held by various government ministries with the Ministry of Education, Culture, Sports, Science and Technology as a key player for two days every year during the summer vacation since 2012.



Because last year's event was covered in the media, more parents and their children visited the venue this year than expected. They enjoyed valuable experiences by touching different medical devices they cannot usually see and picking up devices such as endoscopic equipment used in tests, forceps used in laparoscopic surgery, instruments to remove clots in blood vessels, and biological valves for the heart. This year's event also included an exhibition on physical examination. Children could put on lab coats and practice giving an examination.

Value of Medical Technology <Diagnostic and Therapeutic Devices>

Spread of Pocket Echo



Ultrasound diagnostic devices are significantly less invasive to subjects compared to x-ray equipment and are used in many medical settings. However, because conventional devices are heavy and most of them are equipped with wheels, they need to be pushed to move around. For this reason, it is difficult to use them in small spaces or outside of hospitals.

A pocket-type echo which can be used like a stethoscope is well supported and used in many medical settings, not only those outside of hospitals such as home care/house calls, medical helicopters, doctor's cars or DMAT, but also inside hospitals such as in the ICU, hospital wards, and outpatient clinics.

When a patient's condition suddenly changes, doctors are concerned about a patient's condition, or in an environment where there are no adequate testing means, many doctors highly value this reliable pocket-type echo which can be quickly taken out of their pocket. Even in developed countries, there are many situations where it is impossible to secure adequate medical means depending on the time and location. Not limited to this ultrasound diagnostic device, there seems to be an increased need for small medical devices that can close such medical gaps.

(Article written with full responsibility by Masayuki Murai, GE Healthcare Japan Corporation)

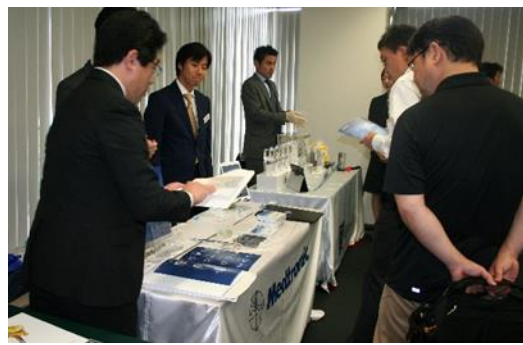
AMDD Holds the 25th Media Lecture - Valvular Heart Disease Quietly Increasing in an Aging Society -

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held the 25th Media Lecture on July 17 in Tokyo. Under the topic of “Valvular Heart Disease Quietly Increasing in an Aging Society - Extending Patients' Healthy Life Span with the Most Appropriate Diagnosis and Treatment,” we asked two doctors to deliver lectures by classifying the topic from the diagnostic method to the latest treatment method for valvular heart disease.

First, Dr. Hiroyuki Watanabe, Director of the Heart Center of Tokyo Bay Urayasu/Ichikawa Medical Center talked about the diagnosis of valvular heart disease. Dr. Watanabe pointed out that the number of patients with valvular heart disease is increasing in an aging Japan and that valvular disease itself is becoming diverse due to aging. He also stressed the need to treat the disease with a diverse team that have a high degree of professionalism.

Next, Dr. Shuichiro Takanashi, Chief Director of the Department of Cardiovascular Surgery of Sakakibara Heart Institute talked about the treatment of valvular heart disease. He talked about valve replacement, valve reconstruction surgery, and other treatments, using images of actual surgery, as well as about the latest treatment for valvular disease such as TAVI. (See inserted articles for summaries of the lectures by Dr. Watanabe and Dr. Takanashi)

At the back of the venue, medical devices such as image diagnostic equipment, biological valves, and mechanical valves, which are actually used in the diagnosis and treatment of valvular heart disease, were exhibited.



Left: View of the media lecture

Right: View of the exhibition of products

Valvular Heart Disease Quietly Increasing in an Aging Society

The summaries of the lectures by Dr. Hiroyuki Watanabe and Dr. Shuichiro Takanashi at the AMDD's Media Lecture titled "Valvular Heart Disease Quietly Increasing in an Aging Society," held in July, are featured below.

Valvular Heart Disease to be Tackled by a Heart Team

What is Valvular Heart Disease?

Valvular heart disease is a disease that causes stenosis or regurgitation because of an abnormality in blood flow as a result of deformation of a valve. Valvular disease is mainly classified into two types: stenosis and regurgitation.

Aortic stenosis is a typical disease of stenosis and refers to the condition in which the aortic valve located in the exit of the left ventricle, which sends blood to the whole body, hardens and gets stuck because the opening of the valve is limited. A complete cure for aortic stenosis by medication is difficult and a surgery called aortic valve replacement (AVR) is necessary.

