Together with Little Carlos

This booklet contains information from the presentation “Together With Little Carlos,” arranged by OB/OG under the sponsorship of the student’s association and Kyoto Branch of the university’s alumni association, which was held at the Trias Festival of Kyoto Prefectural University of Medicine and its Nursing School (College of Medical Technology) between November 3-5, 1993.

“Little Carlos” was a Mexican boy, one year and two months old. He was diagnosed with lymphatic malformation, and came over here to Japan to the Children’s Research Hospital, Kyoto Prefectural University of Medicine, to receive a new treatment now available only in Japan for this intractable disease. His family had to raise money from the sale of their house and car. After knowing this fact, I decided to establish the “Fund for Saving Children of the World Who Suffer from the Intractable Disease Lymphatic Malformations.” The response to the establishment of this fund was tremendous, and donations came from many kind individuals.

Although the establishment of the fund came merely from my strong desire to be of some help to Carlos’s family, some students took special note to my actions. This summer, Mr. Masaaki Kuroda, 4th year student of the Medical School, and Ms. Yukari Kuroki, 2nd year student of the Nursing School, came and requested me to make a presentation at the Trias Festival. My first understanding was that they wanted me to make a presentation on the new treatment OK-432 therapy against lymphatic malformations now drawing attention of the medical society. However, I was wrong. They wanted me to discuss about the way “that a doctor should be when treating a patient.”

I did understand at that time that the students were interested in studying medicine not just as a science but they wanted to know how to become a doctor of humanity, able to stand face to face with suffering patients. I was much pleased to hear such words from such young students, and was willing to take on the job.

The presentation took place from 10:00 to 11:40 AM on November 3. Because this was not like my usual presentations at meetings of the medical society, I was not fully satisfied with my discourse. Therefore, I decided to write this booklet, should there be anything I left out or misunderstood during my public lecture. It is my great pleasure if this booklet can be of any service to deepen your understanding.

Shuhei Ogita
December 1993
Together With Little Carlos

Prologue

To all my friends here today at the Trias Festival: Good Morning everybody and welcome to this session.

Let me start by asking a question to all of you. What would you do if you noticed that a small child, not yet able to crawl, might die from a disease - that is, a disease which is not treatable in the child's home country - a disease that is only treatable at a distant and foreign place across a vast ocean? How would you act, if you were the child's father or mother?

Heraldo Perezales came over here to Children's Research Hospital, Kyoto Prefectural University of Medicine from Mexico crossing the Pacific Ocean, hoping to get help for his son Carlos suffering from this serious illness.

A correspondent of the Mainichi Newspaper in Mexico, Mr. Yoshinori Nakai, wrote as below in the opening remarks of his article titled, “Let prayer for help reach the Miracle God! A boy suffering from an intractable disease bets his 'small life' on Japan” in Sunday Mainichi Weekly Magazine:

"Across the Pacific Ocean, from Mexico, came a 'small life' seeking help from doctors of Japan. It was 'Little Carlos,' a boy only a year and two months old. His mother's prayer for help echoed so deep into my heart. Will her prayer reach the Miracle God?"

What made the Carlos's family to turn to a distant country Japan in the Far East?

Today I will speak why this Mexican patient has come all the way to Kyoto for treatment.

It began with a telephone call from Mexico:

I recall it was April last year. A telephone call came from Mexico City. It was Mr. Takaharu Morino, a medical attache of the Japanese Embassy. "A Mexican baby wishes to receive treatment from you. Can you tell me a little about the treatment?"

This was the only hope left to win a fight against a stubborn illness for Carlos's family.

In the midst of the Mexican-American border running 3,326 km (2,067 miles), lies a city named Ciudad Juarez. Next to Ciudad Juarez and separated by the Rio Grande River, lies the American city El Paso, Texas. Fans of Western films are probably familiar to El Paso being the town where the famous "Billy the Kid" took an active part in gun fighting.

Ciudad Juarez is a desert town where many Maquiladora (bonded manufacturing companies) were invited to set up their plants and it has been rapidly growing since then. Some of Japanese companies are also operating there.

