Seventeen Months’ Experience with the Hoeltzenbein Dialyser in Paediatric Patients

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Introduction

During the last 17 months we have had the opportunity to perform a clinical evaluation study of the Hoeltzenbein low prime dialyser.

This report gives experimental and clinical evaluation data for the new artificial kidney. Clinical testing was performed in a long term study covering more than 600 haemodialyses.

MATERIALS AND METHODS

The Low Prime Dialyser In 1970 Hoeltzenbein reported the first experimental data concerning the newly developed capillary film artificial kidney (Hoeltzenbein, 1970). This low prime dialyser which since then has undergone several modifications, consists of multiple plastic plates which are sandwiched between layers of 10 μ Cuprophane PM 100 membrane sheets. The plates are individually wrapped and placed in pairs, back to back, to form a functional dialysing unit. Each plate provides a multiple pyramid support structure for the membrane. The core of the dialyser contains 152 plates with a total effective membrane surface area of 0.92 m². Blood film thickness is 90 μ. Blood and dialysate are distributed to their respective compartments by manifolds formed by the plastic case which contains the dialyser core assembly.

Both the blood and dialysate inlets are at the bottom of the dialyser, and both outlets are at the top, avoiding the necessity to rotate the dialyser during the set-up and priming procedure. However, it should be mentioned that the blood and dialysate are flowing in a countercurrent fashion within the dialyser.
With external dimensions of 7x15x15 cm, the dialyser weighs only 1.0 kg. The average dynamic priming volume is 70 ml with a compliance rate of 14 ml per 100 mmHg transmembrane pressure (Hoeltzenbein, 1972).

The Hoeltzenbein dialyser was evaluated both experimentally and clinically.

**In Vitro Tests** In vitro clearance studies were performed using an aqueous test solution containing urea (MW 60), creatinine (MW 113.1), BSP (MW 838) and vitamin B12 (MW 1355). Deionised water with a flow rate of 500 ml/min served as dialysate, provided by two different delivery systems, the Gambro AK 3A with moderate degassing and the Gambro AK 5A with optimal degassing. Samples were taken from the arterial and venous ports of the dialyser, and clearances were calculated using the formula

\[ C = \frac{C_{Bi} - C_{Bo}}{C_{Bi}} Q_B. \]

**Clinical Testing** A long term study was performed on 17 paediatric patients aged from 3 to 14 years, and on 5 adolescents aged from 14 to 20 years.

Two groups of patients were studied: Group I — 14 children aged from 3 to 14 years and 5 adolescents, 14 to 20 years, who were on the Hoeltzenbein kidney for a short time period only, mainly due to the limited availability of the dialyser. In this patient group clearance and ultrafiltration studies were performed as well as a comparative blood loss investigation.

All the patients except two were in end-stage renal disease with an endogenous creatinine clearance of less than 1 ml/min, 3 children were anephric, 2 children, aged 3 and 9 years underwent dialysis for acute renal failure. Twenty children had been on haemodialysis treatment for a time period of 1 to 80 months before using the Hoeltzenbein dialyser. Group II — The second group of patients consisted of 3 children within the range from 8 to 14 years in whom a long term clinical evaluation of the Hoeltzenbein dialyser was carried out over a time period of 12–17 months covering 550 haemodialyses.

Dialysis was performed 3 times a week for four to five hours, on an ambulatory basis. The children were on a liberal diet. Only potassium and water intake was restricted.

During the clinical study the dialysis performance was standardised. Of the total extracorporeal priming volume 120 ml were discarded before connecting the patient to the dialyser. Prefilling with blood was not necessary in any instance. Heparin was administered according to the following scheme: an initial loading dose of 2,500 USP units was given followed by 1,500 USP units every two hours. During dialysis the actual body weight of the patient was constantly monitored using an electronic bed scale with an accuracy of ± 50 g. At the end of dialysis wash back was performed using 120 ml of physiological saline (Hergemöller, 1975). All dialysers were then dismantled for an optical study of the residual blood volume.

The delivery systems used in the long term clinical study were the Gambro AK
3A and AK 5A. Dialysate flow was kept at 500 ml/min at a temperature of 39°C. Blood flow was 100 ml/min during the first hour of treatment and then adjusted to 150 to 300 ml/min in the following hours using Sarns blood pumps which were calibrated daily.

The in vivo clearance data were obtained using the Gambro AK 5A dialysate delivery system, dialysate flow 500 ml/min, temperature 37±0.1°C, with the transmembrane pressure as low as possible.

Blood samples were taken from the inlet and outlet ports of the dialyser. The erythrocytes of the samples were reinjected after a sedimentation time of 15 min (Falda, 1971). Serum was analysed for urea and creatinine using a 6-channel autoanalyzer.

![Graph](image)

Figure 1. In vitro clearance spectrum of the Hoeltzenbein dialyser
RESULTS

_in Vitro Results_ Average in vitro clearance values (Figure 1) obtained for the solutes studied corresponded well with the clearance data stated by the manufacturer. $^{131}$I-BSP clearance, however, after priming the dialyser with unlabelled BSP was lower than stated, possibly resulting from an initial BSP sorption by the plastic materials of the artificial kidney.

Moderate dialysate degassing reduced the clearance values by up to 20%.

_Clinical Results – Solute Removal_ Figure 2 gives the urea and creatinine clearance values for varying blood flow rates. Depending on blood flow a clearance decline for both urea and creatinine was obvious when we compare the clearance values taken in the early phase of dialysis with those of the late phase. Clearances in the early phase of treatment were taken 1 hour after starting dialysis, those of the late phase 3 hours later.

One might conclude from Figure 3 that it seems advisable to start dialysis with a high blood flow during the first two hours of treatment and then reduce it, or to perform dialysis keeping mean blood flow constant.