The valves to be replaced include the mechanical valve, biological valve, etc. and each valve has pros and cons. Patients who use mechanical valves are mostly those under 65 years old. Although the mechanical valve does not deteriorate, patients must take a drug called warfarin for the rest of their life that makes blood less likely to clot. Biological valves are for patients aged 65 years or older. While they do not need to take warfarin, they do have to undergo repeated surgery to replace the biological valve because it deteriorates.

Mitral valve incompetence is regurgitation and it refers to the condition in which the movement of a valve called the mitral valve, located between the left atrium and the left ventricle, slows down and becomes unable to completely shut, causing some blood to leak from the left ventricle into the left atrium. Because this disease is often seen in young people and athletes, the phrase "healthy patients with valvular disease" is used in the guidelines.

The treatment for mitral valve incompetence is valvuloplasty. Regurgitation of blood at 60ml (equivalent to 1 bottle of Tabasco) per heartbeat is considered serious and requires surgery. The ability of a patient's body to repair itself is important for this diagnosis, and we must correctly discern the valve's ability to repair.

Response to Aging Patients

Despite the advancement in treatment techniques, it is said that 30 to 50% of patients are not appropriately treated. One of the reasons is because of a rapid increase in elderly patients. At our hospital, more than half of the patients are over 70 years old and very elderly patients over 90 years old are not uncommon. In the age when valvular heart disease was frequently attributed to rheumatic fever, the majority of patients were young and we could start to treat them quickly if they showed any symptoms. However, because the majority of patients are now elderly, they are no longer physically strong and have multiple diseases. It is difficult to decide on the timing to perform surgical treatment and we have no choice but to take a wait-and-see approach for many patients. For the treatment of elderly patients, we must take into account not only their data, such as from CT scans, but also their level of living autonomy and frailty.

Delayed discovery also increases the number of untreated patients. For example, shortness of breath is one of the symptoms of stenosis. Because the elderly often have shortness of breath on a daily basis, they do not notice their own symptoms in some cases. When shortness of breath becomes severe, it is already too late to see a doctor. At that point, the heart function itself has already weakened, which makes treatment difficult.

The American Heart Association (AHA) has issued guidelines for the indicators of treatment. The guidelines list 5 points to confirm: 1) symptom, 2) topical severity, 3) cardiac response, 4). effect on the circulatory system, and 5) presence or absence of arrhythmia. The clinical condition is classified into 4 stages: A. risk of developing, B. ongoing, C. severe asymptomatic, and D. severe symptomatic. Stage C refers to patients whose condition is serious but they have no symptoms, as often seen in the elderly. The guidelines clearly show the presence of such patients, which is groundbreaking.

The Future of Treatment of Valvular Disease

A less invasive surgery called transcatheter aortic valve replacement (TAVI) is increasing as a medical therapy for valvular heart disease. Since TAVI can treat the disease with a catheter without thoracotomy, it has been applied to high-risk very elderly patients and physically fragile patients. However, some report that the prognosis after TAVI is similar to that after valve replacement for moderate-risk patients. I would like to wait and see what possibilities the future holds. There are other cutting-edge treatments such as MitraClip which make it possible to attach a clip to the valve using a catheter.

Because the treatment for valvular disease continues to evolve, we cannot keep up with it unless both internists and surgeons are on the treatment team. Not only us doctors but also other people including nurses and physical therapists, and of course patients and their families undertake the treatment as a team.

The common language between internists and surgeons who are often prone to clash with each other is “diagnostic imaging.” The data is a deciding factor in making the final judgement using echo, CT and MRI data. I used to team up with Dr. Takashi at the same hospital, taking advantage of the common language. We learned from each other by learning the procedures for surgery, explaining the diagnostic imaging, etc. I think that cross-learning and cross-training in such a team will become more important than ever in the future.

*This article was summarized by the editorial department based on a lecture given by Dr. Watanabe.



Hiroyuki Watanabe

Heart Center Director,

Tokyo Bay Urayasu/Ichikawa Medical Center

Graduated from Hirosaki University School of Medicine in 1987. Joined the Third Department of Internal Medicine, Chiba University, in 1987. Resident of the First Department of Internal Medicine, Osaka City University, in 1995. Head Physician of the Department of Cardiovascular Medicine, Kobe City Hospital Organization Kobe City Medical Center West Hospital in 2003. Director of Department of Cardiovascular Medicine and Head of Echocardiogram, Sakakibara Heart Institute in 2010, Director of Heart Center, Tokyo Bay Urayasu/Ichikawa Medical Center in 2012.

Surgical Treatment for Valvular Heart Disease

Type and Treatment of Valvular Heart Disease

The heart is divided into four chambers: right and left atria, which receive blood, and right and left ventricles, which pump blood out of the heart. Valves are located between these chambers; there are four valves called the tricuspid valve, mitral valve, pulmonary valve, and aortic valve. Of these, the mitral and aortic valves are the main targets for cardiac surgeons. The aortic valve is located in the center of the heart, while the mitral valve is located in the left back of the aortic valve.