Carlos's father, Heraldo (37 years old), was a self-employed tradesman of various materials to be used in those manufacturing plants from working gloves to uniforms for Maquiladora companies. He had crossed the Mexican-American border many times to purchase those
Carlos's full name is “Carlos Perezales.” His nickname is “Carlito.” He was born as the second child and eldest son of Patricia and Heraldo Perezales.

Carlos's course of pregnancy went smooth. Nothing unusual to the fetus was reported. Patricia and Heraldo crossed the border to the United States to give birth to their second child, the advantage being ownership of American citizenship when born within the U.S.

On July 19, 1991, Carlos was born at Southwestern Hospital in El Paso. He was born a boy of 3,100 g (6.8 lbs.) and a height of 49 cm (19.3 inches). Heraldo did not notice any abnormalities with the Carlos's body, other than his head perhaps being slightly large. However, the doctor in charge pointed out that that the area from the bottom of Carlos's face to his neck was abnormally swollen, and informed Heraldo that this was a tumor. Heraldo became shaken with the fear that his son may carry cancer.

At Southwestern Hospital, there were neither facilities nor doctors of expertise that were able to treat or judge Carlos's unusual condition. Within two and a half hours following birth, Carlos was transferred by an ambulance to Providence Memorial Hospital, also located in El Paso.

The doctor in charge of newborn babies at Providence Memorial Hospital was a son of a Mexican immigrant and was able to speak Spanish. A detailed description of Carlos's condition was given at this time. The disease was lymphatic malformation. The lesions put heavy pressure on the trachea of the throat and made breathing difficult. To prevent suffocation, the lesions had to be surgically excised. They were told that there were two doctors who were able to handle such surgery. One was a military doctor, and the other practiced in Houston, Dr. Bloss in Texas Children's Hospital. Houston was their choice.

To Houston:

El Paso was 1,000 km away from Houston. Heraldo chartered a small jet to transport Carlos to Houston. However, due to storms and tornadoes, Carlos finally arrived in Houston six days after birth. The arrival was during the night. An examination immediately followed after being carried in by an ambulance from the airport. Two days later, Dr. Bloss gave detailed explanation of the conditions.

On July 29, 1991, 10 days following birth, the first surgical operation to secure respiration took place. It was a surgical operation on the windpipe. A hole was opened on the trachea and a tube was inserted into it. After coming out from the anesthesia, it was found that milk could not pass through the gullet. The esophagus was compressed by the lymphatic malformations and his tongue came out of his mouth. Another operation took place on the digestive system. Endoscopic gastrostomy was added to open a hole on the stomach to directly
insert a tube into it.

On August 6, one week following these initial procedures, an operation on the lymphatic malformation was done. Dr. Bloss attempted to surgically excise the lymphatic malformations, but the cysts could not be completely excised, due to the danger of affecting the blood vessels and nerves of the surrounding area. Dr. Bloss decided to make a re-operation eight months later.

I would like to share with you a joke of sarcasm Heraldo told Mr. Nakai of the Mainichi Newspaper.

“In Mexico, there is a proverb that reads, ‘Children bring a piece of cake,’ which means children carry wealth and fortune with them. However, he has eaten the cake we own.”

August 6, 1991 was the starting day when Carlos was eating up all of the cake his parents had. However, this is something not to be blamed because, at this time, lymphatic malformation's first choice of treatment was surgical excision.

The fight was from this day:

From this day, the fight of the Perezales family began. Sleepless nights followed day after day. Air passing through the tube inserted in the trachea. When the tube became blocked from secretion from the trachea, all would end. Heraldo and Patricia took turns sucking the tracheal secretion from the tube, so as to prevent the tube from being blocked.

Although on case-by-case, in the intensive care unit (ICU) of the Children's Research Hospital of my practice, a nurse comes to suck the secretions from the tube every 10 to 60 minutes. Carlos's parents repeated this procedure for a period of eight months. To do this well, the couple took a three-day intensive CPR (cardiopulmonary resuscitation) course in the U.S. They even learned how to pour liquid food directly into the stomach as a way of nutrient replenishment.

