ROUND TABLE DISCUSSIONS
COLLECTION AND RECORDING OF DATA FROM PATIENTS ON RDT

Chairman: Prof. P. Michielsen, Louvain

The Chairman: Le nombre de malades traités par hémodialyse allant toujours croissant, il devient difficile de suivre avec précision leur évolution; il y a donc là un problème très important de savoir comment rassembler les données cliniques et biologiques et comment les utiliser. Ce problème est encore compliqué par la multiplication des centres d’hémodialyse en Europe d’où la difficulté de rassembler et d’analyser les différentes données, si l’on désire établir un rapport annuel valable sur le développement de l’hémodialyse en Europe. Je pense qu’une standardisation des résultats s'impose, ce qui est le sujet même de cette table ronde.

I think everybody will agree on the need for the standardisation of the collection of data, but I think we have a double problem here. The first problem is to establish a day-to-day sheet to follow each individual dialysis, and the second most important problem is to establish a kind of master sheet, where, for instance, with a monthly entry on this master sheet, all these individual data would be reported. This master sheet is the most important point, of course, and this could be used not only to follow the individual patients, but also, for instance in a computer, to analyse the data for inclusion in the annual report of the Secretary/Treasurer.

First of all, I should like the members of the panel to express their views on the day-to-day sheet which could be filled in for each individual dialysis. There are three possibilities; one is to have just a sheet of paper where the blood pressure and so on of the patient is marked; the second is to use a punch card and the third is to use a card that can be fed into a computer. May I ask the members of the panel who have experience with one or the other of these systems to comment on them?

Confortini (Verona): Je crois qu'il est nécessaire d'avoir une feuille pour chaque dialyse ou mieux encore une carte qui puisse être utilisée dans un ordinateur, seul moyen pour traiter correctement les informations recueillies, comme nous le faisons dans notre centre où chaque mois sont effectuées 400 dialysées.

The Chairman: So you think that the computer card is very useful even at this stage of the collection of the data, because you have a very large unit with 400 dialyses a month. I suppose not everybody will agree with this and that maybe other people, who perhaps have smaller units, would not be satisfied with a computer card?

Fritz (Bonn): In the past we tried different systems to collect the daily data. First, we had a punch card and this seemed to me to be very good, but the problem in the continuous use of this card was that only I myself could fill in or punch the card. I could not allow anyone else to do this because, if I was on vacation or something, when I returned I found that only half the punch cards were filled in and the other half were filled in wrongly. Even with instructions for the punch card, I could never find anybody who would use the punch in the same way as I was using it. Therefore, we left the punch card and tried a computer sheet. In Bonn, we have a very big computer unit, with a special Professor of Medical Statistics, who forced me to do this, saying that it was the only way to collect data. Together we developed a very nice computer sheet for daily value collection, but we needed so much time to fill in the whole sheet that there were not enough people to make the entries. My opinion is that, before you
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start to collect data, you should think about the work you are taking on and there should be
a satisfactory relationship between the effort of collecting it and its usefulness. You can over-
record your values, in which case, after a few months, nobody will use the sheets any more.
We have therefore returned to a very simple system only collecting the data on the usual
sheets. We have questions only about the shunt, the type of the kidney, the dialysate system—
because we use different types—blood transfusion and then the biochemistry values. Natu-
really, these values are never all used at the same time. There are different sheets for acute renal
failure and then we naturally need many more values than for the chronic patients.

SHALDON (London): I feel quite strongly about the daily records in dialysis, because I think
they reflect to a large extent the anxiety and inexperience of the majority of nephrologists
performing dialyses today. If we considered ourselves as pioneers in the use of insulin and
looked upon the amount of daily records that the average diabetic keeps, this should be our
goal in maintenance dialysis. I think it is very important to define what type of dialysis we are
doing in relation to the data we keep. Obviously, if we are involved in the evaluation of
new equipment or new techniques in research and development, then a standard data sheet is
not applicable. Similarly, if we are only concerned with short-term dialysis and intensive
care under our own direct observation, the type of data we should keep is clearly different.
But, as it is clear that the vast majority of patients who will be maintained on dialysis will be
making their own observations many times and as the reliability of these observations is
always suspect, one begins to wonder what is the value of these observations. For a number
of years I have had the opportunity of conducting an experiment in not collecting data,
rather than collecting data, and seeing whether this makes any significant difference to the
clinical problems in the management of these patients, and it does, because there are un-
doubtedly patients in whom overhydration and hypertension can develop unless accurate
weight and blood pressure are checked. Therefore, there seems to be a minimum requirement
of data observation, which is, I think, related to weight and blood pressure. I am extremely
doubious that there is any value in any other form of clinical or biochemical observation based
on an individual dialysis. I think that, in an effort to emancipate this treatment and to make
it more available, we should consider this before getting bogged down in a lot of useless
statistics.