Diseases of the mitral valve include mitral valve incompetence and mitral valve stenosis. Mitral valve incompetence is a disease in which the valve no longer functions normally and blood backflows from the left ventricle into the left atrium. In many cases, mitral valve incompetence is treated with valvuloplasty which reconstructs the deformed valve with the patient's own-valve. In surgery, the valve is reconstructed by expanding the tissue after removing the hardened extra tissue and suturing a ring to the patient's own valve.

In the case of asymptomatic valvular disease, the guidelines recommend that patients who have a 90% probability of being unable to maintain a favorable condition for 10 years should not receive surgery. Thus, this is an extremely difficult surgery. However, we are proud of our achievements in that, among the patients who received valvuloplasty at this hospital, only one-tenth of them need to undergo repeat surgery in 10 years. Since the difficulty level is high, valvuloplasty is a surgery that is not easily applicable to patients whose condition is not serious.

The major disease of the aortic valve is aortic valve stenosis. In this disease, the aortic valve hardens, which narrows the blood pathway and worsens the blood flow. Aortic valve replacement is performed for the treatment of this disease. I perform aortic valve replacement using a method called simple ligation which does not require excessive buffers. Because I can insert a relatively large valve with this method, even if the patient needs repeat surgery later, I will be able to treat the patient with a catheter.

In some cases, the blood flow is disrupted not only due to the aortic valve itself but also as a result of a damaged artery. In such a case, we perform a surgery to reconstruct the aortic root, while preserving the valve. There are two methods for this surgery: reimplantation (David surgery) and remodeling (Yacoub surgery). What we are doing is valve-sparing aortic root reconstruction/aortic valvuloplasty, which can be said to be an ideal surgery that combines Yacoub surgery with annulorrhaphy. If the patient's own valve is preserved, he/she can live without taking warfarin. This is good news especially for young patients.

The artificial valves used for valve replacement include the mechanical valve, the biological valve, and the patient's own valve. The patient's own valve uses his/her own pulmonary valve. While a mechanical valve that does not deteriorate is suitable for young patients, because they need to take warfarin for the rest of their lives, biological valves are used mainly for elderly patients and those at a high risk of embolism, etc. A benefit of the patient's own valve is that he/she does not have to take warfarin. However, because we need to perform surgery on both the artery and the pulmonary artery, the operative stress is larger.

Future Treatment of Valvular Disease

In the midst of fast-evolving treatment methods, a less invasive surgery called MICS is attracting attention. It requires only a 5cm incision in the skin and approaches the heart by inserting a special instrument without having to break the breastbone. So we can do the same surgery as in median incision. Because we do not need to cut the bone, we can significantly reduce the postoperative burden on patients. Patients can be discharged from the hospital and return to their normal daily lives within about five days after surgery by enriching rehabilitation. Of course, MICS also has disadvantages. It is said that the risk of complications increases because the duration of surgery is long.

Cardiac surgeons team up with physicians in the department of cardiovascular medicine to perform surgery which uses a catheter; this is called a transcatheter aortic valve implantation (TAVI). Because TAVI does not require thoracotomy (no need to open the heart with surgery), elderly and physically fragile patients can also receive it. We are stably producing good therapeutic results.

The scientific community, for example, now provides training courses on catheter-based treatment for surgeons. We have entered an era when surgeons must also understand medical treatment. While it may be difficult for physicians in the department of cardiovascular medicine to master the techniques, it is important for us to acquire their medical mindset. Once we can understand it, we can make objective decisions.

Dr. Watanabe and I used to work together until not long ago. Under the diagnosis made by Dr. Watanabe, we performed surgery. If there was any problem, we gave each other feedback. Both of us tried to improve and develop our techniques by learning from the other. I believe that such cross-learning will be more important in the future. I would like to continue to provide treatment, while mutually enhancing our techniques by making full use of the “common language” that Dr. Watanabe talked about.

*The article was summarized by the editorial department based on the lecture given by Dr. Takanashi.



Shuichiro Takanashi

Chief Director, Department of Cardiovascular Surgery,
Sakakibara Heart Institute
Member of Japan Research Promotion Society
for Cardiovascular Diseases

Graduated from Ehime University School of Medicine in 1984. Became a clinical resident in the Department of Thoracic Surgery at Hyogo College of Medicine in 1986. Became Director of Department of Cardiovascular Surgery at Shin-Tokyo Hospital in 2001. Became Chief Director of Department of Cardiovascular Surgery at Sakakibara Heart Institute in 2004. Became specially-appointed Professor in Department of Cardiovascular Surgery at Teikyo University School of Medicine in 2009, Vice Hospital Director of Sakakibara Heart Institute and Chief Director of Department of Cardiovascular Surgery in 2012, and Visiting Professor, Keio University School of Medicine in 2015.

Value of Medical Technology

Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.