Why were these procedures not done at a hospital? The reason lies in the fact that medical fees in the U.S. are extremely expensive. In Japan, one day under ICU costs 47,000 yen. Adding the suction procedures of the tracheal tube and nutrients through endoscopic gastrostomy to be 2,650 yen, this totals 49,650 yen. When medication and treatment is further imposed, the expenditures will be added up. However, due to various institutional and public benefits, the burden on the Japanese household amounts to almost none.

On the other hand in the U.S., one day under ICU amounts to $2,000 (approximately 200,000 yen). Treatment fee will be added.

Because nothing unusual was found in the fetus, Carlos was not under insurance.

As the couple spent their entire time overseeing him, their jobs were interrupted and were burdened by the high medical expenses – putting them in financial difficulties.

The big question for them was how to proceed with treatment. Dr. Bloss planned a second operation in March 1992 after Carlos had gained some weight, creating a possibility of excising
the cysts in wider area. The couple, however, was hesitant.

“\textbf{The blood vessels and nerves around the neck are of great importance. The fear of affecting the vessels and nerves are too large with surgery. In addition, unless the cysts are completely excised, the cyst will continue to spread. This means that the operations have to be repeated over and over.}”

The couple then discussed the situation with Dr. Rodolfo Monrroy in Ciudad Juarez. Although Dr. Monrroy is a pediatrician, he was fully aware of the difficulty of treating lymphatic malformations.

\textbf{Discovery of my treatment}

\textbf{Japan has the best solution:}

Heraldo searched through journal articles at a library in the U.S. It was then that he came across my article in the \textit{Journal of Pediatric Surgery} (vol. 26, 263-270, 1991). “\textit{This was it… Nightmares will be over. A normal life will return}.” Dr. Monrroy agreed as well.

Heraldo’s next project was in getting contact with the author of the article - me. Heraldo wrote a letter to me, but for some reason, it did not get to me. Heraldo, then wrote a letter to the Japanese Embassy in Mexico City. The letter, dated February 17, 1992, read as follows:

\begin{quote}
\textit{“I wish to obtain a direct contact with these doctors, and inquire further about the result of their research. I am asking a great favor of his Excellency of Ambassador Tanaka and Medical Consultant of the Embassy Dr. Morino, to help me with the procedures. My son Carlos’s second operation is scheduled for next March.”}
\end{quote}

To Dr. Morino, this was the first request from a Mexican citizen for direct help from Japan on medical procedures. Heraldo’s strong wishes reached me through Dr. Morino. This was the first point of contact between Little Carlos and me. This all happened in April of last year.

Thereafter, Carlos’s medical history, photograph, ultrasonic records, and results of CT and MRI scans were sent to me by air mail, and an investigation into the possibility of successful treatment was immediately conducted. Telephone calls and faxes went back and forth between Ciudad Juarez, Mexico City, and Kyoto. At that time, I did not know that Ciudad Juarez was hundreds of km away from Mexico City.

I predicted the success of the treatment, but felt that it would be a big burden for the family to come over to Kyoto for the treatment. I suggested that Carlos would receive treatment in his home country.

However, the medicine used for the treatment was not familiar to Dr. Monrroy and the medical community of Mexico. The drug was not yet approved in the U.S. In addition, because the area of treatment was the neck, the doctor in charge had to have much experience in such treatment. Considering all these factors, a decision was made for the family to go to Kyoto for the treatment.

\textbf{We would like to go to Kyoto for the treatment:}
Request for the therapy from patients of foreign countries were not unusual. As of April 1992, we had treated children suffering from lymphatic malformation of 57 medical facilities in 22 foreign countries. Among these patients, a few came over to Kyoto for the treatment.

A rough estimate of the medical fees was informed to them. They required inexpensive accommodations (around $100 per night). Sanjo-Karasuma Hotel, on the bus route to the hospital, was chosen and booking was made for them. Carlos's hospitalization was scheduled for October 1992 and dates of examination were booked accordingly.

It was at the end of August when Dr. Morino gave me a hone call. “Is there any possible way to have Carlos be treated as a ‘patient for clinical study’? His family had raised money from the sale of their house and car to pay for the medical expenses.”

