ARTIFICIAL ORGANS 2000 ESAO

Satellite Symposium on the Occasion of the 25th Anniversary of the Department of Nephrology of the Ss. Cyril and Methodius University, Skopje, R. Macedonia, November 25–26, 2000

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ABSTRACT

Artificial Organs 2000 Satellite Symposium of European Society for Artificial Organs (ESAO) was organized by the Macedonian Society for Nephrology, Dialysis, Transplantation and Artificial Organs (MSNDTAO) and the Macedonian Academy of Sciences and Arts (MASA) on November 25-26, 2000 on the occasion of the 25th Anniversary of the Department of Nephrology of the Ss. Cyril and Methodius University, Skopje, R. Macedonia.

The main topics of this symposium were: Blood-purification techniques, Artificial Kidney, Metabolic- and Cardiac-Assist Systems as well as Biomaterials to be used for Artificial Organs.

H. Klinkmann (Glasgow, United Kingdom), D. Falkenhagen (Krems, Austria), U. Baurmeister (Wuppertal, Germany), V. Bonomini, S. Stefoni (Bologna, Italy), R. Vanholder (Ghent, Belgium), S. Stiller (Aachen, Germany), H. Mann, H. Melzer (Aachen, Germany), J. Pop-Jordanov, N. Pop-Jordanova (Skopje, R. Macedonia), B. Stegmayr (Umea, Sweden), M. Mydlik, K. Derzisova, O. Racz, A. Sipulova, J. Boldizsar, E. Lovasova, M. Hribikova (Kosice, Slovak Republic), A. Jörres (Berlin, Germany), M. Polenakovic (Skopje, R. Macedonia), J. Vienken (Bad Homburg, Germany), S. Bowry (Bad Homburg, Germany), E. Piskin (Ankara, Turkey), J. Klinkmann, W. Schimmelpfennig, H. Lantow, W. Rigger (Teterow, Germany), A. Sikole (Skopje, R. Macedonia), A. Oncevski, P. Dejanov, V. Gerasimovska, M. Polenakovic (Skopje, R. Macedonia), J. Wojcicki (Warsaw, Poland), K. Affeld (Berlin, Germany), G. Rakhorst et al. (Groningen, The Netherlands), Z. Mitrev (Skopje, R. Macedonia), S. Kedev, G. Guagliumi, O. Valsecchi, M. Tsepili (Skopje, R. Macedonia, Bergamo, Italy) have presented their papers at the Symposium. The presentations provoked a fruitful discussion and it was concluded that they should be published.

The papers were published in the International Journal of Artificial Organs of the European Society for Artificial Organs (ESAO) as a special issue on “Artificial Organs 2000 ESAO Satellite Symposium - Skopje, R. Macedonia”, Guest Editors: M. H. Polenakovic, Skopje and J. Vienken, Bad Homburg; Vol. 25, No. 5, 2002.

Keywords: Artificial Kidney, Blood Purification, Vascular Access, Cardiac Assist Technology, Metabolic Assist, Tissue Engineering, Psychophysiology

Fig. 1. Program of the Symposium

In 1943 W. Kolff created the first artificial organ – the “artificial kidney”, which partially replaced the function of the natural kidney (1).

The first hemodialysis in R. Macedonia was performed in May 1961 according to the writing of Prof. T. Stojcevski, at the Transfusion Institute of R. Macedonia, by Dr. Berisav Vujasin (2).

The hemodialysis was performed with a Kolff-Brigham rotating drum artificial kidney. The patient was anuric after a suicidal poisoning. Despite the several hemodialyses, the patient died.

This first artificial kidney is kept at the Institute of Nephrology in Struga.

In 1965 we have obtained a new artificial kidney “Websinger” with a sigma motor pump, with possibilities for use of disposable Kolff “twin coil” dialyzer (3). Between 1959 and 1971 hemodialysis (HD) was performed only in patients with acute re-

nal failure on the Renal Unit at the Department of Medicine, Medical Faculty in Skopje (3).

In May 1971, a Unit for Chronic HD was founded at the Renal Unit and the program of maintenance hemodialysis (MHD) was started with five Stuttgart Fresenius machines and 12 patients dialyzed on twin coil dialyzers. That was a great incentive for the development of HD in the Republic of Macedonia enforced by the great number of patients with end stage renal disease (4).

The health workers at the Nephrology Clinic were the driving force in the development of HD and, thus, the application of artificial organs (kidney) in medicine. It were almost 25 years since the establishment of the Nephrology Clinic.

The members of the European Society for Artificial Organs (ESAO) proposed to organize a satellite symposium of ESAO on artificial organs - Artificial Organs 2000 in Skopje, on the occasion of 25 years

since the establishment of the Clinic for Nephrology. It was considered that such a symposium will positively affect the development and application of artificial organs in R. Macedonia and beyond. It was agreed that the symposium would be organized by the Macedonian Society for Nephrology, Dialysis, Transplantation and Artificial Organs (MSNDTAO) and the Macedonian Academy of Sciences and Arts (MASA) on behalf of ESAO, on November 25-26, 2000 at the MASA premises in Skopje.

The symposium was opened with the welcoming addresses by: G. Efremov, President of the Macedonian Academy of Sciences and Arts, D. Falkenhagen, President of the European Society for Artificial Organs (ESAO) and H. Klinkmann, Dean of the International Faculty for Artificial Organs (INFA). The Opening Speech was delivered by M. Polenakovic, President of the Organizing Committee.