Maintaining the blood flow high, or even increasing it after a certain dialysis...
Clearance (ml/min)

150

100

50

60 120 180 240 Min. of dialysis

\[ Q_B = 150 \text{ ml/min} \]
\[ Q_B = 200 \text{ ml/min} \]
\[ Q_B = 100 \text{ ml/min} \]

\[ Q_D = 500 \text{ ml/min} \]
\[ T = 37^\circ C \]

Figure 3. In vivo urea clearance studied at different blood flow rates versus elapsed time has elapsed, does not seem to improve dialyser efficiency.

*Water Removal* Ultrafiltration capacity of the Hoeltzenbein dialyser in relation to transmembrane pressure was studied in vivo at a blood flow rate of 200 ml/min

Ultrafiltration (ml/hr)

800

700

600

500

400

300

200

100

0

0 100 200 300 400 Transmembrane Pressure (mm Hg)

Figure 4. Ultrafiltration in clinical application
The ultrafiltration regression line (Figure 4) was calculated on the basis of 100 individual paired data. The in vivo ultrafiltration rate correlates well with the in vitro data as stated by the manufacturer.

**Residual Blood Volume** A blood loss study was performed measuring the residual blood volume of 23 Hoeltzenein dialysers in 10 patients. Blood samples of the patients were labelled with $^{111}$Indium and reinjected at least 1 hour prior to dialysis.

Reperfusion technique was standardised using 120 ml physiological saline, followed by an air rinse. The artificial kidneys as well as the extracorporeal blood lines were then measured for radioactivity in a whole body counter in comparison with a 1 ml blood sample taken immediately before dialysis. Residual blood volume in the Hoeltzenein dialyser was consistently low amounting to 2.1 ml with only slight variation (Möhring, EDTA 1976).

This finding was in accordance with the fact that all dialysers when dismantled were visually very clean.

![Graph](image)

**Figure 5.** Long term clinical data of 3 children on the Hoeltzenein dialyser for more than 1 year
Long Term Clinical Application  To assess adequacy of the Hoeltzenbein dialyser in long term use a study was carried out on 3 children aged 8, 12, and 14 years. Two of the children had been on haemodialysis before, one of them for 7 months (GW), and the other one for 25 months (HS). On the third child haemodialysis was started using the Hoeltzenbein kidney from the beginning (Figure 5).

Concerning the multiple parameters reflecting the adequacy of long term haemodialysis treatment (Gotch, 1972), Figure 5 selectively represents information about the degree of azotaemia, the control of anaemia, and the physical development of the children subject to the study.

Pre- and post-dialysis urea and creatinine values which were averaged over a period of 2 months clearly indicate that azotaemia can well be corrected to a tolerable degree using the Hoeltzenbein dialyser 3 times a week 4 to 5 hours. The mean decrease of blood urea was 71%, of creatinine 60%.

Haematocrit as an additional and important standard for the adequacy of maintenance dialysis treatment remained stable in all 3 children or even increased in one child (MH) from 14% to 24%. No transfusions were given during the study. All children, however, had been transfused shortly prior to this investigation. The transient decline of haematocrit observed in the 14-year old girl (GW) was due to hypermenorrhoea.

Body weight slightly increased and the growth rates observed ranged from 1 to 3 cm.

The clinical course (Table I) of the children on the Hoeltzenbein dialyser has been without major complications for more than one year. No untoward effects

TABLE I. Longitudinal Study – 3 children on the Hoeltzenbein dialyser for 12–17 months

<table>
<thead>
<tr>
<th>Dialysis</th>
<th>MH</th>
<th>GW</th>
<th>HS</th>
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<tbody>
<tr>
<td>Effectiveness dialysis</td>
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<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Dialysis Time</td>
<td>↓</td>
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<tr>
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<tr>
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<tr>
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<tr>
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</tr>
<tr>
<td>General Well-Being</td>
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<td>↑</td>
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<tr>
<td>Possibility For Rehabilitation</td>
<td>↑</td>
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</tbody>
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= Unchanged
↑ Improved
↓ Decreased

related to the dialyser were noticed. Membrane rupture rate was only 1 of 673 (0.15%). No clotting problems were observed and no disequilibrium signs nor pyrogenic reactions were noticed.

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Laboratory data such as complete blood count, serum enzymes and protein electrophoresis have been within normal limits. All 3 children were normotensive during the study. Hypertension, which had been obvious in one child (HS), was well controlled without additional medication.

Though 120 ml of the extracorporeal priming volume was discarded, little if any decrease of the blood pressure was observed in the initial phase of dialysis.

Peroneus motor nerve conduction velocity has remained unchanged. The children’s cardiac situation studied by radiographic, electrocardiographic, and sonographic examination revealed not only a reduction of the heart/lung quotient, but an improvement in myocardial function.

The Holtzenbein dialyser was well tolerated by all children on short and long term application. The acceptability of this new dialyser was obvious for those children who had experienced other types of dialyser.

DISCUSSION AND CONCLUSIONS

Summarising our long term experience we can draw the following conclusions. Clearance of small-sized solutes and of middle molecules can be considered adequate at clinically useful blood flow rates.

Ultrafiltration is satisfactory and predictable.

The relatively low priming volume offers the possibility of using this dialyser even in small children, and the advantage of discarding the priming volume in bigger ones.

Compliance is comparably low. Residual blood volume is consistently low even at wash back volumes of only 120 ml. The dialyser is convenient in size and easy to handle, with no inherent risk of leakage or pyrogenicity.

The Hoeltzenbein dialyser can be recommended without any restrictions for the paediatric age group offering the advantage of shortening overall dialysis treatment time.

Acknowledgments

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References


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