“Patient for clinical study” is a system where the patient accepts an experimental or developmental treatment for further study of the treatment, or where the patient will be able to get free treatment in compensation for full cooperation to the learning of medical students. This system was applied to the people who were unable to pay for the medical expenses.

In other words, Carlos’s family had not enough money to come over to Kyoto to get treatment. I do not know about level of life in Mexico. It was only recently that I read in a newspaper that the minimum wage per hour in Mexico is US$1.50. I am still not able to estimate the price for that Carlos’s family sold their house and car. I knew nothing about Carlos’s long fight against his illness. All these stories came to my attention much later.

Trusting a foreign doctor in a foreign country, and to putting the life of their son in the doctor’s hands, required a lot of courage. As a doctor, there was nothing more grateful to be trusted so much. “The only words in my heart were, "I want to be of some help for them!"

An episode of a mother from Brazil:

I would like to share with you an episode. There is a letter from a mother who lives in Vitoria, Brazil. The first letter was dated August 12, 1991. However, because I was unable to read this first letter written in Portuguese, I wrote a letter addressing the problem. A second letter from the same woman came three months later, and I would like to share it with you.

Vitoria, ES Y December 11, 1991

Dear Dr. Ogita,

My name is Maria Ribero. Thank you for your letter and a present.

I sent a letter to you on August 12, 1991. However, because you are not able to read it in Portuguese, I am sending the letter translated into English.

I had a baby that was diagnosed with lymphatic malformations on the left cheek. The baby was hospitalized for four months. Although the baby received a surgical operation, she did not get well. Thereafter, the doctor made a surgical operation on the trachea, but the
results were unfortunate.

I live in Vitoria, and these operations were made in Rio de Janeiro. After a few days following the second operation, the doctors in Rio de Janeiro found the medicine called OK-432 in a medical journal in English. This is a unique medication that will be able to save the life and face of my child.

The doctor’s discovery of this medication was too late - my baby died on September 4. I believe my baby is at peace at the moment, because I believe my baby is in the Kingdom of Heaven, together with God. The life of my baby lasted for only six months. Without erasing a smile from my face, I live with another child. He is seven years old, and is my only child.

The photographs I sent you are of my baby and of the other child. I would like to have these photographs returned to me. When I had sent you these photographs, I did not realize my baby was going to die. At the moment, I do not have any photograph of my baby at hand.

If possible, would you please send me photographs of landscape in Japan? I would like to put up one photograph in the hospital that housed my baby for four months, and would like to put up the second one in my home.

I hope that you will be able to render your intelligence to the happiness and welfare of others. I know that you are a messenger of God.

I will never forget you. I will always pray for you and the friends in your hospital. I would like you to know that Jesus Christ loves you and he is the only god in the world.

I hope that you are a follower of Jesus Christ and are able to believe in him.

I hope that you will always think of the following words: Psalm 23: The Lord is my shepherd; I shall not want.

Let me end here. I greatly appreciate your contribution to the science.

May God Bless You.

As she found OK-432 therapy too late, she lost her small irreplaceable life. Every time I read this philosophical letter, I feel the mother’s grief, and it causes pain in my heart. I could not hold back my tears.

Children in foreign countries diagnosed as lymphatic malformations do not know of OK-432 developed in Japan, and will have continuous fear of death throughout their life. Children born in poverty will not be able to receive adequate treatment and will have no choice but to die. This is irrational...

My spiritual background:

I am not a follower of Christ. Nor am I devoted follower of any one. Most of my spiritual beliefs are from my mother. My mother often said to me, “do not do anything that makes others point you out from the back…even if you wear rags, hold a heart of brocade... be
honorable and do what you believe is best. I live with these words in my heart."

I did not grow up in a family of poverty, but because I lived with three other brothers, I did not grow up lavishly. My mother sacrificed her pleasure for her children’s happiness. Do what you can for others first - I believe I learned this from my mother.

I spent my junior and senior high school years at Rokkou Gakuin in Kobe City, a Catholic missionary school. It was my father who decided on my attendance to this school. He was fully satisfied with the educational principles of the school rather than as a college preparatory school.