Prominent scientists from abroad and from the Republic of Macedonia gave presentations at the symposium:

H. Klinkmann (Glasgow, United Kingdom): Blood purification in clinical medicine by apheresis and adsorption technologies; D. Falkenhagen (Krems, Austria): New developments and artificial liver support; U. Baurmeister (Wuppertal, Germany): Adsorptive porous system (APoS) for the treatment of whole blood plasma; V. Bonomini, S. Stefoni (Bologna, Italy): Priority choices in renal replacement therapy; R. Vanholder (Ghent, Belgium): Vascular access: future directions to follow; S. Stiller (Aachen, Germany): Kt/V β -2m new parameters of

dialysis adequacy?; H. Mann, H. Melzer (Aachen, Germany): Testing protein permeability of dialysis membranes using SDS-PAGE; J. Pop-Jordanov, N. Pop-Jordanova (Skopje, R. Macedonia): Psychophysiological comorbidity and computerized bio-feedback; B. Stegmayr (Umea, Sweden): Various clinical approaches to minimize complications in peritoneal dialysis; M. Mydlik, K. Derzisova, O. Racz, A. Sipulova, J. Boldizsar, E. Lovasova, M. Hribikova (Kosice, Slovak Republic): Vitamin E as an antioxidant agent in CAPD patients; A. Jörres (Berlin, Germany): Extracorporeal treatment strategy in acute renal failure; M. Polenakovic (Skopje, R. Macedonia): Dialysis and PF therapy in 2000 in R. Macedonia; J. Vienken (Bad Homburg, Germany): Polymers in nephrology; S. Bowry (Bad Homburg, Germany): Dialysis membranes of today; E. Piskin (Ankara, Turkey): Biodegradable polymeric matrices for bioartificial organs; J. Klinkmann, W. Schimmelpfennig, H. Lantow, W. Rigger. (Teterow, Germany): LIFE 18 a new technical solution for an integrated apheresis machine; A. Sikole (Skopje, R. Macedonia): The impact of anemia on heart morphology in chronic renal failure; A. Oncevski, P. Dejanov, V. Gerasimovska, M. Polenakovic (Skopje, R. Macedonia): Approach to vascular access for hemodialysis experience from R. Macedonia; J. Wojcicki (Warsaw, Poland): Intensive diabetes treatment new trends in technical support; K. Affeld (Berlin, Germany): Problems and challenges of permanently implanted cardiac assist system; G. Rakhorst et al. (Groningen, The Netherlands): Animal models for cardiac assist research; Z. Mitrev (Skopje, R.

Fig. 2. Kolff-Brigham Rotating Drum Artificial Kidney

Macedonia): Transplantation or alternative surgical therapy in patients with ischemic dilatative cardiomyopathy and aneurysmatic augmentation of the left ventricular cavity; S. Kedev, G. Guagliumi, O.

Valsecchi, M. Tsepili (Skopje, R. Macedonia, Bergamo, Italy): Heparin-coated stents in acute coronary syndromes: a randomized comparison with uncoated stents in unselected native coronary lesions.

Fig. 3. *Opening of the Artificial Organs 2000 ESAO Satellite Symposium*

Fig. 4. *M. Polenakovic – Opening of the Artificial Organs 2000 ESAO Satellite Symposium*

Fig. 5. From left to right: M. Polenakovic, H. Klinkmann, I. Tadzer and A. Sikole

Fig. 6. From left to right: K. Affeld, M. Polenakovic, J. Vienken, G. Efremov and H. Klinkmann

Fig. 7. H. Klinkmann and D. Falkenhagen

Fig. 8. *J. Pop-Jordanov*

Fig. 9. *From left to right: G. Rakhorst, M. Polenakovic and D. Falkenhagen*

Fig. 10. *Participants in the Symposium*

The presentations provoked a fruitful discussion and it was concluded that work should be done on the development of artificial organs for each human parenchymal organ. Artificial organs need to be widely available to any patient who needs them.

The quality of the presented papers, the achievements in the research and the new ideas for the artificial organs led to the conclusion that the presented presentations should be printed in the International Journal of Artificial Organs of the European Society for Artificial Organs (ESAO) as a special issue.

We, from R. Macedonia, were especially honored that ESAO dedicates a special issue to the International Journal of Artificial Organs: "Artificial

Organs 2000 ESAO Satellite Symposium - Skopje, R. Macedonia".

The special issue of the journal came out in May 2002; No. 5; Vol. 25.

We enclose the foreword to the Artificial Organs 2000 ESAO Satellite Symposium entitled "25 Years of active research on artificial organs at the Department of Nephrology at the Skopje University of Ss. Cyril and Methodius" by M. H. Polenakovic and J. Vienken, published in the International Journal of Artificial Organs, Vol. 25, No. 5, 2002, p. 345 (5).

In addition, we enclose the abstracts of the printed papers:

Foreword

Research on Artificial Organs has a long and enduring history in Macedonia, mainly at the University of Ss. Cyril and Methodius in the Macedonian Capital of Skopje. Here, intensive investigations on Artificial Organs have been performed in cooperation with the Department of Nephrology. A series of excellent publications in peer-reviewed journals have appeared in recent years confirming the high standard of research in this Balkan country.

In November 2000, the Department of Nephrology of Skopje University, St. Cyril and Methodius, celebrated its 25th anniversary. The European Society for Artificial Organs (ESAO) took this as an opportunity to organize the Symposium "Artificial Organs 2000". This symposium took place in Skopje on November 25-26, 2000 at the Macedonian Academy of Sciences and Arts and attracted many renowned speakers and participants from all over Europe. Not surprisingly, it proved an interesting fact to the public: a close relationship exists between the University of Skopje and other European Universities, as well as an intense and reciprocal interest in cultivating collaboration between these Institutions. This symposium has further demonstrated that open and friendly cooperation is possible between European and Macedonian scientists despite the turbulent political situation of the Balkan Peninsula.

The main topics of this symposium were: Blood-purification techniques, Artificial Kidney, Metabolic- and Cardiac-Assist Systems as well as Biomaterials to be used for Artificial Organs. Selected papers of this symposium are collected in this special number of the International Journal of Artificial Organs. We believe that this issue represents a highly interesting overview of current aspects of scientific research in the field of Artificial Organs. We hope that the papers published here will stimulate further scientific cooperation and foster mutual understanding between the Balkan and other European countries.