The CHAIRMAN: Thank you very much for this comment. I note that at least you are con-
vinced that you must register something, be it only the blood pressure, the weight and maybe
also the type of dialysate used—the surface used and the duration of dialysis—all of which are
things which could, if they were collected, bring useful information if brought together for the
yearly dialysis report. However, we have not yet discussed the third possibility—the punch
card.

Puis-je demander au Dr. Mion d'expliquer rapidement comment le problème de la carte
perforée a été résolu à Montpellier?

MION (Montpellier): Nous avons adopté le système de la carte perforée dans le but de ras-
sembler sur le même document les informations concernant d'une part le déroulement de la
dièse, d'autre part l'état du malade entre chaque dièse. L'utilisation de cette carte est
simple, et elle peut être réalisée aussi bien par l'équipe médicale que par l'équipe d'infirmières.
Comme dans un centre d'hémodialyse il est parfois difficile de contrôler toutes les données
cliniques et techniques de la dièse, il me semble que certains paramètres particulièrement
importants peuvent figurer à part sur cette carte et peuvent ainsi être immédiatement ex-
plorés du point de vue statistique. Comme le Dr. Shaldon l'a dit, je ne crois pas que ce
système de carte ait pour but de couvrir une longue période d'observation; par contre ce
système est très utile et très pratique pour de courtes périodes d'étude. Par ailleurs j'aimerais
demander au Dr. Fritz, qui nous a dit qu'il avait également utilisé le système des cartes

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perforées mais qu’il avait abandonné ce système parce qu’il était trop difficile à suivre régulièrement, combien de temps il avait utilisé ce système?

Fritz (Bonn): Simplement pour un très court temps, environ 4 mois.

Mion (Montpellier): J’aimerais dire encore que le système de cartes perforées que nous avons utilisé ne nous a pas donné de problèmes difficiles à résoudre.

Kennedy (Glasgow): I think it is very important in this question of the recording of the day-to-day data to bear in mind who is going to do this. In the majority of hospital dialysis units, this data has to be collected and recorded by nursing staff and/or technicians. I rather think, along with Dr. Fritz, that, if we impose on these staffs, who have a lot of other things to do, a series of punch cards that they have to complete at the end of each dialysis session—and I think it would have to be done at the end of each session to be anything like accurate—this may impose a burden which will merely lead to it being done improperly or incompletely. I would make a plea, probably somewhere between Dr. Fritz and Dr. Shaldon, for a relatively simple system for day-to-day recording of things like haematocrit, weight before, weight after, blood pressure and so on, and that we should devise some form of more systematised collection at a second level, but not at a primary, bed-side, level.

The Chairman: I think that the value of the data on the second level will depend on the number of observations on the primary level, so, if you only make a few observations of blood urea, of course the significance of your mean value obtained after one month will be very low.

Kennedy (Glasgow): In connection with this, I think there should be data recorded at every dialysis for things like weight and blood pressure, complications and so on, but I do not think that blood urea and creatinine or other figures should be recorded before and after every single dialysis, once the patient has been stabilised. It may be necessary at a 'run-in' period when someone starts maintenance dialysis, but, after they are stabilised, I do not think these things should be recorded every time. We must bear in mind that the more investigations we do, the more the blood loss from these patients is increased each month.

Méry (Paris): Je partage tout à fait l'opinion du Dr. Kennedy. Je voudrais dire aussi que je suis d'accord avec ce qu'a dit précédemment le Dr. Fritz à propos de l'utilisation des cartes perforées. Nous avons eu à l'Hôpital Necker, à Paris, la même expérience que lui: nous avons essayé d'utiliser des cartes perforées très complètes, mais nous avons abandonné leur emploi pour les mêmes raisons que le Dr. Fritz.

Fritz (Bonn): May I make some remarks on what Dr. Shaldon has said? I think we must completely differentiate between the needs of the patients and our needs for statistical purposes. I agree completely with Dr. Shaldon that, for the patient's needs, it is only necessary to collect blood pressure, pulse, and perhaps sometimes some blood values, but I must agree with Dr. Michielsen: I think we should have at least every week one value of urea, creatinine, etc., to give us an average for our statistical work every month. You cannot make average values with one blood value every month or perhaps every two months.