The school had a religious time called “Catechism.” The father held lectures on the teachings of Christianity. I believe my spirit of service and devotion to others was also influenced by these lectures. I am not a member of Christianity, but I believe there is much to have learned from its teachings.

I want to be of some help:

“I want to be of some help, but how?” Therefore, I quickly went to talk with the Administration Office of the university about these matters. Unfortunately, there was not a system of patients for clinical study any more. There were also no such funds or endowments in Kyoto Prefecture or in Kyoto City to support children from foreign countries coming over to Japan for medical treatment.

A solution to the problem came from a very familiar place. I do not usually carry matters of my business into my household. However, I explained the details of Little Carlos to my wife. As a result, I found that for some reason my wife had been making contributions to such social welfare groups as the “UNICEF • attn: Tetsuko Kuroyanagi” and “Little Yuino Nomura Fund”.

Some of you may remember the “Little Yuino Nomura Fund”, and she was a patient of mine diagnosed as congenital biliary atresia who had to go to Australia to receive a liver transplant.

When Japanese children went to foreign countries to receive special treatment, should not the Japanese people assist foreign children to come to Japan for special medical procedures?

Establish a fund:

I made up my mind to establish a fund. However, I was first worried whether the information media would pick it up. Fortunately, I had connections with people of information media through past treatment of lymphatic malformation of a baby from the Netherlands, I wrote a letter to newspapers. It was September 3, 1992.

A few days later, I received good news that a news writer was going to come to see me. However, I had to resolve a big problem - how should I deal with the privacy of Carlos’s family? This request of financial assistance was actually taken up by Dr. Morino of the Japanese Embassy in Mexico, not from Carlos’s family. I had to get permission from Carlos’s family.
The privacy problem got solved soon. A correspondent of the Mainichi Newspaper in Mexico called me with regard to the treatment therapy. On September 12 the news on the Little Carlos was reported in an article with the title, "Please treat the Illness of My Son" in the Mainichi Newspaper in Tokyo. Let me refer to the part of the news article.

“A Mexican boy, one year of age and suffering from lymphatic malformation, to arrive in Japan in coming October with his family accompanied by his doctor in order to get treatment. They would like to receive a new method of therapy available only in Japan. The boy’s parents had to sell their car and house to raise money to come to Japan. They said We believe Japan is the only solution to our son’s problem. We hope that this treatment will be available to other children suffering from the same disease.”

Next problem is whether they would accept the financial assistance. We understand Mexicans are people of great self-respect. Even if funds of good will are offered, it would be impossible to force them to take it, especially if one had sold their house and car to raise funds. We went through much twists and turns before the news on the fund was released.

As a best and final solution, I asked Dr. Morino to directly take the story of the establishment of the fund to Carlos’s parents’ attention. Carlos’s parents were willing to take the funds, although they had heard nothing of the funds previously.

**Little Carlos fund in the newspapers:**

Through such course of events, the news on the Little Carlos Fund was first made in the morning paper of the Kyoto Newspaper on September 22, 1992 by Mr. Ichiro Kawamura, a news writer in its Social Section. Thereafter, the story of Little Carlos was covered with kind comments by many newspapers: Messrs. Manabu Urakubo and Kimio Kamoshida of the Mainichi Newspaper, Mr. Tomohiro Murayama of the Asahi Newspaper, and Ms. Tomoko Takemura of the Yomiuri Newspaper, to name a few of them.

The article met with a public response. Many warm donations were made. I would like to share some words from these kind people.

“I am currently unemployed, but would like to donate some money canceling the planned outing.”

There was an anonymous letter put in my mailbox along with 200,000 yen: “My child was fortunately saved at the Children’s Research Hospital. Thanks to public benefits, there was little financial burden on us. I would like to donate some money as if I paid the medical bill of my child.”

Another letter: ‘My grandchild, nine years of age, died a short life due to lymphocytic leukemia at your hospital. Day after day, a sad day follows leaving pain in my heart. Everyone did all what he/she could do to fight illness, but we are still left with much regret. We have been wondering if there is more that could have been done to save my grandchild. We would not like to experience these feelings any more. Please save Little Carlos.”