Twenty-five years of research on Artificial Organs at the University of Skopje deserve warm congratulations for such a successful program in such difficult political times. Twenty-five years of scientific success encourage us to hope that many years of scientific exchange and efficient cooperation lay ahead of us.

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Vascular access

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INTRODUCTION

Without adequate vascular access, it is impossible to offer efficient hemodialysis to patients with end-stage renal disease. Vascular access problems are a cause of decreased delivery of dialyser blood flow as well as of reductions of effective dialysis time. The logical consequence is a fall of total clearance. By its influence on dialysis adequacy, vascular access has a final impact on patient morbidity and mortality. Once all access possibilities have been exhausted, the patient will be faced with a life-threatening condition. During the last decade, nephrologists have been confronted more and more frequently with such a potentially fatal evolution. Hence, there is no debate that vascular access is the Achilles heel of today's hemodialysis. However, it is also the Cinderella, because progress in research and development have been much slower and less adequate than in any other field of dialysis care.

The ideal access should consistently allow for repeated cannulation and should provide adequate blood flow to maximize dialysis delivery and this indefinitely long. Complications such as thrombosis, infection and hemorrhage should be absent. Such an ideal access does however not exist as of today.

In a study from the United States, access-related problems were held responsible for 48% of hospitalization (1). Hence, the quality of vascular access is not only a medical issue, but also a socio-economic matter. The nephrologic community thus needs reliable research data that should make it possible to improve access quality.

The most important presently available access possibilities, together with those that are still the subject of research and development, are summarized in Table 1. The purpose of the present paper is to discuss these possibilities one by one and to point out the potential advantages and disadvantages.

One of the obvious problems with vascular access is that, from the moment the first access is created, an ongoing process is started that will end with the loss of all access possibilities, if the patient survives long enough. A careful application of all possibilities will postpone this moment and will help to sustain life and quality of life longer than if access systems are constructed and monitored carelessly.

The Cimino-Brescia fistula

In 1966, Cimino, Brescia, Apoll and co-workers first described the classical radio-cephalic fistula (2). Until then, shunts composed of artificial material, that bridged the arterial and venous vascular beds, had been used as access systems. Because of the foreign nature of these shunts, clotting and infection were frequent complications. The arterio-venous (AV) fistula, on the other hand, consisted of endogenous endothelialized vessel material. Therefore, infection and thrombosis became substantially less preponderant. Ideally, the AV-fistula is constructed in the lower arm. Alternative locations are more proximally in the arm, up to the elbow and above. These sites can be used as an alternative option if vascular quality in the lower arm is insufficient. In some situations, such as hemodialysis in diabetic patients, this higher location is even the approach of preference, because of the dubious quality of the more proximally located vessels.

The creation of the Cimino-Brescia fistula needs the presence of adequate and patent arteries and veins. This implies a timely referral of the patient to the nephrologist. When a patient has progressive renal failure so that it can be expected that he/she will need renal replacement therapy within due course, one arm should be preserved for the future creation of a vascular access system. By preference, the non-dominant arm is chosen for this approach, if the quality

¹ Weekly Review, 2002

0391-3988/347-07 \$03.50/0

Approach to vascular access for hemodialysis: experiences from the Republic of Macedonia

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ABSTRACT: Eight thousand eight hundred and forty nine different vascular hemodialysis accesses were performed in the period from 1976 until 1999 at the Department of Nephrology, Skopje. 3,114 native arterial-venous fistula (AVF), 715 arterial-venous shunts (AVS), 4,964 temporary or permanent catheters (4,411/88.86% femoral, 410/8.26% subclavian, 143/2.88% jugular) and 56 PTFE vascular grafts. Femoral catheterization (4,312/86.86%) is the favoured solution if a temporary vascular dialysis access is taken into consideration. The most popular chronic dialysis angio-access in our country is native AVF (90.5% of 3,440 permanent dialytic vascular accesses). The tunneled subcutaneously positioned catheters as a permanent dialytic angio-access were present in 270 cases (7.9%); 99 in femoral veins (our original method), 123 in subclavian veins and 48 catheters in jugular veins. The synthetic vascular grafts-PTFE (polytetrafluoro-ethylene) represent only 1.6% of all dialysis angio-accesses. The number of preventive AVFs created in patients with preterminal end-stage renal disease eventually increased: from 14% in the eighties, 20.8% after 10 years and 31.50% in 1999. Most of the preventive AVFs are done in outpatients 71.8% in 1999. This year 44.4% of all chronic vascular access were created in the same way.

We prefer femoral catheters for both temporary and permanent access because our results show that femoral catheterization has a lower rate of early complications when compared to the subclavian catheterization group; the rate of late complications (thrombosis, stenosis, infections) is lower or the same; infections in femoral catheterizations are less frequent, compared to subclavian and jugular ones.

Our contributions in the field of vascular access surgery are the three original methods which are constantly used at the Department: 1. Combination of temporary (AVS) and permanent vascular access (AVF) using the same blood vessels, performed in one surgical act; 2. Tunneled femoral catheter as a permanent vascular access for hemodialysis (2 types: on the abdominal wall and on the inguinal region - thigh); 3. Reduction of hyper-flow in AVF without the operation of "banding", with ligation of the artery before arteriovenous anastomosis. (Int J Artif Organs 2002; 25: 354-64)

KEY WORDS: Native AVF, Hemodialysis catheters, Tunneled femoral catheters

INTRODUCTION

The first hemodialysis (HD) in the Republic of Macedonia was performed in 1959 on a patient with acute renal failure (ARF). In the period 1959 to 1971

only patients (pts) with ARF were dialyzed (1).

