UPDATE IN KIDNEY AND PANCREAS TRANSPLANTATION

The Update in Kidney and Pancreas Transplantation meeting, sponsored by the Mayo Foundation, will be held Saturday, September 7, 1996, at the Mayo Clinic, Rochester, MN. This 1-day meeting will focus on the latest information concerning kidney and pancreas transplantation and medical problems encountered in the care of patients after transplantation. The program features lectures and interactive clinical case presentations designed for physicians who participate in the medical care of patients who have undergone kidney or pancreas transplantation. Current information bridging basic immunohistochemistry to the clinical setting will be provided. New immunosuppressive agents and their current role in transplantation will be reviewed. The evaluation of living donors, chronic allograft dysfunction, cytomegalovirus infection, transplantation in children and adolescents, and late medical complications after kidney or pancreas transplantation will also be discussed. Tuition: $150. For information, call 800-323-2688.

MORPHOLOGIC FINDINGS IN RENAL DISEASES AND TRANSPLANTS: CLINICO-PATHOLOGIC CORRELATION

Morphologic Findings in Renal Diseases and Transplants: Clinico-Pathologic Correlation, sponsored by the Armed Forces Institute of Pathology and the American Registry of Pathology, will be held October 1–4, 1996 at the Holiday Inn, Silver Spring, MD. For information on this continuing medical education course, contact AFIP-Education, Washington, DC. Telephone: 202-782-5021/9280; Toll-free: 800-577-3749 (U.S. only); DSN 662-5021/9280.

EIGHTH INTERNATIONAL SYMPOSIUM OF NEPHROLOGY AT MONTECATINI

The Eighth International Symposium of Nephrology at Montecatini will be held October 7–9, 1996 in Montecatini Terme, Italy. The title of the Symposium is "Progression of Renal Disease: Evaluation, Growth Factors and Other Mechanisms." The deadline for submission of abstracts for presentation is June 15, 1996. For further information regarding attendance, accommodations, or presentations, contact Claudio Bianchi, M.D., Professor of Nephrology, Unità di Nefrologia, Clinica Medica 2, University of Pisa, 56100 Pisa, Italy. Telephone: +39-50-592573; fax: +39-50-553414.

PSYCHONEPHROLOGY 1996

On October 18–20, 1996, The Tenth International Conference on Psychonephrology, also called Psychonephrology 1996, will be held in New York City. This meeting is devoted to psychosocial and ethical issues surrounding patients on forms of dialysis and recipients of renal transplants. For further information including submission of abstracts for the Free Communicative section, contact: Norman B. Levy, M.D., Coney Island Hospital, Department of Psychiatry, 2601 Ocean Parkway, Brooklyn, NY 11235. Fax: 718-616-5314.

NATIONAL KIDNEY FOUNDATION (NKF) ANNUAL SCIENTIFIC MEETING

The Annual Scientific Meeting of the National Kidney Foundation will be held November 1-3, 1996, at the Ernest N. Memorial Convention Center in New Orleans, LA. This meeting will offer participants a better understanding of the pathogenesis, diagnosis, cure, and prevention of kidney diseases. The presentations will provide the most current information to help participants formulate decisions in the direct care of their patients. Program highlights include Are You Ready for Xenotransplantation?; Vexing Programs In Dialysis Patients; Glomerular Disease Progression? A Debate of the Issue; Dialysis Outcomes Quality Initiative (DOQI) Recommendations. The meeting is a multidisciplinary program offering four separate tracks targeted toward nephrologists, renal dieticians, nephrology social workers, and nephrology nurses and technicians. The National Kidney Foundation, Inc. is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians, and designates this continuing medical education activity for 16.0 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association. For registration information, call 800-622-9010 or write to The National Kidney Foundation, 30 East 33rd Street, New York, NY 10016.

SIXTH ALEXIS CARREL CONFERENCE ON CHRONIC REJECTION AND GRAFT ATEROSCLEROSIS

The Sixth Alexis Carrel Conference will be held in Banff, Canada on December 4–7, 1996. The meeting is aimed at transplant physicians, surgeons, pathologists, and immunologists, as well as health care professionals with an interest in transplantation. For information regarding registration and abstracts, please contact the conference organizer: Dr. Leendert C. Paul, St. Michael's Hospital, 30 Bond Street, Toronto, Ontario M5B 1W8, Canada. Telephone: 416-867-3701; fax: 416-867-3709; e-mail: lpaul@utoronto.ca.
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Recruiters, employers and candidates in the nephrology community can connect in New Orleans, November 3-6, 1996, at the ASN-sponsored Job Placement Service. Last year, over 300 people participated in this valuable service, many of whom either found the job they were looking for or found a qualified candidate to fill an open position. The service is a unique once-a-year opportunity to make satisfying employment matches in nephrology.

