

# AMDD VOL.5

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## NEWSLETTER

\*English translation of Japanese newsletter

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### **Prostate cancer: From medical checkups to surgery and prognosis**

As in other countries, the incidence of prostate cancer in Japan is said to be increasing, accompanying aging population and westernization of the diet. Professor Yoichi Arai of the Department of Urology at the Tohoku University School of Medicine comments on medical checkups and treatment for prostate cancer.

#### **16% of male cancer patients have prostate cancer**

Early-stage detection of prostate cancer is increasing rapidly. As our population ages, we cannot overlook the importance of the propagation of simple and convenient PSA screening tests and the establishment of safe and precise examinations using rectal echocardiogram testing. In the U.S., prostate cancer holds the top position in cancer morbidity, and one out of every six men will suffer prostate cancer in their lifetime.

Until now, prostate cancer morbidity among Japanese men was determined to be about 10% of that in the U.S., but according to cancer patient registrations at Tohoku University Hospital in 2007, the most common type of cancer is prostate cancer, and one sixth of all male cancer patients have prostate cancer. Among elderly male cancer patients, one fourth have prostate cancer.

As early detection of prostate cancer has become possible, choices of medical treatment methods have diversified. In addition to radical prostatectomy, radiation therapy and hormone therapy treatment, the new choice of "observation of progress and no further treatment" has been added. The latter is known as *active surveillance* (PSA monitoring treatment).

The physician does PSA checkups from time to time to monitor any changes in the patient's condition, and carries out concrete medical treatment when the PSA level rises. Although the most common incision currently used in Japan is midline laparotomy, it is

expected that minimally-invasive surgery such as endoscopic surgery—which requires only tiny incisions—and robotic assisted laparoscopic surgery will increasingly be used. In the U.S., robots are used for over 80% of all radical prostatectomies. In addition to radiation therapy that applies X-rays from outside of the patient's body, brachytherapy, the implanting of small radiation sources in the affected area, is increasing in popularity.

### **Artificial urinary sphincter for serious urinary incontinence**

Erectile dysfunction (ED) and urinary incontinence can occur as complications after radical prostatectomy.

ED occurs when the erectile nerves running along the sides of the prostate gland have been damaged during surgery. Erectile dysfunction treatment drugs are effective for this. Also, after anastomosis of the bladder and urethra near the sphincter, a powerful sneeze can cause urine leakage because of abdominal pressure on the bladder. In most cases, pads (diapers) for urine leakage will not be needed for longer than six months, but 1-3% of patients suffer a continuing serious urine leakage problem following radical prostatectomy. This occurs when the sphincter that tightens the urethra has been damaged. The number of patients relieved of this problem by implanting an artificial urinary sphincter is increasing.

We have over 30 years of actual results in clinical practice of artificial urinary sphincter implant surgery. Under general or spinal anesthesia, one or two incisions are made near the scrotum, a cuff that functions as a urinary sphincter is wrapped around the urethra, a control pump is inserted under the skin of the scrotum, and a pressure control balloon to hold fluid is implanted in the abdomen. The patient applies finger pressure on the control pump to move fluid out of the cuff into the balloon and allow urine to flow out.

4,500 surgeries to implant artificial urinary sphincters (3% of the number of radical prostatectomies) are carried out annually in the U.S., 110 (1.6% of the number of radical prostatectomies) are done annually in Austria, and about 100 a year are carried out in Korea, where health insurance coverage for this surgery was approved 4 years ago. In Japan, the average is 7 cases per year, and only AMS products are implanted. Artificial urinary sphincter implant surgery is done at only 5 institutions, including Tohoku University Hospital and the National Cancer Center Hospital, and patients must pay ¥1,700,000 for this surgery. Also because foreign material is placed in the patient's body, it is necessary to be alert for infection. The Japan Urological Association has estimated that about 400 patients per year are suffering serious leakages of urine, so we have started a committee to propagate this surgery.

\*Professor Arai's comments were prepared for publication by the editorial department Professor Arai, Department of Urology, Graduate School of Medicine Tohoku University

Professor Yoichi Arai Graduated from the Faculty of Medicine at Kyoto University in 1978. He trained in the Department of Urology at the Kyoto University Hospital and then worked in the Department of Urology of Toyooka Public Hospital. Professor Arai an Assistant and Lecturer in the Department of Urology Kyoto University Hospital in 1987, and then Chief Manager of the Department of Urology at Kurashiki Central Hospital in 1993. He has held his current post since 2001 and is also concurrently the vice director of Tohoku University Hospital.

## **Medical device innovation by bundling industrial wisdom**

The Japan Federation of Medical Devices Associations (JFMDA), American Medical Devices and Diagnostics Manufacturers' Association (AMDD) and European Business Council (EBC) Medical Devices Committee, jointly submitted a written proposal concerning the Japanese government's national "Strategy for a healthy nation through life innovation" on April 26. We asked Kazuro Ogino, Chairman of JFMDA, the medical devices industry association of Japan, to comment on the challenges and development of Japanese medical device industry.

