PART XXII

JOINT MEETING EDTA/ISAO — SESSION 1

Chairmen:  J P Merrill
            T Drüeke

PART XXIII

JOINT MEETING EDTA/ISAO — SESSION 2

Chairmen:  J Hamburger
            N K Man
CHAIRMAN'S INTRODUCTORY TALK

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In these brief introductory remarks I would like to take my cue from Dr Kerr and make some general comments about efficacy and cost in haemodialysis. I do not believe that I shall duplicate any of his observations.

The effective clinical artificial kidney has run the gamut from the immense rotating model to the compact hollow-fibre model. When we discuss efficacy we must remember that probably the most efficient dialyser in terms of low molecular weight solute transfer was indeed the large rotating model and if I remember correctly, Dr Gabriel Richet, then working with Professor Hamburger, had made a bigger and better rotating model after spending some time with us. In the very early days of haemodialysis we made one important observation whose significance did not occur to us until some time later. We found in our first clinical trials that patients who had progressed to terminal uraemia gradually over a period of years did extremely badly when treated with this very efficient dialyser. The reason is, as we all know, that it was too efficient and that such patients who had compensated for their chemical and biological deterioration over a period of years could not be normalised in a matter of hours. Thus such an apparatus had more built-in efficacy than was warranted.

Over the subsequent years there has been a constant debate about the efficiency of dialysers, their application to the removal of various solutes and even the treatment of clinical problems other than renal failure. The debate about flow rates and membrane area in the removal of 'middle molecules' continues and of course the debate about the role of 'middle molecules' themselves still rages. The debate about the efficacy of dialysis in the treatment of schizophrenia has largely abated. Controversy about the role of urea in the uraemic syndrome and the relative merits of acetate and bicarbonate baths continues and one has only to look at Volume 1 of Controversies in Nephrology to see discussed such problems as 'controversy in self-care dialysis'; 'rehabilitation of renal patients; issues of controversy' and 'Hemofiltration. Does it have a special role?' Too often we forget, however, that the haemodialyser has no metabolic or synthetic functions similar to the normal kidney. For example the normal kidney produces about 50% of total body glucose
in starvation; it plays an important role in creatine metabolism; and all of us are aware of the renal role in production of renin-angiotensin, erythropoietin and the active metabolite of vitamin D. In the past few years our treatment of patients with chronic renal failure has vastly improved, particularly with regard to hypertension, the incidence of coronary artery disease, and of metabolic bone disease. For example, in the post-transplant patient five years ago the incidence of aseptic necrosis of the hip in one clinic was as high as 40% and in most clinics as high as 15%. A number of studies documented the fact that the bone disease began in the early part of renal failure, continued during dialysis and that corticosteroids played a minimal role. Our improved ability to manage hypertension, calcium metabolism and even lipid metabolism has greatly improved the outlook of chronic dialysis patients. This of course is not an improvement of the efficacy of the dialyser. Much of the difficulty with evaluating efficacy was based on the fact that we did not know what we needed to measure to prove efficacy. The numbers of patients were too small and the techniques varied from place to place. This problem has recently been attacked by a very large scale study, using a multitude of techniques for the study of the patients. The National Cooperative Dialysis Study in the United States embodied nine hospital university groups and evaluation of the patient by many techniques, including social, psychological, as well as chemical and physical. The group was monitored by oversight and advisory groups composed of independent experts with no other relationship to the study. It included a patient safety committee, and a data monitoring committee. The kinetic modelling of urea metabolism was used in the study, not because this molecule was necessarily responsible for any part of the uraemic syndrome, but because it was easy to measure and one might presume that certain other potential toxins are correlated. Different dialysing areas and different membranes were employed, but time was constant in each study group which was compared. The results are of interest because of the size of the study group, the careful monitoring, and the many parameters used to evaluate efficacy. Their conclusions were relatively simple: they found no evidence that removal of middle molecules played a significant role, although a minor role could not be ruled out. Morbidity among the patients appeared to be less when they were treated by prescriptions associated with relatively more efficient urea removal to maintain lower average concentrations of urea nitrogen if the dietary intake of protein and other nutrients was adequate. Even though urea is not necessarily the uraemic toxin, it probably represents a marker molecule and the conclusions reached make eminent common sense.

Cost

Another aspect of dialysis, which now includes chronic peritoneal dialysis, which continues to stir much controversy and concern is the cost. I shall limit myself to observations from the United States and a few comments thereon.

In 1972 the End-Stage Renal Disease Program (ESRD) was created as an Amendment to the Social Security Bill, extending Medicare coverage to the care of ESRD patients by dialysis and transplantation. Prior to the enactment of this coverage
there were perhaps 750–1000 patients requiring dialysis. In 1979 this number had risen to almost 46,000 patients at a cost of $138–$160 per treatment on an out-patient basis, or an annual per capita cost of $16,000 for a total cost of $850 million. The projected number of patients for 1981 is 68,000 and for 1985, 84,000 with a total cost to the Medicare System of 2.6 billion dollars. This is a staggering sum which has begun to concern legislators and physicians alike. Perhaps of even greater concern is the fact that while the average age of patients on dialysis in 1972 was about 40, the average age as of 1980 was greater than 50, 20% of these were greater than 65. Home dialysis is a less expensive form of treatment. Whereas in 1971 40% of patients on dialysis were done in the home, in 1979 this percentage had dropped to 13%, although there is a wide variation between the different States in this percentage. In addition, a large number of diabetics whose prognosis is generally agreed to be considerably worse than non-diabetics, have been included in both dialysis and transplantation programmes. A number of questions have been raised about this by both physicians and legislators. Among the most controversial is whether or not older patients are being included in the programme simply because there is a guaranteed form of reimbursement. In addition, the question has been asked, although not answered, as to whether patients are being segregated in dialysis facilities, particularly those which are profit-making enterprises because of the economic advantages. No firm answers are available, although volumes of questions have been raised. In addition, the Congress has suggested a number of remedies such as mandating home dialysis, which has met with great scepticism on the part of most nephrologists. Both at the State and the Federal level the controversy still rages. To the new administration, which is looking for ways to save money, the prospect of a $2.5 billion target in 1984 is inviting. As recently as the end of June both the National Association of Patients on Hemodialysis and Transplantation, as well as the past President of the National Kidney Foundation have published extensive and detailed reports of their concern for some of the methods proposed by the legislators to attack the problem of cost. At least in the United States the controversy is active and continuing with a good deal of persuasive argument on both sides, but no immediate prospect of resolution.