The chronic hemodialysis program at the Department of Nephrology in Skopje started with 12 pts in 1971. Now, in 2000, in the Republic of Macedonia we have 18 Hemodialysis Centers with more than 1,000 pts. At the

0391-3988/354-011 \$05.50/0

¹ Weekly Review, 2002

Various clinical approaches to minimise complications in peritoneal dialysis

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ABSTRACT: The main reason for a failure of peritoneal dialysis is due to technical problems or infections. By starting PD immediately after the insertion of a dialysis catheter (instead of starting HD before optimal healing of the PD-catheter) it may be easier to achieve acceptance for PD by the patients. An easy and tight access is achieved when inserting the PD-catheter through the rectus muscle, fixing it with three purse string sutures, two of them fixing the inner cuff between the peritoneal membrane and the inner rectus fascia. Thereby early and late leakage will be rare and good drainage is normally achieved besides a low risk for exit site infections. Using Coloplast® adhesive insulin can be injected into the PD bags in a simple way even by patients with bad vision. Using ultraviolet light, as additional exchange device (UV-box), the risk for peritonitis is reduced compared to classic manual connection. Using the Y-set or duo-bag system the risk for peritonitis is further lowered. Malfunction by disconnection of the intraperitoneal part of the catheters can often be corrected without surgery using a bent stylet. A controlled study showed that antibiotic prophylactics could significantly reduce the risk for peritonitis in the follow up after insertion of PD catheters. Additionally the risk for peritonitis is reduced using a special connector for the PET-sampling procedures. X-ray of catheter location in the abdominal cavity can be performed by injection of 20-ml contrast media into 100 ml of PD fluid residing in the PD-bag. After mixing, small portions of this fluid can be infused into the abdomen for X-ray delineation of the location. An increased ultrafiltration failure during PD may be due to use of beta-blocker medication. After ceasing this medication recovery may occur. Avoiding pots in the room used for PD-exchange may lower the risk for peritonitis further. A devoted nurse and physician will keep up the patients' spirit and help to convert patients not suitable for PD to HD or the other way round. By such measures the incidence of peritonitis can be reduced to 1 in 40 treatment months or less. (Int J Artif Organs 2002; 25: 365-72)

KEY WORDS: Dialysis, Acute dialysis, Peritoneal dialysis, Congestive heart failure, Surgery, Catheter survival, Peritonitis, Malfunctioning

Peritoneal dialysis (PD) corresponds to about 20% of chronic dialysis (1) and only exclusively is a part of acute dialysis. Data indicate that in general PD is as efficient as HD in adequacy and long term survival (2). Despite this fact and a lower cost for PD in general (3) there is hesitance to include new patients in PD programs. This difference varies from centre to centre and the inclusions are most prominent in e.g., Mexico,

over 90% (4) and UK, about 45% while it is very limited in Japan (about 6%) (1).

Beyond economical considerations there is also hesitation to initiate PD due to the risks for complications. Several technical failures causing a change from PD to HD may occur in the initial phase, before commencing chronic dialysis (leakage, outflow obstruction, perforation, bleeding, post-operative

¹ Weekly Review, 2002

0391-3988/355-08 \$04.00/0

Vitamin E as an antioxidant agent in CAPD patients

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ABSTRACT: Oxidative stress, increased lipid peroxidation and decreased activity of antioxidant systems may contribute to the accelerated development of atherosclerosis in chronic renal failure patients during renal replacement therapy. The aim of the study was to investigate the influence of vitamin E (400 mg/day) on some antioxidant defense parameters in CAPD patients. In fourteen CAPD patients, erythrocyte antioxidant enzymes, superoxide dismutase (SOD), glutathione peroxidase (GPX) and catalase (CAT), the concentration of plasma malondialdehyde (MDA), vitamin A, vitamin C and vitamin E were investigated. The study was divided into two periods. Each period lasted six weeks. In the first period patients received orally vitamin E 400 mg/day, in the second period they did not receive vitamin E or other antioxidant drugs. Each parameter was determined at the beginning of the study and at the end of each period. Six CAPD patients were treated by erythropoietin (EPO) and received orally pyridoxine 20 mg/day and the others without EPO treatment received pyridoxine 5 mg/day. Six-week treatment by vitamin E (400 mg/day) led to the significant increase of serum vitamin E (from 33.6±9.0 to 49.3±15.5 µmol/L) and to the significant decrease of MDA (from 2.62±0.5 to 2.36±0.4 µmol/L). The mean values of erythrocyte enzymes were in or under the lower margin of normal range and were not influenced by vitamin E in CAPD patients. The results of our study showed that orally administered vitamin E is a very important antioxidant agent for CAPD patients. (Int J Artif Organs 2002; 25: 373-8)

KEY WORDS: Vitamin E, Antioxidant defense parameters, CAPD patients

INTRODUCTION

Atherosclerosis is a leading cause of death in patients with end-stage renal disease including those on long-term renal replacement therapy (1, 2). Increased oxidative stress and consequent increased oxidizability of low-density lipoproteins (LDL) has been proposed as an explanation for accelerated cardiovascular complications in chronic renal failure patients undergoing dialysis (3).

Alpha-tocopherol (vitamin E) is a liposoluble vitamin

placed on cell membranes and its main function is to protect polyunsaturated fatty acids against oxidative aggression, thus preserving its integrity (4). Vitamin E is the most abundant antioxidant present, and also the only significant antioxidant in LDL. It is a chain-breaking antioxidant, trapping peroxyl-free radicals and it is an important protective factor (inverse risk) in cardiovascular disease development (1, 4-6).

However, there are discrepancies about serum vitamin E levels in uremic patients on hemodialysis and CAPD.

¹ Weekly Review, 2002

0391-3988/373-06 \$03.00/0

Artificial Kidney, Blood Purification and Vascular Access

Filtration fluid for hemodialysis treatment

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ABSTRACT: Bacterial contamination of dialysis fluid has long been recognized as a problem in hemodialysis. Cytokines released as a consequence of contaminated dialysis fluid are believed to be responsible for many acute and chronic side effects in patients undergoing renal replacement therapy. For several years now, attempts have been made to eliminate pyrogenic substances and ensure a sterile and endotoxin-free dialysis fluid. A recent dialysis fluid filter known as DIASAFE[®], containing a membrane based on Polysulfone[®] (Fresenius), was tested for a period of 1,000 hours (approx. 14 weeks). Dialysis fluid samples were collected once weekly before and behind the filter and cultivated for detection of microorganisms and endotoxins. Additionally, starting after the fourth week of the study, serum samples were collected weekly and the B2-microglobulin concentration was determined.