The Chairman: Pour résumer, je crois donc que tout le monde est d'accord pour estimer nécessaire le recueil de certains paramètres pour chaque dialyse correspondant à un malade donné; par contre le type de document utilisé varie selon les possibilités de chaque centre,
allant du document complet fourni à un ordinateur jusqu’aux cartes perforées ou même de simples feuilles manuscrites.

The second and more important point, to which we come now is the master flow sheet. I think this is the most important point because the quality of this sheet will enable us to follow our individual patients adequately and it will be upon the basis of these sheets that we shall try to answer some of the questions which have come up so repeatedly—for instance, the duration of dialysis which is desirable, the surface of dialyser which is desirable, the comparison between different membranes, the quality of the rehabilitation obtained. All these data could be obtained if we could bring together all the information obtained regarding the individual dialyses done by the members of the E.D.T.A.

Does everybody agree that we need such a master flow sheet? If everybody agrees on this what are the main points which would be needed on this sheet? Possibly the first point would be the type of dialyser used. If we want to be able to compare the different dialysers in the yearly report of the E.D.T.A. I think this must be mentioned for each individual dialysis. Does anybody want to comment on this?

CONFORTINI (Verona): Je crois que pour le moment il est nécessaire de recueillir le plus de données possibles et de traiter ces données de façon adéquate par l’utilisation d’un ordinateur. Un essai en ce sens a été fait en Italie. Quelques exemples illustreront certains résultats que nous avons déjà obtenus. La première diapositive (Fig. 1) montre la relation qui existe entre le nombre d’heures de dialyse par semaine et la survie. Nous avons également obtenu des renseignements intéressants en ce qui concerne la composition du bain de dialyse et le

![Bar chart showing mortality rate related to hours of haemodialysis—weekly in patients treated with KiiI kidney. The highest death rate is in the group of patients with less than 20 hours’ haemodialysis—weekly.](image)

*Fig. 1. Mortality rate related to hours of haemodialysis—weekly in patients treated with KiiI kidney. The highest death rate is in the group of patients with less than 20 hours’ haemodialysis—weekly.*
COLLECTION AND RECORDING OF DATA FROM PATIENTS ON RDT

Systolic blood pressure

BEFORE D.

AFTER D.

N=211

Weight gain between dialysis

Fig. 2. Weight gain between dialysis and rise in systolic blood pressure. Pressure control is more difficult if weight gain is more than 1 kg.

contrôle de l'hypertension. La diapositive suivante (Fig. 2) montre la relation qui existe entre l'augmentation de poids entre les dialyses et les chiffres de pression systolique.

Un autre point sur lequel j'aimerais insister c'est la nécessité de standardiser la manière d'exprimer les résultats de la dialyse. En suivant la méthode utilisée par Barnes pour le Kidney Transplant Registry nous avons calculé certains résultats de la dialyse et nous les avons comparé avec les résultats de la transplantation (Fig. 3). La survie du shunt artério-veineux peut être calculée de la même manière.

The Chairman: Je vous remercie vivement pour ces documents très intéressants qui montrent bien ce qui pourrait être fait si chacun faisait l'effort de se soumettre à la discipline de recueillir très régulièrement et de manière très stricte toutes les informations sur la dialyse.

En ce qui concerne le type de rein utilisé, chaque feuille devrait comporter le nombre d'heures de dialyse, le type de membrane utilisé et la surface du dialyseur. La même chose devrait être faite pour le liquide de dialyse, ce qui permettrait d'évaluer s'il existe une certaine corrélation entre l'hypertension et la concentration en sodium, ou encore la relation entre les manifestations ostéo-articulaires et la concentration en calcium.

Another point which should be mentioned, in my opinion, is the laboratory data, but time is too short to discuss all the individual entries on this master sheet. However, I think that everybody could agree that, if we develop a master sheet to be used by all the members of the E.D.T.A., we must have the possibility of recording many data and that everybody who wants to collect only a part of this must be free to do so, while, for those who wish to collect more, space must be provided so that they can do so. Do you all agree with this?

