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Dialysis Therapy in the 1990s

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Osaka, October 5-6, 1989

Dialysis Therapy in the 1990s

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Preface

This volume of *Contributions to Nephrology* contains the proceedings of the symposium 'Dialysis Therapy in the 1990s', which was held at the Ohno Memorial Hospital and Osaka Hilton International in Osaka, Japan, in October 1989. This symposium was sponsored by the Ohno Memorial Hospital to commemorate its 65th anniversary and the construction of the new Ohno Memorial Hospital and was cosponsored by the Osaka Kidney Foundation, Japan. We were also very honored to hold the symposium under the auspices of the International Society for Artificial Organs, International Society of Blood Purification, Japanese Society for Dialysis Therapy, and the Osaka Society for Dialysis Therapy. More than 180 distinguished guests and participants discussed and shared information about the problems of patients suffering from end-stage renal disease and on dialysis therapy.

This symposium was intended as a chance for leading physicians, scientists and researchers from the countries of the East and West to come together in the same field of dialysis treatment for chronic renal failure to predict the kinds of treatment of the next decade and to take up some of its problems.

One of the themes of this symposium was the treatment and care of end-stage renal disease in Asia. Asian countries are faced with a lot of problems concerning the treatment of end-stage renal disease, some of which have already been overcome in Europe, the United States and Japan. We hoped that this symposium helped us understand the present conditions of renal care in Asia and promote our cooperation. Another theme was the treatment of renal anemia by recombinant human erythropoietin, which has been known to have a significant effect on the treatment of renal anemia. However, its actual clinical use has just started, and we focused on the future of this dramatically effective treatment. This symposium on 'Dialysis Therapy in the 1990s' was also devoted to two lectures by Prof.

S. Shaldon and Dr. T. Matsuda and the art chaired by Prof. J.L. Funck-Brentano to foresee the near future of dialysis therapy.

We would like to express our heartiest gratitude to the participants for their presentations and discussions and to everyone who helped organize this workshop. Lastly, we thank all of the companies who sponsored this symposium and our symposium staff, especially Mr. T. Kataoka, Miss Y. Sumikawa and Miss K. Matsuyama.

Hiroshi Tanaka, MD, PhD
Yoshioki Ohno, MD, PhD
Taketoshi Kisimoto, MD, PhD
Masanobu Maekawa, MD, PhD

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Invited Lecture

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Short Haemodialysis

Stanley Shaldon

Department of Nephrology, University Hospital of Nîmes, France

In 1982 during the European Dialysis and Transplant Association meeting in Madrid, the late Peter Kramer created a sensation. He announced: 'The proportion of deaths in the Federal Republic of Germany was twice as high in short dialysis compared to long dialysis and that of deaths due to myocardial infarction was higher in males on short dialysis' [1]. In spite of this warning, the time allotted to the individual haemodialysis for end-stage renal disease patients has continued to be shortened. It will be the purpose of this paper to examine the background to the original standardisation of treatment schedules, as well as the initial stimulus for shortening treatment times, then to summarise the present position of haemodialysis therapy and finally to comment on future trends.

Early Standardisation of Haemodialysis Treatment Schedules

In 1960-1961, several groups including our own [2] attempted to copy the initial success of Scribner et al. [3]. None were very successful, and the analysis of failure revealed a difference in technique which was that the patients were receiving less dialysis hours per week than those in Seattle. Thus by 1965, it was possible to state with conviction that 'the appearance of the "underdialysis syndrome" is insidious and may take several months to years to develop...It is preventable by lengthening the hours of dialysis' [4]. Thus the first decade of dialysis became associated with long dialysis of 10-14 h administered twice to four times per week, usually on the Kiil dialyser with a low blood flow without a blood pump. This demanding form of treatment produced excellent results in control of blood pressure, treatment of anaemia and patient well-being and rehabilitation. It led to forms of dialysis such as auto-administration and home haemodialysis, where the patient participated actively in his own treatment [5]. As hospital

staff and facilities were limited, these methods permitted an initial rapid expansion of the numbers of patients on treatment. The benefits were often outstanding. A particular example was the extraordinary rise in haematocrit from 15–35% in a bilaterally nephrectomised patient dialysing 4×10 h per week overnight, using intramuscular testosterone 500 mg per week [6]. This result suggested that a criterion of 'good dialysis' would be the rise of haemoglobin. However, after a number of years these methods were considered socially unacceptable, and pressures on shortening treatment times increased. Subsequently only one centre in the world maintained its patients on long hours of haemodialysis, the 'Centre du rein artificiel' at Tassin in France. This centre claims that the highest mean haematocrit without erythropoietin, 30%, and the lowest incidence of hypertension [7]. However, it has today one of the highest incidences of dialysis-related amyloidosis, greater than 60% at 10 years and 100% at 15 years [8]. The relevance of these observations in relation to the number of hours per week of dialysis will be discussed later.