The filter reduced microorganisms at a rate of at least 10⁶ and in the majority of cases (86% of samples) by more than 10⁷. Under clinical conditions the stability and microbiological functionality of the filters could be demonstrated for more than 1,000 hours and 150 disinfecting cycles. In four cases of endotoxin burden (>0.5 IU/ml) in the dialysis fluid in front of the filter the concentration behind the filter was lower than 0.1 IU/ml, indicating effective reduction of endotoxins. A tendency to a reduction of B2-microglobulin in serum from 32.5 ± 3.9 mg/L to 21.5 ± 5.3 mg/L was observed. These results indicate that the dialysis fluid filter used was effective, dramatically reducing the bacterial contaminants in dialysis fluid, thus protecting patients from the potentially harmful acute and long-term life-threatening consequences of contaminated dialysis fluid. (Int J Artif Organs 2002; 25: 379-85)

KEY WORDS: Hemodialysis, Dialysis fluid, Filtration, Pyrogen, Endotoxin

Artificial Kidney, Blood Purification and Vascular Access

Extracorporeal treatment strategy in acute renal failure

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ABSTRACT: The mortality of acute renal failure remains high (around 50-70%) despite manifold improvements in terms of techniques and equipment for renal replacement therapies as well as patient monitoring and intensive care support. At present, it is not clear if the method chosen for renal replacement therapy, i.e. intermittent hemodialysis or continuous hemofiltration, might impact on the outcome of these patients. While earlier retrospective studies suggested that CVVH might result in better survival and renal recovery in acute patients, recent prospective studies indicated that this may not be the case or, conversely, outcomes may be better with IHD. These studies were, however, not evenly conducted in terms of illness severity or were too small to produce conclusive results. In addition, a meta-analysis of 9 published prospective studies in 692 pts. indicated a similar mortality with CVVH vs. IHD. Some of the studies enrolled for this meta-analysis, however, suffered from methodological and/or randomization problems, thus this important question remains to date unanswered. Typically, CVVH is chosen for treating patients with hemodynamic instability and volume overload. In such cases, however, CVVH should be performed with a filtrate volume of at least 35 ml/kg body weight per hour as this was shown to be associated with better survival as compared to smaller filtrate volumes. A second controversy exists to date whether the choice of the dialyzer membrane might be of relevance for the outcome of patients with acute renal failure. Earlier studies indicated that the use of biocompatible membranes in these patients may result in improved patient survival and renal recovery. More recently, however, similar studies could not confirm these results. Another meta-analysis of controlled prospective trials (671 patients in 7 separate studies) calculated a relative mortality risk of 1.01 for cuprophane vs. biocompatible membranes. Thus, the choice of the dialyzer membrane should be based on individual assessment rather than treatment bias. (Int J Artif Organs 2002; 25: 391-6)

KEY WORDS: Acute renal failure, Hemodialysis, Continuous hemofiltration, Biocompatibility

Metabolic and Cardiac Assist Technology and Other Scientific Realms

Ischemic dilatative cardiomyopathy and aneurysms of the left ventricular cavity: transplantation vs alternative surgery

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ABSTRACT: Patients with ischemic end-stage heart failure due to severe coronary disease associated with dilatative cardiomyopathy have an annual mortality of 30-50%. Between July 1987 and December 1999, 21 patients at the University Hospital in Frankfurt, and 25 patients from Skopje underwent total ocular repair with simultaneous coronary artery bypass. (Int J Artif Organs 2002; 25: 401-10)

KEY WORDS: Transplantation, Dilatative cardiomyopathy, Aneurysmal dilatation of left ventricle

Artificial Kidney, Blood Purification and Vascular Access

Dialysis in adults in year 2000 in the Republic of Macedonia

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ABSTRACT: 1,019 adult patients with terminal renal failure were treated with dialysis (D) in the first part of the year 2000 in the Republic of Macedonia. 1,010 patients (99%) were treated with chronic intermittent (maintenance) hemodialysis (HD); while nine patients (1%) were on continuous ambulatory peritoneal dialysis (CAPD). For the children, a special peritoneal dialysis program was developed: 509 patients per month of the population (199) were on dialysis.

The Republic of Macedonia is, therefore, among those central and eastern European countries with a higher PAF number in the treatment of end-stage renal disease, following Croatia, the Czech Republic and Slovenia.

The patients were treated at 18 Centres in a network of HD Centres at a distance of 30-60 km from their place of residence in order to facilitate their access to treatment and to avoid all patients who have had symptoms indicating need for treatment with D were accepted for treatment. The government paid all the expenses of the treatment and the salaries of the staff. 56% were male and 44% were female patients. The youngest patient was aged 3 and the oldest was 82 years old. There has been an increase in the age of the patients on D as well as an increase in their number. In 1993 we had 727 patients being treated with D, and now we have 1,019 with a consequent increase in the number of patients with ESRD and a need for D and renal transplantation. Monthly per year at the different Centres ranged from 6-15% in 1999 and the average is 12%.

Glomerulonephritis (GN) - both primary and secondary - is the main cause of renal failure (RF) in some Centres up to 15%. Tubero-interstitial disease follows GN. ADPKD patients constitute 6-8% with a difference among the Centres of 3-25%, and diabetic nephropathy is found in 10%, 5-15% in different Centres. 11-61% of patients have an unknown etiology.

352 patients are on treatment with human recombinant erythropoietin (rEPO) - in some Centres up to 60%. The mode of application was subcutaneous and the usual dose is 20 U/kg body weight and the mean maintenance dose of EPO per patient weekly is 4,000 U.