Shaldon (London): Can I just add one point, which I think you mentioned briefly and which Dr. Kennedy stressed in our previous discussion? This is that I find extremely unsatisfactory the objectivity of assessment of not-easily-measured parameters—that is, social parameters. We have all been guilty of quoting percentages of reability in individuals without really defining what we mean by this and I think that, in terms of cost-effectiveness
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Fig. 3. Comparison between dialysis and transplant survival data. Survival rate of haemodialysis in Europe at two years (C) is comparable with that of cadaver (G) and living unrelated (H) transplants.

The haemodialysis survival of selected groups (A) is better than monozygotic twin transplants (D).

**Dialysis**

- A = Verona 1968
- B = Italy 1967
- C = EDTA 1966

**Transplant**

- D = Monozygotic twins
- E = Sibling
- F = Parent
- G = Cadaver (local X-ray)
- H = Living unrelated (local X-ray)
- I = Royal Melbourne Hospital 1967

and the social acceptability of treatment, we must try to be more objective and I think that one of the most useful things would be arbitrarily to define what we mean by ‘rehabilitation’ and what we mean by ‘percentage rehabilitation’. Personally, I have no idea myself; other than that I doubt there being such a thing as 100% rehabilitation on a chronic dialysis patient. Therefore, what do we mean by this?

I think this is terribly important because, to compare different dialysers, one must look more for positive clinical health and results other than absolute ones such as survival. We do not have any objective parameters on this and we must have them on this master sheet: it is not good enough just to ask, what is your percentage rehabilitation rate?

The CHAIRMAN: Thank you very much for this comment. You have introduced the next point which must be recorded on this master sheet—the clinical state of the patient. If we have to choose between different types of dialyser, different types of membrane, different
surface areas and so on, and different times of dialysis—two, three or four dialyses a week—
naturally we need objective data on the clinical status of the patient. I think Dr. Kennedy made
a very good contribution on this point: could you comment on this?

KENNEDY (Glasgow): Thank you, Dr. Michielsen. As you know, I feel quite strongly about
this and I think the present terms 'rehabilitated' or 'partially rehabilitated' used in publica-
tions and in reports are capable of varied interpretation. I should imagine that Dr. Druk-
ker’s slide this morning which showed a certain percentage of patients rehabilitated on
R.D.T. was representative of a very heterogeneous population indeed and that they would
not all be comparable if we got down to a strict analysis. I think there is need for an objective
grading system which would allow the patient data of one unit to be compared objectively
with that of another unit. It would allow comparison between different methods of treatment
—the number of hours of dialysis a week and so on. In Glasgow, we have devised such a
system on the basis of allocating points to a patient if he develops any of the known complica-
tions of R.D.T. No accurate statistical assessment is available so far, because we do not
really know what determines success or not, but we have given a largish number of points
for the development of complications that are known to be positively harmful and a rather
smaller number of points for those that are apparently, at our present state of knowledge,
relatively less harmful. The system is quite a comprehensive one: it ranges over the various
systems of the body and the biochemical data that one would collect in these patients and,
depending upon the number of points a patient collects, he is graded into one of four catego-
ries—A, B, C or D. A representing a well patient on the basis of this objective system. This
is shown in some detail in the demonstration and I would be very interested indeed in any
comment on it.

The Chairman: De ce qui vient d'être dit par le Dr. Shaldon et le Dr. Kennedy je voudrais
retenir deux points: tout d'abord la dialyse chronique ne donne jamais de réhabilitation à
100%, ensuite la nécessité de mettre au point une évaluation du degré de réhabilitation des
malades sur des bases objectives.

I think it is the opinion of the members of the panel that they should devise a single master
sheet on which, with a monthly entry, all the data concerning the type of dialyser used,
laboratory data and the clinical status of the patients could be reported. This master sheet
could then be used with or without a computer: this is just a matter of design. I think if we
make up a sheet at this moment it should be prepared so that it could be used by a computer
and, on a basis of this sheet, the yearly report on dialysis could be compiled.

Now I should like to ask the members of the Assembly, if such a master sheet was de-
veloped, how many members would use it? Can we have a show of hands of those in favour of
this master sheet? Well, I think a large majority is in favour of one single master sheet which
could be used by the majority of members, so I think the next point is to ask some of the
people to make up such a sheet and then this could be submitted to the members, maybe at
next year's meeting.

IMMUNODEPRESSIVE THERAPY IN KIDNEY TRANSPLANTATION

Chairman: Prof. J. Hamburger, Paris

The Chairman: Notre Président, le Dr. Walsh, nous a demandé s'il était possible de répondre
da la question suivante: existe-t-il actuellement, en 1968, une méthode idéale d'immunosuppres-
sion en transplantation rénale?