By registering, employers will have access to candidate curricula vitae, and candidates will able to review job descriptions. In addition, a limited number of private interviewing areas will be available on site at the ASN Annual Meeting.

Whatever or wherever your nephrology employment needs, New Orleans will be the place to find the perfect match. Early registration is recommended for this popular ASN service. For information and registration materials, contact:

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1200 19th Street, N.W., Suite 300
Washington, DC 20036-2422
202/857-1190
E-mail: asn@sba.com

Join the ASN in New Orleans in 1996.

The American Society of Nephrology’s 29th Annual Scientific Meeting and Exposition will be held November 3-6, 1996, at the Convention Center in New Orleans, Louisiana.

ASN members will automatically receive the Call for Abstracts and Preliminary Program. Nonmembers can receive meeting information by contacting the ASN Office at 1200 19th Street, N.W., Suite 300, Washington, DC 20036, Phone: 202/857-1190; Fax: 202/223-4579.

We look forward to seeing you there!

Abstract Deadline - Thursday, June 6, 1996
Annual Meeting Advance Registration Deadline - Tuesday, September 17, 1996
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BRIEF SUMMARY: Please see package insert for full prescribing information.

WARNING: Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should use Neoral®. Patients receiving the drug should be hospitalized in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the use of the drug.

Neoral® may be administered with other immunosuppressive agents. Increased susceptibility to infection and the development of lymphomas and other neoplasias may result from the degree of immunosuppression.

Neoral® Soft Gelatin Capsules (cyclosporine capsules for microemulsion) and Neoral® Oral Solution (cyclosporine oral solutions for microemulsion) have increased bioavailability in comparison to Sandimmune® and Sandimmune® capsules (cyclosporine oral solution, USP). Neoral® and Sandimmune® are not bioequivalent and cannot be used interchangeably. Concomitant administration of Neoral® and Sandimmune® may be associated with increased cyclosporine concentrations in patients taking Neoral® and that dose adjustments be made in order to achieve and maintain therapeutic drug levels.

For a given trough concentration, cyclosporine exposure will be greater with Neoral® than with Sandimmune®. At a fixed dose of Neoral® capsules compared to Neoral® particular caution should be exercised. Comparison of blood concentrations in the population of cases of Neoral® bioavailability obtained using current assays must be done with detailed knowledge of the assay methods employed.

INDICATIONS AND USAGE: Neoral® is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allograft recipients. Neoral® has been used in combination with azathioprine and corticosteroids.

CONTRAINDICATIONS: Neoral® is contraindicated in patients with a hypersensitivity to cyclosporine or to any of its ingredients.

WARNINGS: (See brief WARNINGS)

Cyclosporine, the active ingredient of Neoral®, can cause nephrotoxicity and hypertension when used in high doses. It is not unusual for serum creatinine and BUN levels to be elevated during cyclosporine therapy. These elevations are transient and do not necessarily indicate rejection, and each patient must be fully evaluated before dosage adjustment is initiated.

Based on the historical Sandimmune® experience with oral cyclosporine, nephrotoxicity has been reported with cyclosporine therapy, and cyclosporine has been linked to cases of nephrotoxicity, 35% of cases of cardiac transplantation, and 37% of cases of liver transplantation. Mild nephrotoxicity was generally noted 2-3 months after transplantation and the incidence returned to baseline levels. Significant elevations of serum creatinine at a range of 35-45 mg/dl and 2.0-2.5 mg/dl respectively. These elevations were often reversible. Neoral® may be associated with more frequent and severe elevations of serum creatinine. More overt nephrotoxicity was seen early after transplantation and was characterized by a rapidly rising BUN and serum creatinine. During treatment, concentration episodes, can occur; these concentration episodes may differ from each other. This form of nephrotoxicity is usually responsive to cyclosporine dosage reduction.

Allergic or specific diagnostic criteria which reliably differentiate renal graft rejection from drug toxicity have not been found, a number of parameters have been associated with one or the other. It should be noted that up to 20% of patients may have transient nephrotoxic episodes. A form of a cyclosporine-associated nephropathy is characterized by serial deterioration in renal function and morphologic changes in the kidneys. From 5% to 10% of patients may experience drug-related decreases in glomerular filtration rate, decreases in proteinuria, and increases in serum creatinine. A decrease in glomerular filtration rate by 30% or more may be seen in patients receiving cyclosporine. These decreases may be associated with decreases in proteinuria, and increases in serum creatinine. When considering the development of cyclosporine-associated nephropathy, at a 24% of patients have an association between the appearance of interstitial fibrosis and higher cumulative doses of cyclosporine. In high cumulative dose episodes of cyclosporine therapy, the renal interstitium may show significant fibrosis, marked dilatation of tubules, and arteriolar, and a striped form of interstitial fibrosis with tubular atopy. Though none of these morphologic changes are specific for the cyclosporine-induced nephropathy, they may be an important clue to its diagnosis. It requires evidence of these findings.