Among these messages, a letter that really made me happy was the one saying “To Little Carlos that suffers from the same disease... Dr. Ogita please make your best effort to save him.”
It was from the parent of unsuccessful patient of mine. Many donations came from within our university as well.

Nurse Adachi of the intensive care unit of the Children's Research Hospital had lived in Bolivia for two years as a member of Japan Overseas Cooperation Volunteers. She volunteered her services as Spanish language interpreter. Students of the Spanish Research Group of Kyoto University of Foreign Languages also worked as volunteer interpreters. The nurses and Chief Nurse Nishiki of the Fourth Ward of the Children's Hospital put together a collection of common and useful questions and answers in Spanish.

**Little Carlos Came:**

Carlos came to Japan on October 4, 1992 by All Nippon Airways flight 39. Nurse Adachi and I went to the airport to meet with the family. From the first impressions, we knew that they were a very nice family. His elder sister, Jessica (seven years old) was a little lovely girl and I was assured by the parent's warm love to their children. We found out later that total travel time was over 25 hours from Ciudad Juarez to Itami Airport. They were tired. We took them from Itami to Hachijo-guchi by limousine bus, then to Sanjyo-Karasuma Hotel by taxi.

Hospitalization on October 5. Examinations took place on the 5th and 6th. The results were more serious than anticipated. The CT and MRI records we had received before were those that had been taken prior to surgery. The cysts of the lesions were broken during previous surgery. The operation given in the U.S. had caused the lymphatic malformation cysts with a gossamer-thin lining to fragment, and the lesions extended to his tongue. The initial prediction of 10 days of hospitalization was not enough to get the job done.

One session of treatment requires a month of hospitalization. Several sessions are needed for the complete treatment. We decided to have Carlos stay in Japan for two sessions and have him go back to Mexico until the next. The two sessions were held on October 7 and 12, with therapy on the region of the left neck and left bottom of the face.

**What is OK-432 therapy?**

Now I would like to explain the details of the OK-432 therapy, using the slides. About 75% of patients are diagnosed by the age of two. Another 5% are diagnosed in later years. It is not uncommon for one to be diagnosed during adulthood. I personally have treated a few patients around the age of fifty.

Lymphatic malformations commonly appear in the cervical region, followed by the axillary region, buccal region, and thoracic wall. Concerning types, the macrocystic type is common in the neck, whereas the cavernous type is common on the tongue and cheek. It is very difficult, in fact, impossible to preserve the nerves and blood vessels running through the lymphatic malformations untouched when excising the lymphatic malformations.

Complications after a surgical procedure have been reported: damage to vital structures such as nerves and blood vessels, dysfunction, recurrence, and cosmetic problems. Another surgery is very difficult. OK-432 is a medicine to treat cancers by its immune system stimulating activity. OK-432 is normally injected into the skin, and it is widely known that it
causes inflammation of the skin where the shot was made. However, it is also well known that this inflammation does not leave marks on the skin.

Spontaneous resolution occurs. However, it has been rarely expected to happen. Therefore, treatment was attempted to cause inflammation on the lymphatic malformations. However, this was also unsuccessful.

Dr. Tsuto, my colleague at the Children's Research Hospital, and I discussed the use of OK-432 for the treatment of lymphatic malformations and we decided to make a trial treatment after various preparations. Our first patient was a child of an acquaintance. In four months following treatment, the lymphatic malformations on the right shoulder completely regressed. The skin became normal looking as well without any cosmetic problem.

My first patient from overseas was a boy from the Netherlands. He had difficulty in breathing from the moment of birth due to the lymphatic malformations. The lymphatic malformations ran from his chin to the cervical area. The lymphatic malformations also ran through the trachea and blocked the respiratory tract. The lymphatic malformations in the trachea were treated in the Netherlands. However, breathing did not become easier, and an operation on the respiratory tract became necessary. In addition, this posed a high risk due to the heaviness of the lymphatic malformations. To secure respiration, a tube was inserted into the respiratory tract from the nose. Another tube was inserted to send nutrients to the body.