### **JFMDA's mission: to ensure a stable supply of medical devices**

The Japan Federation of Medical Devices Associations now consists of 20 organizations, representing about 4,900 affiliated companies. JFMDA members supply about 300,000 items, ranging widely from large medical diagnostic imaging devices, to materials used in ophthalmology and dentistry, and sanitary articles. All this merchandise directly affects patients' lives, so we pay particular attention to the safety of each item.

The worldwide market for medical devices has grown, but Japan's medical device market is shrinking. Japanese medical devices held a 15% share of the world market a decade ago, but they have recently dropped to only 10%. Particularly notable is that Japan's imports of medical devices are more than double its medical device exports, creating a huge trade deficit. Japanese diagnostic equipment still shows international competitive power, but in the present situation, Japan depends on imports for quite a large portion of the most advanced medical devices used here.

The Japanese medical device industry's most important mission is to maintain the supply of medical devices at all times. If the industry cannot cope immediately with emergency situations, this will interfere with surgery and emergency treatment, and endanger patients' lives. We must maintain mechanisms that enable us to provide a stable supply of the most advanced medical devices to patients in Japan, regardless of whether these products are domestic or imported. There is an enormous variety of medical devices, and each enterprise and nation has its strong and weak areas. The role of JFMDA in this global environment is to create an atmosphere that is conducive to creating better medical devices to continuously support the most advanced medical treatment for Japanese patients.

### **"CE mark" for enterprises in Europe**

Japan currently depends on imports for many advanced medical devices. The fact that Japan is weak in developing medical devices is related to the burden of clinical testing. Japan's system for clinical testing is not yet complete, requiring much labor, time, and expense, and dampening the ambition for developing and commercializing new devices. When a company is trying to develop very good products but finds this is not profitable, such products will never be produced and sold. For a medical device to be introduced to medical institutions, it is necessary to pass examinations and obtain approval from each nation. Japan's Pharmaceutical Affairs Act is so strict that advanced medical treatment technology from around the world arrives in Japan much later than in Europe and the U.S. and many patients in Japan cannot enjoy the benefits of advanced technology. This "device lag" hampers not only overseas enterprises but also Japanese enterprises.

In Europe, however, when an enterprise has obtained a "CE mark" from a quality control system approval organization, that enterprise can sell its products with the company itself

taking responsibility for them. Special devices such as artificial hearts must undergo clinical tests in human beings, but clinical tests in Europe require fewer cases than in the U.S. Also, in Germany, hospitals can try new products, opening a route that allows the rapid introduction of good products. For such reasons, advanced medical devices are used in Europe first, spreading to the U.S. and Asian countries next, but in some cases, by the time advanced medical devices are approved in Japan, they are already outdated.

### **Arranging an environment where enterprises can act freely**

In order to vitalize the medical device industry in Japan, we must create an environment where enterprises can act freely.

Simplifying the mechanisms of administration and increasing the efficiency of examinations are important now. For instance, once the administration has examined individual enterprises and confirmed that these enterprises have established appropriate check systems in their product development, the administration won't need to take time to examine every item for each enterprise.

Drastic reform is needed, including revision of the Pharmaceutical Affairs Act. We have recently noted a change of consciousness on the administrative side. The Japanese government announced its new growth strategy, "Strategy for a healthy nation through life innovation" in June. In April, three medical device industry associations, from Japan, the U.S. and Europe, demanded a review of the system regarding 3 points: "vitalizing research and development," "acceleration of approval" and "evaluation of innovation," and requested the reflection of these points in a working plan.

To date, the development of medical devices has been carried out based on suggestions from medical practitioners, but the possibility of technical innovations should open up if clinical research on devices suggested by enterprises is permitted. Our government must lead the medical device industry by determinedly standing up for the viewpoint of ordinary people. Regarding this, the government must improve the problem of the medical system collapse presently occurring in Japan. Industry cannot operate effectively while the actual sites of medical treatment are in disarray. The first thing necessary to vitalize the industry is regulatory reform. When each enterprise can demonstrate its specialties, and an environment where enterprises can act freely is achieved, the industry will be spontaneously vitalized.

Mr. Kazuo Ogino  
Chairman, The Japan Federation of Medical Devices Associations (JFMDA)  
Chairman and Chief Executive Officer, Nihon Kohden Corporation

Mr. Ogino completed the post graduate course in electrical engineering in the Graduate School of Science and Engineering at Waseda University in 1966, and then joined Nippon Telegraph and Telephone Corporation. He joined Nihon Kohden Corporation in 1985, becoming President and Chief Operating Officer in 1989, and then Chairman and Chief Executive Officer in 2008.