The Cimco-Biocompare antitoxemic filter is being applied as a standard vascular access. The survival rate of our patients treated with maintenance HD at 5 years was 58%, CAPD and peritoneally renal transplantation are to be better developed as alternative methods in treating terminal renal failure. (Int J Artif Organs 2002; 25: 385-90)

KEY WORDS: Chronic renal failure, Hemodialysis, CAPD, EPO, Survival

Artificial Kidney, Blood Purification and Vascular Access

Priorities in renal replacement programs

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ABSTRACT: The various alternative programs in renal replacement therapy have precise meritocratic ranking which unfortunately is still largely ideal today. New directions and scientific plans (bioartificial kidney, new immunomodulators, gene therapy) have to be followed to make today's ideal ranking become reality. (Int J Artif Organs 2002; 25: 397-400)

KEY WORDS: Renal replacement therapy

Metabolic and Cardiac Assist Technology and Other Scientific Realms

Sodium and body fluid homeostasis in profiling hemodialysis treatment

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ABSTRACT: Acute adverse side-effects of hemodialysis such as hypotension, muscle cramps, osmotic imbalance and thirst are induced by the interference with fluid and electrolyte balance occurring during treatment. Changes in osmolality due to alterations of plasma sodium concentration during hemodialysis strongly influence fluid distribution between extracellular and intracellular fluid volume. Increased sodium dialysate concentration induces fluid shift from the intracellular to the extracellular compartment. This shift leads to a more efficient ultrafiltration by increasing plasma refilling volume but also to an increased thirst. Treatment of hypotension, cramps and nausea with hypertonic saline solution leads also to a considerable retention of sodium. Profiling hemodialysis consists in deliberately changing ultrafiltration and dialysate sodium in order to combine an efficient ultrafiltration with a balanced sodium handling and to prevent side-effects during treatment. Continuous measurement and control of blood volume seems to be the best method to prevent hypotensive episodes. Profiling of sodium should not be the cause of a positive sodium balance. The clinical benefits of sodium profiling to the patients have still to be proven. (Int J Artif Organs 2002; 25: 421-6)

KEY WORDS: Body fluids, Profiling hemodialysis, Sodium

Validation of a two-pool model for the kinetics of β_2 -microglobulinS. STILLER¹, X.Q. XU², N. GRUNER¹, J. VIENKEN¹, H. MANN³¹Dialysis Center, Aschen - Germany²Renal Division, Renji Hospital, Shanghai Second Medical University - China³Preventive Medical Care, Bad Honberg - Germany

ABSTRACT: Secondary amyloidosis due to beta-2-microglobulin (β_2 -m) is a serious long-term complication in patients on regular dialysis therapy. β_2 -m can be considered a middle-molecule marker used to facilitate the assessment of dialysis efficacy. For this purpose, a validated model that calculates characteristic efficacy parameters, such as K_{β_2} , TAC and generation rate, is needed. There is general agreement that β_2 -m-kinetics should be described by a two-pool model, but little has been published to validate such an approach.

We measured the β_2 -m concentration profiles of eight stable patients during hemodialysis (HD) at the start of treatment, after 30 minutes, after 60 minutes, and every hour until the end. Thereafter they were measured at 10-minute intervals for an hour. The dialyzer clearances were determined from the plasma concentrations in front of and behind the dialyzer twice during each session - after 1 hour, and 4 hours from the start of treatment. The kinetic parameters of a two-pool model (i.e. V_1 , the compartment volumes V_1 and V_2 , the mass transfer coefficient K_{β_2} , and the generation rate G) were determined from the optimal fit of the measured concentration profile. The table below summarizes the results by giving the mean and standard deviation for each parameter.

V (liters)	V ₁ /V ₂	V % TBW	K _{β₂} (ml/min)	G (mg/kg/day)
10.0 ± 1.6	4.60 ± 1.8	28.4 ± 3.1	56.3 ± 25.2	2.50 ± 0.66

Inter-individual differences in V_1/V_2 and K_{β_2} were high, ranging from 2.5 to 10.0 for V_1/V_2 and from 26 to 140 for K_{β_2} . Error analysis suggested that these wide ranges were due to the method and that in reality the probable range of V_1 is 25-36% of TBW, of V_2/V_1 3.5-5.3, and of K_{β_2} 30-80 ml/min. With standard values for these three parameters ($V_1 = 30\%$ of TBW, $V_2/V_1 = 4.4$ and $K_{\beta_2} = 55$ ml/min), equal for all patients, and their respective ranges, $K_{\beta_2}V$ can be calculated with a standard deviation of 13%. $K_{\beta_2}V > 1.2$ secures the maximum possible β_2 -m removal with three HD treatments a week.

Conclusions: The parameters of a two-pool model of β_2 -m kinetics can be derived from concentration profiles obtained under routine dialysis conditions, but accuracy is not completely satisfactory. Similar to the dialysis dose for urea ($K_{\text{urea}}V$), the dialysis dose for β_2 -m ($K_{\beta_2}V$) can be calculated from the pre- and post-dialysis concentrations of β_2 -m, body weight, ultrafiltration and dialysis time. $K_{\beta_2}V_{\text{max}} > 1.2$ secures the maximum possible removal of β_2 -m in HD with three sessions per week. (Int J Artif Organs 2002; 25: 411-20)

KEY WORDS: β_2 -microglobulin kinetic modeling, Parameter definition

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0301-3088/01/0101-0101 \$05.00/0