This child was unable to leave ICU for seven months following birth. His medication fees were the highest among child patients in the Netherlands. The insurance company in the Netherlands would like him to be treated in Japan if the treatment in Japan could help him. He was sent to Kyoto for treatment, with all the expenses borne by the insurance company.

After seven to ten days following the treatment, there was a time of danger. In this therapy, there is a period when the lymphatic malformation becomes more swollen than the time prior to therapy. The lymphatic malformation of this child became swollen as well. Respiration was secured after pushing the respiration tube by 5 mm further into his tract. Dr. Deguchi, who was responsible for him, was on duty at that night and I left the hospital once. Heading home, I went to Kawaramachi Station of Hankyu Line, but turned back to the hospital and stayed there for the night.

A few months later, his photos were sent to me from the hospital in the Netherlands, showing his skin with noticeable regression in the size of the lymphatic malformation. The hospital also informed me that the operation on the respiratory tract was successful and that he was safely able to come out of ICU to his home.

In this July when I was invited to make a presentation at Nijmegen University in the Netherlands, I could reunite with the boy. He had grown up and was able to move and play like a normal child. However, because he had a tube down his respiratory tract for a long time, his larynx did not function properly.

OK-432 is not approved in the U.S. Dr. Smith, Pediatric Otorhinolaryngology Division of University of Iowa, acknowledged the significance of OK-432 therapy and invited me to the States to present a lecture at the Annual Head and Neck Cancer and Reconstructive Surgery Course. I proposed a collaborative study of the therapy in order to obtain the FDA approval
for OK-432 and we started the study together. I also gave explanations on clinical side of the treatment as well at the university. Because I do not have a doctor’s license in the U.S., I stood behind the residents and coached them on the procedures.

The girl who is living in Chicago, Shauna was diagnosed with lymphatic malformations in the bone, which was also known as Gorham-Stout syndrome. The lymphatic malformation in the bone melts her bone. In the first report of this disease, it was reported to have a “boneless arm.”

The lymphatic malformation of this girl extended from the second rib to the right shoulder joint. Half of the second rib cage had already melted, and respiration became difficult due to pleural effusion. As her father was an orthopedic surgeon, he was able to give an accurate diagnosis of his daughter. At the same time he understood that there was no treatment method for this disease. Losing all the hope, he was overwhelmed with grief. Soon, he heard about my treatment and contacted me. In fact, I did not know that such disease exists. I studied about this disease with the references provided by him.

I sent the medication, along with treatment procedures to him. Although this patient was living in Chicago, they flew to San Francisco to be treated by a famous pediatric surgeon. One or more faxes had been sent to me every day informing of the progress of the treatment and inquiry about the treatment method. There were times when I gave instructions on the treatment method by time schedule and its progress.

Shauna sent to me a letter of appreciation when all was finished successfully.

**Greeted by a mariachi**

I would now like to introduce a video. This was filmed in June 1993 during the visit with Dr. Tsuchihashi, Head of Pathology Dept. of University Hospital, to Providence Memorial Hospital in the U.S. and Centro Medico Hospital in Mexico.

To our surprise, we were greeted with music by a mariachi band after a long flight to Mexico.

Newspapers and TV’s in the U.S. also made coverage on OK-432 therapy and Little Carlos, and the “Little Carlos Fund U.S.A.” was established. I also appeared on television and gave explanations on lymphatic malformations and on OK-432 therapy.

Now, I would like to return to Little Carlos. This is a video during Carlos's family's stay in Kyoto, made possible by Mr. Takeshi Maeda, reporter of Kyoto Branch, Yomiuri TV.

I think Carlos's family will spend Christmas in Kyoto this year. With the help from the fund, they plan to come to Japan on December 5. From the 6th, Carlos will be hospitalized for three weeks and will receive therapy. The first priority is to treat the lymphatic malformations compressing the trachea and the gullet. Because Carlos had received surgery first, our treatment was made very difficult. His father Heraldo was aware of the situation very well.

Crossing the Pacific Ocean and being treated by a foreign doctor in a foreign country — how
Heraldo is feeling?

Believing in faith from God and praying for miracles, they came to us for mercy. I really wish to do all what I can do.