## **Patient's Voice**

### **Learning how to cope with chronic disease**

By Ms. Mihoko Chiwaki, Japan Chronic Disease Self-Management Association, specified non-profit corporation

With the aging of society and lifestyle changes, the number of people with chronic diseases is increasing every year. Chronic diseases are long-term illnesses. For people with acute diseases, the goal of medical treatment is complete recovery. On the other hand, for people with chronic diseases, the goal is to live and cope with their diseases while controlling associated discomfort as much as possible.

One support program for chronic disease patients is the “Chronic Disease Self-management Program (CDSMP).” The CDSMP is a patient education program which started in the 1980s in the U.S. at the Patient Education Research Center at the Stanford University School of Medicine. The program is designed as a series of two and a half hour workshops held once a week for a total of 6 times (6 weeks), with chronic disease patients working as program directors, enabling participants to build confidence and develop techniques for self control of their diseases. The workshops have a fixed curriculum. The CDSMP has now been developed in 22 nations and areas around the world. A distinctive characteristic of these workshops is the sympathetic interaction among peers (colleagues). Large volumes of evidence in many country attests to the success of these workshops.

This association was established in Japan in 2005, when the CDSMP was introduced. Between then and July 2010, 96 CDSMP workshops were held, with a total of 915 participants. A before-and-after comparison survey of workshop participants carried out by the Health Sociology class of the Graduate School of Medicine and Faculty of Medicine, The University of Tokyo, found significant improvement in patients' self-care measures, understanding of the degree of patients' recognition of their disease conditions, and improvement of patients' feelings about their own health.

Patients with a wide range of chronic diseases can participate in the CDSMP. Although the types of diseases differ, the suffering of chronic disease patients has common characteristics, and participants learn self-control techniques which are useful for solving their problems. Patients learn communication skills, something not previously provided in patient education, and they also learn about matters that require special attention when they start using new medical treatment methods.

One patient with Type 1 diabetes who participated in the workshop took the opportunity to study various treatment methods and was able to consider suitable treatment methods together with the doctor in charge, finally deciding to use an insulin pump, which has been helpful in improving blood sugar control.

Advancements in medical devices used for diagnoses and medical treatment give patients more choice when selecting suitable medical treatment, leading to improved QOL (quality of life). However, even the best, most excellent medical treatment does not always provide a single right answer that fits all patients. I want to expand the CDSMP further to support people with chronic diseases so that they can find the best, most suitable selection of treatments.

#### About Ms. Chiwaki

Born in Chiba prefecture (1978)

Developed fulminant type 1 diabetes at age 22 (2000)

Developed hyperthyroidism (2005)

Trained as chronic disease self-management program leader and started leadership activities (2005)

Became Secretariat of the Japan Chronic Disease Self-Management Association (2007)

## **Medical Journalist Viewpoint**

### **New perspectives on the appraisal of medical device innovation**

By Mr. Toshihiko Yano, Senior staff writer, Science and Technology Department, editorial bureau, Nihon Keizai Shimbun

In June, in its science and technology section, the Nihon Keizai Shimbun published a series of articles on, “Barriers to growth of the medical device industry in Japan.” Our aim was to determine the potential of Japan's medical device industry—which lags behind the medical device industries in the U.S. and Europe in the fields of artificial hearts and catheters—being able to overtake these industries in the U.S. and Europe, and whether or not it can really grow into a competitive industry as the Japanese government has planned.

One matter that came up while I was collecting data is that medical treatment in Japan is based on having every person in the country insured. With their strong overtones of being public services, the question is whether or not we can position the medical device industry and drug development as growing industries.

(Annual) expenditure for medical treatment in Japan totals roughly 34 trillion yen. In the future, as the population ages, medical treatment expenses are expected to increase by about one trillion yen every year. Certainly, if we consider medical treatment as an industry, it is unparalleled as an attractive market with such certain growth.

However, a major difference from other industries is that the underlying funds invested in this market come basically from taxes, insurance premiums, and payments by patients. If technological innovation is pushed further while ignoring costs, solely from the viewpoint of “saving lives,” this will surely bounce back as a burden on society in the form of a sharp increase of medical expenses.

Signs of this are visible now. New types of cancer treatment drugs have appeared one after another. Even if prolonging life is the only effect that can be expected, that brings joy to patients and their families. But the cost of such drugs can be several hundred thousand yen per month, and can easily exceed a million yen. In this system with high medical expenses, the burden on each patient does not exceed a fixed amount, but the nation's people bear the financial burden. High medical expenses appear surprisingly great from the viewpoint of healthy people who are not involved with hospitals. It is necessary to discuss whether or not such expensive medical treatment, even that using the leading edge biotechnology is appropriate. There are similar cases in the field of state of the art medical devices.