First Attempts to Shorten Haemodialysis Therapy

The first attempt to significantly reduce dialysis time was reported by Cambi et al. [9] in 1973. They had taken the initiative to reduce dialysis time to 4 h three times per week from 10 h three times per week. He also replaced the Kiil cuprophane ($11 \mu\text{m}$) 1.0-m^2 dialyser for several disposable cuprophane dialysers, coil and plate, of about the same surface area but with a thicker membrane ($20 \mu\text{m}$). The sodium concentration of the dialysate was increased from 130 to 137 mmol/l, but the blood flow was not increased and remained at about 200–250 ml/min. The motivating factor was to increase the patient population being treated in the centre. The results were reported as excellent with extreme patient preference, rise in haematocrit and reduction in blood transfusion requirement and improvement in peripheral nerve conduction time. Curiously the blood urea concentration before dialysis rose by 30%. These empirical results coincided with the rapid expansion of the disposable dialyser industry, and cuprophane dialysers of various shapes, sizes and thickness rapidly flooded the market. The erosion of the old standards was very rapid, and soon only Laurent et al. [7] were left doing 10 h three times per week. The stimulus to this curious revolution in treatment modality was the need to treat more patients. However, the short- and medium-term results were convincing, and it became the paradigm of the seventies, particularly as it required no modifications of machines used to monitor dialysis and make dialysate. No comment was made at this time of the effect of raising the

sodium concentration in the dialysate upon patient weight gain or blood pressure.

Modern Era of Short Haemodialysis Therapy

With the advent of short-hour dialysis, not all groups were content to leave the surface area of the dialyser unchanged with the concomitant rise in blood urea reported by Cambi et al. [9]. Indeed, we as others increased the surface area of the dialyser [10]. The results were less satisfactory, and an increase in patient intolerance with more episodes of dialysis hypotension was noted. This had a moderating effect on short-hour dialysis in spite of patient preference and economic pressures. It was to take several years until acetate was found to be the cause of these symptoms with large surface area dialysers and its replacement by bicarbonate was accepted as one of the key necessities in short dialysis [11–13].

The needs of high efficiency dialysis based upon kinetic modelling rather than empiricism received a strong boost with the much appreciated publication of the National Cooperative Dialysis Study of the USA [14]. Using urea as the marker of adequacy of dialysis, and kinetic index of the removal of urea, the so-called Kt/V , it was concluded from the National Cooperative Dialysis Study that an index of 1.0 for Kt/V was necessary for adequate dialysis [15]. Inadequate dialysis was assumed to be a case failure in the study. What these relative value judgements really mean is obscure. No mortality data are available, and again no consideration of blood pressure control or cardiovascular morbidity was evaluated in the study protocol.

Nevertheless, once numerology entered the dialysis prescription field, it only required industrial development of the 'right' high-technology devices for the present scene of haemodialysis to appear.

Spearheaded, yet again, by economic motives and utilising patient preference for shorter hours, the advent of dialysis or haemodiafiltration for 2–3 h three times per week appeared practical from 1984 onwards.

The Minnesota group emphasise the need for bicarbonate dialysate, ultrafiltration control and rapid blood flow with large surface area dialysers [16, 17]. They have the biggest experience with the largest population employing this type of therapy. Essentially based on kinetic indices (e.g. Kt/V) they claim adequate results in comparison with more conventional therapies. The problem of hypertension is not well addressed, and higher dialysate sodium levels of 142–147 mmol/l are employed with larger interdialytic weight gains than on longer dialysis. Nevertheless, there has been no worsening in mortality in up to 5-year survival rates and definite reduction in patient morbidity. Others have had less success. Notably,

Wizemann [18] has abandoned short high-efficiency dialysis as he found a deterioration in left ventricular function. Others, particularly Wauters and Bercini-Pansiot [19], persist and claim that the use of antihypertensive drugs is preferable to prolonging dialysis sessions. The outcome parameters of long-term studies of these very-short-hour treatments is still uncertain, and the excessive weight gains and increase in hypertension will have to be evaluated.

It is therefore appropriate to mention that a recent report from the USA [20] indicates that there was a recent increase in annual mortality rate which coincides with the advent of very short dialysis. This increase was not seen in Japan [21] where there has been no similar reduction in treatment time. Thus, the Tassin legend is worth repeating that until now the best survival rates and blood pressure control have been obtained by long-hour dialysis in Tassin.

The Future of Short Haemodialysis Therapy

Two new factors are complicating the dialysis field today. The first is the correction of anaemia by recombinant erythropoietin. This reduces plasma water and hence has a predictable reduction effect on clearances of dialysers for given blood flows. One would anticipate that this will necessitate a certain increase in dialysis time. Of more importance is the reported increase in hypertension with erythropoietin therapy. Under these conditions, the combined effect of anaemia correction and short dialysis may prove to be too much for the dialysis patient.