**OK-432 therapy in the world:**

In Japan, 37 facilities from Hokkaido to Kagoshima have taken part in joint research, and the therapy is now in the process of getting permission of treatment under medical insurance from the Ministry of Health and Welfare.

In the rest of the world, OK-432 therapy has been tested at 92 facilities of 33 countries in Asia, Africa, Europe, Scandinavia, and North and South Americas.

This year, I made presentations on the therapy in El Paso and Iowa in the U.S., Merida in Mexico, Padova in Italy, Nijmegen in the Netherlands. I also made a conference presentation in Manchester, Great Britain.

Despite these efforts to make the world aware of the treatment, there are still many people who are not aware of such treatment developed in Japan.

When I visited Merida City in Yucatan Peninsula of Mexico, Mr. Nakai of the Mainichi Newspaper asked me “Why have you gone so far?”

My answer was: ‘It is difficult to find a new treatment method to a disease. It is even harder to receive respect and approval of the new treatment method from others. There is a patient who needs my treatment by my therapy in the country across the Pacific Ocean. As a doctor and researcher of the new treatment, there is nothing more grateful to be of some help. What a blessing it is! I am willing to go anywhere as long as my knowledge and experience can be of any assistance.”

Recently I was invited by the Medical Society of Sweden to talk on OK-432 therapy at the Congress of the Scandinavian Association of Pediatric Surgeons in next May.

**From St. Jude’s Hospital:**

I would like to share some words from a letter I received from St. Jude’s Hospital in the U.S., a hospital famous for treating pediatric cancer.

Precious Life

Life is a precious gift.

Most people never realize the value of their life until faced with death. For children with cancer or other rare childhood disease, this lesson comes early - too early. Before they ever learn to live, some must learn to die.

While many children lose their battle against these dread diseases, thousands more survive. Thanks to the staff at St. Jude Hospital and their life-saving research.
Twenty years ago, children diagnosed with leukemia were offered little hope. Today, because of research, childhood leukemia is considered curable.

St. Jude stands on the threshold of a dream - that someday no child will lose his/her life to catastrophic illness. But there is still much work to be done, more diseases we must conquer.

You can help make this dream a reality by sending your tax-deductible gift to St. Jude. Give the gift of life.

In conclusion:

The medical students, nursing students, and medical staff here, by no doubt, stand here at the entrance of a dream to come true. I ask every one to contribute your excellent ability to the development of medicine and those people who suffer from diseases. And, all medical students, please be willing to dedicate yourselves to distributing your fortune you are now enjoying to your patients and their families. I am closing my presentation with these words wishing the dream come true.


Afterword:

There is no boundary of language, nationality, or faith in the parent's love to his or her own children and sympathy from others with those loves. After the news in Japan was reported in Texas, U.S.A. and in Chihuahua, Mexico, the “Little Carlos Fund, U.S.A.” was established, giving priority to children of poverty in the Continent of North and South America.

Little Carlos and his family found an entrance to life. However, OK-432 therapy is still not available to many children who suffer from lymphatic malformations in foreign countries, and they have to lose their lives. Many are still stuck under the financial door.

Although a treatment method is found for a once deadly disease, its application still remains at a low end. We must make every effort to spread the treatment method throughout the world through contribution to academic journals, presentations at international conferences, education of the people who are not in the medical society, and another problem - solution for financial problems. It is a long way to conquer many diseases. Through Carlos's case, I would like to convey these things. I hope the booklet can be of some help to the students who are groping for the way “that a doctor should be when treating a patient.”

Postscript: Item 1, Article 7-2 of the Drugs, Cosmetics and Medical Instruments Act provides about orphan drugs. OK-432 was named as an orphan drug in the Notification No. 41 of the Ministry of Health and Welfare and it was published in the official gazette (volume 1286).

The information I have provided in this presentation from the time of Carlos's birth until getting in contact with Dr. Morino of the Japanese Embassy in Mexico is by courtesy of Mr. Yoshinori Nakai, Correspondent of the Mainichi Newspaper in Mexico from his article “A boy suffering from an intractable disease bets his ‘small life’ on Japan” in October 11, 1992 issue of Sunday Mainichi Weekly Magazine.

Shuhei Ogita