Biomaterials and their Application

Biodegradable polymeric matrices for bioartificial implants

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ABSTRACT: Biomaterials made of polymers, metals or their alloys, ceramics and their composites, are used as implants to restore or to replace the damaged soft and hard tissue/organ functions for an intended time period. Biomaterials made of synthetic materials are very simple materials compared to their natural counterparts, they only replace very simple functions of the damaged tissue during healing. Natural tissues have been used for both soft and hard repair and replacement, but they do have serious limitations such as: shortage of donor tissue, donor site morbidity, unpredictable resorption characteristics, immunogenic response, risk of disease transmission, and ethical limitations. Tissue engineering is a relatively new approach, in which healthy mammalian cells are used with supporting matrices, usually made of either natural or synthetic polymers as composite bioartificial implants. Primary cells, especially embryonic stem cells, cell lines, hybridomas, genetically modified cells are considered as potential sources for this application. Both closed and open matrices are used as support matrices. Nondegradable and biocompatible microcapsules and hollow fibers are utilized in closed systems, especially for immunoprotection of the transplanted cells. Biodegradable polymers, both natural and synthetic are used in the preparation of bioartificial implants carrying only autogenic cells. (Int J Artif Organs 2002; 25: 434-40)

KEY WORDS: Bioartificial implants, Tissue engineering, Biodegradable polymers

Biomaterials and their Application

Dialysis membranes today

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ABSTRACT: In recent years, hemodialytic therapies have evolved from the simple, diffusion-dependent removal of small molecular weight substances from blood to advanced therapy modalities involving the convective removal of larger uremic solutes. The clinical benefits of removal of substances such as β_2 -microglobulin (β_2 -m) have been reported by several authors: elimination of large-molecular weight "uremic toxins" is now widely accepted as being beneficial to the overall quality of life of patients.

This trend would not have been possible without parallel technical developments, especially that of new membranes having more open pore structures resulting in higher sieving coefficients and increased hydraulic permeability. Not all polymer types are suitable for the manufacture of high-flux membranes required for convective therapies in which large fluid volumes are exchanged. Amongst the more important criteria are: the selected polymer must be able to undergo steam sterilization, have high endotoxin retention capabilities, be suitable for the fabrication of a range of hydraulic permeabilities and, of course, have high blood compatibility. The aim of this paper is, firstly, to review the major membrane development phases over the last quarter of a century. Secondly, the suitability of current membrane materials to meet the aforementioned requirements will be examined. Thirdly, in view of the recent, rapid proliferation of polysulfone-based membranes, dialysis membranes of the polysulfone family are placed under scrutiny: membranes of this class represent a significant portion of the product portfolio of dialyzer manufacturers today, yet, few end-users are able to distinguish between the latent features of the respective products because of a combination of confusing membrane nomenclatures, classification, trademarks and product claims. (Int J Artif Organs 2002; 25: 447-60)

KEY WORDS: Membrane nomenclature, Polysulfone, β_2 -microglobulin, High-flux dialysis

Metabolic and Cardiac Assist Technology and Other Scientific Realms

Psychophysiological comorbidity and computerized biofeedback

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ABSTRACT: Our previous research on basic and applied psychophysiology comprised the quantum model for subcellular brain processes, the psychosomatic health risk assessment and management, as well as the electrodermal biofeedback psychometrics and therapy. Based on this experience, in the present paper the stress-related psychophysiological disorders in patients dependent on hemodialysis and insulin are considered. The most frequent comorbid psychological disorders appeared to be anxiety and depression, and they are generally under-diagnosed and under-treated. It is concluded that the quality of life of these patients needs to be considerably enhanced. The application of biofeedback, as a complementary cost-effective and non-invasive psychophysiological tool is recommended. In terms of ESAO vocabulary, this technique could be viewed as some kind of artificial ANS/CNS support. Simultaneously, the concept of biocompatibility may be viewed in a larger perspective as "psychobiocompatibility". (Int J Artif Organs 2002; 25: 429-33)

KEY WORDS: Psychophysiology, Comorbidity, Diabetes, Hemodialysis, Biofeedback, Quality of life, Biocompatibility

Biomaterials and their Application

Testing protein permeability of dialysis membranes using SDS-PAGE

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ABSTRACT: Background: Permeability of dialysis membranes for high molecular weight compounds should be similar to that of the glomerular membrane in order to remove uremic toxins like the human kidney does. In order to evaluate permeability of high-flux dialysis membranes SDS-PAGE is applied for examination of filtrate of dialysers during routine dialysis with different membranes.

Method: SDS-PAGE analysis is performed with silver staining method according to the modification of Melzer (5) and consecutive laser densitometry.

Results: The protein pattern of filtrate from dialysis membranes is similar to that of the glomerular membrane containing IgG, transferrin, albumin, alpha-1-microglobulin, retinol binding protein and beta-2-microglobulin. Comparing different membranes there are considerable differences depending on cut-off, charge and adsorption capacity of the particular membrane. In all membranes tested permeability of proteins decreases during one treatment session.

Conclusion: Protein permeability of high-flux dialysis membranes is similar to the glomerular membrane but modified according to pore-size, surface charge, adsorption and time on dialysis. In contrast to the glomerular membrane in each of the investigated membranes protein permeability decreases during function. (Int J Artif Organs 2002; 25: 441-6)

KEY WORDS: Membranes, Permeability, Hemodialysis, High-flux dialysers SDS-PAGE

Biomaterials and their Application

Heparin-coated versus uncoated Palmaz-Schatz stent in native coronary circulation. A randomized study with blind angiographic assessment

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ABSTRACT: The increasing use of stenting to treat more complex lesions and highly thrombotic situations still carries higher risk for subacute stent thrombosis. To assess new heparin-coated stents in a more stringent reality, 40 consecutive patients were randomized in 1:1 ratio to receive either heparin-coated (group 1, 25 stents) or uncoated Palmaz-Schatz stents (group 2, 32 stents). The two groups were similar in baseline clinical, pre- and post-procedural angiographic and angiographic characteristics. High pressure stent deployment without intravascular ultrasound guidance was used. All pts received antiplatelet agents alone. We applied serial angiography (baseline and on 7th day) to evaluate thrombus formation and quantitative coronary angiography (QCA) to define late (6 months, n=39, 100% the eligible pts) neointimal regrowth. There was one subacute stent thrombosis with subsequent acute myocardial infarction and death in the uncoated group.