Health cannot be purchased with money. Japan is very rare among the world's nations in enjoying great longevity for its people, but we must clearly discuss the “price of life” now; otherwise the next generation will have an enormous bill to pay.

The targets of “conquering incurable diseases” and “reducing the burden on patients” must take precedence in the development of medical devices. But technology that actualizes the same functions at low cost could be a new innovation in the field of medical devices. In the Japanese medical device market, a mechanism that correctly evaluates this as “innovation” will be needed.

### **Joint press conference by AMDD and The Japan Federation of Medical Devices Associations (JFMDA)**

Proposal by medical device industry associations in Japan, U.S. and Europe, for planning of new growth strategy

The AMDD, jointly with the JFMDA held a press conference on April 26, 2010, regarding the joint presentation of a proposal by three associations, the AMDD, JFMDA and EBC (European Business Council), to the Cabinet Office, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry.

JFMDA Chairman Kazuo Ogino (Nihon Kohden Corporation) and AMDD Chairman David W. Powell (Johnson & Johnson K.K.) were present. Chairman Ogino of JFMDA explained the content of the proposal in detail, followed by a Q&A session.

The proposal presented focuses on three points: “vitalizing research and development,” “acceleration of approval” and “evaluation of innovation,” requesting that these be reflected in planning of the Japanese government’s new growth strategy, “Strategy for a healthy nation through life innovation.”

The following specific content was included in the proposal.

1. Reviewing of system for vitalization of research and development
  - Introduction of clinical research system as requested by enterprises
  - Clarification of rules for changing specifications of products in clinical testing
  - Acceleration of introduction of medical devices for rare diseases
2. Reviewing of system for speeding up of approval
  - Expansion of the scope of applications for partial changes and elimination of the need to report on very small changes
  - Reviewing of medical device classification rules
  - Reviewing of quality management examination system for individual items
3. Evaluation of innovations
  - Introduction of system for insurance listing for individual brands
  - Clarification of setting of redemption prices for medical devices
  - Reviewing and/or discontinuation of re-calculation system

In his explanation to reporters, JFMDA Chairman Ogino mentioned his hopes for the new growth strategy, and said, “I want to see how the proposal is materialized in new growth strategy.” AMDD Chairman Powell emphasized the importance of actualization of the proposal, saying, “If the entire content of this proposal is carried out, we can expect elimination of the *device gap* and acceleration of the development of new technology.”

## **Value of Medical Technology (Orthopedic material) For an early return to society after bone fractures**

There are approximately 206 bones in the human body. Medical treatment methods of bone fractures differ according to locations, fracture types, and patient age.

Bone healing can often be achieved without surgery, with splints and the like, but for aged patients there is a possibility of becoming bedridden when they must have a bone immobilized for a long time. Therefore, the number of osteosynthesis surgeries has been increasing. A distinctive feature of osteosynthesis is that the operation allows the patient to be able to move sooner. The most common bone fractures among the elderly are fractures of the neck, of the femur, spine, humerus (near the shoulder), and the distal end of the radius (the long bone on the thumb side of the forearm). Osteosynthesis materials are available to fit the shapes of each of these bones. Intramedullary nails that transfer body weight easily and dynamically, and osteosynthesis materials that include plates and pins fitted to bone shapes, and for the femur, shown at right, they must support body weight until the bone has healed. Material quality and surface processing have advanced with the progress of technology. Among the reasons why elderly persons aged 65 years and older require care, 9.3%\* are attributed to falls and/or bone fractures, the next highest risk after cerebrovascular disease, weakening due to age, and joint disease. The advancement of osteosynthesis materials is continuing day by day, helping to keep the elderly from becoming bedridden and allowing younger generations to return to society quickly after bone fractures.

\*Source: National Livelihood Survey, 2007

Ms. Asako Hashimoto, Stryker Japan K.K.

## **The 16th Media Lecture**

AMDD held its 16th Media lecture on March 30, 2010. Two urologists discussed prostate cancer, a male disease, with the theme, “Men’s Health – Prostate Cancer. Early Detection and Appropriate Treatment and Post Treatment Care are Key to Improving QOL.”

First to speak was Dr. Kazuto Ito, Associate Professor at the Gunma University Graduate School of Medicine, who clearly explained the great effectiveness of PSA examination, which is indispensable for early detection. His lecture was titled, “PSA testing to change the landscape of prostate cancer treatment – Latest information and a look at the future of testing.”

Next, Dr. Yoichi Arai, Professor, Tohoku University Graduate School of Medicine, presented a lecture titled, “Treatment for incontinence after prostate cancer surgery – The status of artificial urinary sphincter usage and its spread in Japan.”

A patient also appeared on stage and spoke about his experience of medical treatment for prostate cancer and his use of an artificial urinary sphincter.





### **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

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