When interpreting the development of cyclosporine-associated nephropathy, it is noteworthy that several authors have reported an association between the appearance of interstitial fibrosis and higher cumulative doses of cyclosporine. In high cumulative dose episodes of cyclosporine therapy, the renal interstitium may show significant fibrosis, marked dilatation of tubules, and arteriolar, and a striped form of interstitial fibrosis with tubular atopy. Though none of these morphologic changes are specific for the cyclosporine-induced nephropathy, they may be an important clue to its diagnosis. It requires evidence of these findings.

In the event of severe and continuing rejection, when surgery with pulse steroids and monoclonal antibodies is not effective, it may be preferable to switch to alternative immunosuppressive therapy rather than increase the Neoral® dose to excessive levels.

Patients receiving Neoral® may develop signs of opportunistic infections. The most common infections noted in 4% of cases of renal transplantation, 7% of cases of cardiac transplantation, and 4% of cases of liver transplantation. This was usually noted during the first month of therapy when high doses of cyclosporine were used and associated with elevations of hepatic enzymes and bilirubin. The chemistry elevations usually decreased with a reduction in dosage. As in patients receiving other immunosuppressants, those patients receiving cyclosporine are at increased risk for development of opportunistic infections and other malignancies, particularly those of the skin. The increased risk appears related to the intensity and duration of immunosuppression rather than to the use of specific agents. Immunosuppressive therapy of the transplantation system increases the risk of infection or malignancy, a treatment regimen containing multiple immunosuppressants should be used with caution.

There have been reports of convulsions in adult and pediatric patients receiving cyclosporine, particularly in combination with other anticonvulsant drugs. Care should be taken in using cyclosporine with neuroleptic drugs. (See PRECAUTIONS)

Because Neoral® is not bioequivalent to Sandimmune®, conversion from Neoral® to Sandimmune® using a 1:1 dose ratio may lead to lower cyclosporine concentrations. Conversion from Neoral® to Sandimmune® should be made with increased monitoring to avoid the potential of underdosage.

PRECAUTIONS: General: Cyclosporine is the active ingredient of Neoral®. Hypertension is a common adverse reaction in patients receiving cyclosporine. Renal impairment, hepatic dysfunction, and pre-existing hypertension are common concomitant adverse drug reactions. Hypertension is commonly accompanied by edema, hot flushes, and insomnia. Calcium antiseraum-associated hypertension. However, care should be taken since intolerance with cyclosporine metabolism may occur.

Drug Interactions: During treatment with cyclosporine, vaccination may be less effective; and the use of live attenuated vaccines is not recommended.

Information for Patients: Patients should be advised to change any cyclosporine formulation should be changed and continue to have an adequate supply of Neoral® capsules.

Patients should be given careful dosage instructions. Neoral® Oral Solution (cyclosporine oral solution for microemulsion) should be diluted, preferably with orange or apple juice that is at room temperature. Grapefruit and grapefruit juice affect metabolism of cyclosporine and should be avoided. The combination of Neoral® Oral Solution (cyclosporine oral solution for microemulsion) with milk can be unacceptable.

Patients should be advised to take Neoral® on a consistent schedule with regard to time of day and relation to meals. Laboratory Tests: Renal and liver functions should be assessed repeatedly by measurement of BUN, serum bilirubin, and enzymes. Drug Interactions: All of the individual drugs cited below are well substantiated to interact with Neoral®. The drug interactions reviewed above should be considered in any patient who is receiving concomitant therapy.

DOSAGE AND ADMINISTRATION: The physician responsible for maintenance therapy should have complete information requisite for the use of the drug. Patients may be administered with other immunosuppressive agents. Increased susceptibility to infection and the development of lymphomas and other neoplasias may result from the degree of immunosuppression.
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1 For de novo patients, start with the same Neoral dosage you would use with Sandimmune. For maintenance patients, conversion to Neoral is generally safe and well tolerated. Start with a simple 1:1 dosage conversion to Neoral (see boxed warning). Adjust the Neoral dosage to attain preconversion blood trough concentrations. The daily dose of Neoral should always be given in two divided doses (b.i.d.).

Please see brief summary of prescribing information and boxed warning for Neoral on the adjacent page.

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Reference