The second factor has been the association of β_2 -microglobulin with dialysis-related amyloidosis. Circumstances favouring the development of this disabling complication are uncertain. However, it is a late complication of dialysis therapy. Whether the very high incidence of this complication reported from Tassin will be related to the unique way in which they dialyse is uncertain. The future will certainly define the causative factors involved and may favour short-hour dialysis, as there will be less exposure in time over many years to the 'artificial kidney'. However, until that knowledge is acquired by prospective studies, prudence and caution should remain the guide-words of the dialysis doctor.

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End-Stage Renal Disease Care and Its Treatment in Asia

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Renal Replacement Therapy in Singapore

K.T. Woo

Department of Renal Medicine, Singapore General Hospital, Singapore

This paper discusses the various options available for the patient with end-stage renal failure (ESRF) and presents the national policy and the steps taken to circumvent the problems due to shortage of dialysis facilities as well as cadaver kidneys for the purpose of renal transplantation [1]. The second part of the paper deals with the legal aspects of renal transplantation and discusses the way the Human Organ Transplant Act (HOTA) was passed in an attempt to increase the yield of cadaver kidneys.

Incidence of ESRF

The incidence of ESRF in Singapore is 96 per million population, i.e. every year about 250 new cases of ESRF are diagnosed. This is the same as for Western countries, 90 new cases per million population a year. 51% are males, and 49% are females. 83% are within the economically active age group (18-50 years), and 61% have young dependent children < 18 years of age. 64% belong to the lower middle income group earning < \$1,600 per month. The single largest income group was \$400-799 to which 25% of the patients belong [2]. All prices quoted in this paper are in Singapore dollars which is about half the US dollar.

The causes of ESRF are chronic glomerulonephritis (30%), diabetes mellitus (25%), chronic pyelonephritis (10%), kidney stones (4%), polycystic kidneys (2%), others (4%) and unknown (25%).

Strategies to Retard Progression of ESRF

Patients with even very mild renal impairment are advised a 40-gram protein diet to retard the progression of renal failure due to the effects of

hyperfiltration [3]. It is imperative to stress to patients, irrespective of their underlying disease, the importance of adequate control of hypertension, as uncontrolled or accelerated hypertension can result in ESRF sometimes within a period of 3 years [4]. Patients with IgA nephritis, the commonest form of glomerulonephritis occurring in Singapore, accounting for 54% of all primary glomerulonephritis [5], enter a controlled therapeutic trial consisting of dipyridamole and low-dose warfarin if they have certain bad prognostic features like proteinuria > 2 g/day, glomerulosclerosis $> 25\%$, crescents, hypertension, medial hypertrophy of blood vessels and renal impairment [6, 7]. We have previously reported that this regime could retard the progression to ESRF [8].

Options for Treatment of ESRF

Our national policy is renal transplantation. Patients who have suitable donors (parents or siblings) are encouraged to have living related donor transplantation. Those who fulfil the criteria for the state-supported haemodialysis programme will compete for places through selection by a committee based on objective criteria scored on a point system. Those who do not qualify can apply for subsidised dialysis at the National Kidney Foundation dialysis centres. For the rest, they could opt for continuous ambulatory peritoneal dialysis (CAPD) which costs about \$800 a month. Those who could afford it could have home or private haemodialysis which costs about \$1,500–2,400 a month.

Irrespective of the mode of dialysis, patients can apply to be placed on the Register of Potential Cadaver Transplant Recipients. Entry criteria are based on the fitness of patients to undergo renal transplantation. Patients must not be more than 60 years old. When a kidney becomes available, selection of a suitable recipient is based primarily on blood group and tissue typing compatibility and other medical and socio-economic considerations.

Establishment of Facilities for Therapy

The first haemodialysis service was started in 1968 at the Singapore General Hospital. Since then, throughout the country, there are now 11 haemodialysis centres with 154 dialysis stations with capacity to dialyse 614 patients.

The first cadaver transplant was performed at the Singapore General Hospital in 1970 and the first living related donor transplantation in 1976.

Presently, 155 cadaveric transplantations and 185 living related donor transplantations have been performed.

CAPD was started in 1980. There are now 150 patients on CAPD.

Number of Patients Who Qualify for Treatment

Among 250 new cases of ESRF a year in Singapore, 75% or 187 would have primary renal disease causing ESRF. 15% of these would be excluded from renal replacement therapy because of major illness such as cancer, cerebrovascular accident, mental retardation as well as multisystem disease, leaving about 159 who would qualify for treatment. If patients older than 65 years were excluded, only about 140 would be eventually eligible for treatment yearly.