Conclusion: The implantation of heparin-coated stents in nonselected population is well tolerated and associated with no clinical or angiographic evidence of new thrombus formation, resulting in favorable long-term clinical and angiographic outcome. (Int J Artif Organs 2002; 25: 461-8)

KEY WORDS: Stent, Heparin-coated, Angiography

Twenty years after the Artificial Organs 2000 ESAO Satellite Symposium at the clinics of the Medical Faculty of the University of “Ss. Cyril and Methodius” in Skopje, all types of dialysis and plasmapheresis are performed, kidney transplantations

are performed from a living donor and from cadaver. Dialysis is provided in R. Macedonia to patients who need it in 25 dialysis centers across the country with 1619 patients in 2019 (Table 1).

No.	Dialysis Center	Number of patients
	Department of Nephrology, Medical Faculty, Skopje	33
	Hemodialysis Center, General Hospital “8. September”, Skopje	62
	Special hospital for nephrology and hemodialysis DIAMED – Gjorche Petrov, Skopje	119
	DIAMED – Zelezara, Skopje	132
	DIAMED – Vizbegovo, Skopje	215
	DIAMED – Delchevo	32
	DIAMED – Gevgelija	36
	DIAMED – Shtip	43
	DIAMED – Kochani	50
	DIAMED – Strumica	80
	DIAMED – Kumanovo	84
	DIAMED – Kriva Palanka	28
	Nephrology Center, Struga	120
	Peritoneal dialysis	17
	Home dialysis	1
	Sistina Nephroplus, Tetovo	154
	Sistina Nephroplus, Gostivar	75
	Sistina Nephroplus, Debar	21
	Sistina Nephroplus, Struga	15
	Sistina Nephroplus, Ohrid	40
	Sistina Nephroplus, Kichevo	32
	Sistina Nephroplus, Bitola	69
	Sistina Nephroplus, Prilep	69
	Sistina Nephroplus, Kavadarci	45
	Sistina Nephroplus, Veles	47
	TOTAL	1619

Table 1 presents the hemodialysis centers in N. Macedonia with the patients they treat. The data for 2019 are obtained from D. Gjorgjiev, President of the Association of Renal Patients “Nefron”, Skopje.

In 2020, the first heart transplant was performed at the Medical Faculty in Skopje. Complex heart surgeries as well as on other parenchymal organs are performed in clinics and hospitals.

We try to follow the development and application of artificial organs according to the most modern achievements and guidelines that exist in the world.

Acknowledgement to Goce Aleksoski for the technical assistance.

The paper is part of the project “History of Nephrology in North Macedonia”, funded by the Macedonian Academy of Sciences and Arts

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Резиме

ВЕШТАЧКИ ОРГАНИ 2000

Сателитски симпозиум по повод 25-годишнината на Клиниката за нефрологија на Универзитетот „Св. Кирил и Методиј“, Скопје, Р. Македонија, 25 и 26 ноември 2000 година

Момир Х. Поленаковиќ

Македонска академија на науките и уметностите, Скопје, РС Македонија

Сателитскиот симпозиум на Европското друштво за вештачки органи „Вештачки органи 2000“ беше организиран од Македонското здружение за нефрологија, дијализа, трансплантација и вештачки органи (МЗНДТВО) и Македонската академија на науките и уметностите (МАНУ) на 25 и 26 ноември 2000 година, по повод 25-годишнината на Клиниката за нефрологија на Универзитетот „Св. Кирил и Методиј“, Скопје, Р. Македонија. Главни теми на овој симпозиум беа: Техники за прочистување на крвта, вештачки бубрези, метаболички и кардиолошки системи, како и биоматеријали што се користат за вештачки органи.

Своите трудови на Симпозиумот ги презентираа: H. Klinkmann (Glasgow, United Kingdom), D. Falkenhagen (Krems, Austria), U. Baurmeister (Wuppertal, Germany), V. Bonomini, S. Stefoni (Bologna, Italy), R. Vanholder (Ghent, Belgium), S. Stiller (Aachen, Germany), H. Mann, H. Melzer (Aachen, Germany), J. Pop-Jordanov, N. Pop-Jordanova (Skopje, R. Macedonia), B. Stegmayr (Umea, Sweden), M. Mydlik, K. Derzisova, O. Racz, A. Sipulova, J. Boldizar, E. Lovasova, M. Hribikova (Kosice, Slovak Republic), A. Jörres (Berlin, Germany), M. Polenakovic (Skopje, R. Macedonia), J. Vienken (Bad Homburg, Germany), S. Bowry (Bad Homburg, Germany), E. Piskin (Ankara, Turkey), J. Klinkmann, W. Schimmelpfennig, H. Lantow, W. Rigger (Teterow, Germany), A. Sikole (Skopje, R. Macedonia), A. Oncevski, P. Dejanov, V. Gerasimovska, M. Polenakovic (Skopje, R. Macedonia), J. Wojcicki (Warsaw, Poland), K. Affeld (Berlin, Germany), G. Rakhorst et al. (Groningen, The Netherlands), Z. Mitrev (Skopje, R. Macedonia), S. Kedev, G. Guagliumi, O. Valsecchi, M. Tespili (Skopje, R. Macedonia, Bergamo, Italy).

Презентациите предизвикаа плодна дискусија и беше заклучено дека тие треба да бидат објавени. Трудовите се објавени во the International Journal of Artificial Organs of the European Society for Artificial Organs (ESAO) како специјален број за „Artificial Organs 2000 ESAO Satellite Symposium - Skopje, R. Macedonia“, Guest Editors: M. H. Polenakovic, Skopje and J. Vienken, Bad Homburg; Vol. 25, No. 5, 2002..

Клучни зборови: вештачки бубрег, прочистување на крв, васкуларен пристап, технологија за срцево помагање, инженерство на ткива, психофизиологија