Attrition Rates

The failure rate for renal transplantation is 10% per year. The complication rate for CAPD is 10% per year. The attrition rate for CAPD is 30%, for renal transplantation 10% and for haemodialysis 5%.

National Policy, Human Organ Transplant Act

Since the national policy is renal transplantation, a law called the Human Organ Transplant Act (HOTA) was passed in January 1988 to increase the yield of cadaver kidneys. However, an evaluation of the effects of HOTA showed that the percentage of donors who were ultimately found to be suitable and the number of kidneys harvested for renal transplantation were very low. As of December 1988, among 391 deaths from accidents, 333 were excluded, because they were brought in dead, were Muslims, non-Singaporeans or were outside the designated age group, leaving 58 potential kidney donors. Subsequently only 16% or 18 kidneys were harvested, because the rest were unsuitable due to abdominal injury, sepsis, hypertension or because the potential donors collapsed before brain death tests could be performed. Expansion of renal transplantation as the mode of treating new ESRF patients is therefore limited by the number of suitable donor kidneys.

Every year, of the number of new patients with ESRF who are eligible for treatment ($n = 140$), about 50% do not find their way into the state-supported dialysis programme nor do they get transplanted (living

related donor transplantation). Of the other 50%, 20% received haemodialysis, 15% CAPD, and 15% are transplanted. Those patients who do not qualify for the above treatment programme seek help from the National Kidney Foundation or have private haemodialysis.

Medisave for Dialysis

The government has recently allowed patients with ESRF to use up to a maximum of \$400 a month from their medisave account (which is part of their central provident fund account) for the purpose of dialysis treatment. The central provident fund is a fund set aside by the Singaporean worker every month for old age when he retires from work.

Catastrophic Illness Insurance Scheme

In keeping with the government's policy, a new scheme called the Catastrophic Illness Insurance Scheme will be launched next year. For a very small premium to be deducted from the medisave account, the person is covered by the insurance company for treatment of ESRF. This scheme will cover the whole working population of Singapore (1.5 million workers). The person must not already have kidney failure on entry into the scheme. Those who do not wish to join the scheme can opt out of it. Upon diagnosis of ESRF, the person can claim up to a maximum of \$600 a month for payment of dialysis fees (haemodialysis or CAPD).

Of the 140 patients with ESRF who qualify for renal replacement therapy every year, it is estimated that 20% would be transplanted, 70% would have haemodialysis and 10% CAPD. With the implementation of the Catastrophic Illness Insurance Scheme, it is envisaged that with the demand for more haemodialysis facilities there would be more dialysis centres set up throughout the country, some may even be supported by insurance companies. A saturation level can be expected about the year 2010 in 20 years' time with the number of patients with ESRF reaching a steady number at 1,400.

This at best is only the minimum number, as the projection is based on the static-component method and does not take into account various factors like population aging, shift in age composition and shift in distribution of death due to changing trends in disease composition and improved medical technology whereby patients survive to qualify for dialysis.

If patients with multisystem diseases like diabetes mellitus and systemic lupus erythematosus are included among the patients with ESRF who qualify for the Catastrophic Illness Insurance Scheme, then the expected number would be about 200 a year instead of 140. By the static-component method we would expect a levelling off in 20 years' time at about 2,000 patients with ESRF.

Social Aspects of Renal Transplantation in Singapore

Shortage of Cadaver Kidneys

In 1970, the first cadaveric renal transplant was performed, but up to 1987 (a 17-year period) there were only 85 local cadaveric transplants, averaging 5 a year. Another 33 foreign cadaver kidneys were donated by the US. This shortage of cadaver kidneys is a universal problem.

Obstacles to Kidney Donation

The population of Singapore is 2.6 million. 76.1% of the population are Chinese, 15% are Malays, 6.5% Indians and 2.3% other ethnic groups.

One of the major obstacles to kidney donation has been the local tradition of not parting with the organs after death. This obstacle does not appear to stem from religion. It may be an Asian attitude.

Another obstacle accounting for the low yield of cadaver kidneys is the reluctance of doctors dealing with dying patients and potential donors to broach the subject of kidney donation to the relatives during their bereavement.

The third major obstacle is misconception of brain death. While the donor's heart is still beating, his relatives may refuse to believe that he is 'brain' dead. Relatives therefore refuse to give consent. Hence lack of information or wrong information is one of the main causes for the relatives' refusal to donate the kidneys of loved ones [9].

Opting-In Law

The Medical Therapy, Education and Research Act was passed in Parliament in 1972 to enable individuals to will their kidneys for transplantation in the event of death. This is the Opting-In Law. To date, 27,611 individuals have pledged their kidneys, but it has not produced a single kidney for transplant. The National Kidney Foundation conducted campaigns from 1977 to 1986 to encourage organ donation, but these were expensive, labour intensive and ineffective.