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U.S. News & World Report

The Cleveland Clinic Department of Rheumatic and Immunologic Diseases has a long history of excellence and innovation in the research and care of patients with illnesses such as arthritis, vasculitis and osteoporosis. For the past several years, U.S. News & World Report has consistently ranked the Department of Rheumatic & Immunologic Diseases among the nation’s top five rheumatology programs in a survey combining physician polling with mortality rates and other data. The Cleveland Clinic Foundation has been consistently designated as one of the top five hospitals in America by U.S. News.
Letter from the Chairman

The Cleveland Clinic Foundation’s Department of Rheumatic and Immunologic Diseases has a long-standing commitment to excellence in patient care and training physicians for future generations. The highest quality care depends on continued progress in clinical trials, outcomes research and understanding illness at a genetic, molecular and cellular level. Both clinical and basic research hold the promise of discovering new treatment strategies and cures for our patients.

The Department has grown to include individuals with expertise in all areas of clinical rheumatology. Recruitment has emphasized selection of faculty with complementary skills in the clinical, educational and research arenas. We have had the good fortune of growing in an environment that is primed for collaboration in areas related to our own commitments, which include immunology, metabolic bone disease, orthopaedics, cardiovascular medicine and surgery, pathology and imaging.

We have benefited from extensive collaborative relationships with valued colleagues around the world. Opportunities for discovery are unprecedented and are likely to bear fruit in large part because of team efforts that ignore intellectual and geographic boundaries.

In the following pages, you can visit with members of our Department, meet our specialty teams and collaborators, and consider how we at the “Clinic” can best serve you and your patients.

Gary S. Hoffman M.D., M.S.
Harold C. Schott Chair and Professor
Department of Rheumatic and Immunologic Diseases
Lerner College of Medicine
The Cleveland Clinic Foundation
Introduction: The Osteoporosis Team
The Center for Osteoporosis and Metabolic Bone Disease at The Cleveland Clinic was established in 1999. Dr. Chad Deal, a rheumatologist, is Head of the Center. Dr. Miriam Delaney, Associate Director of the Center, and Dr. Angelo Licata, Associate Director of Clinical Trials, are endocrinologists. All three have interests in clinical evaluation, treatment and clinical trials. The Center has participated in numerous randomized controlled trials of drug therapy for treatment of osteoporosis. Dr. Brad Richmond, a radiologist, is Director of Densitometry, and is in charge of 10 dedicated densitometry technicians.

Osteoporosis: Clinical Evaluation
The National Osteoporosis Foundation recommends a bone density test in all women over the age of 65. Postmenopausal women to age 65 with risk factors may also require testing. In 1999 only one-third of women in our clinics over age 65 had received a DXA (dual energy x-ray absorptiometry). In 2003 over two-thirds of women had a DXA. This improvement resulted from an organized effort to educate physicians and practitioners in the Cleveland Clinic system as well as the placement of DXA centers in the Cleveland Clinic satellite offices. In 2003 more than 11,000 DXAs were performed. A project to develop a DXA database that will combine bone density results with relevant clinical data is underway and will enable clinical research and drug trials to proceed at a faster pace.

Osteoporosis: Clinical Impact
There are more than 1.5 million fractures in the United States every year. Of the 350,000 hip fractures there is a 20% mortality at 1-year. It is estimated that more than 10 million Americans have osteoporosis, defined as a T-score of less than –2.5, and another 34 million have low bone mass that places them at risk for fracture. The majority of fractures occur in patients with osteopenia, a T-score between –1.0 and –2.5. Thus the identification of the “at risk” population depends not only on measurement of bone mass but identification of risk factors such as family history of an osteoporotic fracture, prevalent fracture, low body weight, current smoking, glucocorticoid use and many others. The new definition of osteoporosis by consensus is “a disease characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and increased risk for fracture.” This definition puts new emphasis on bone “quality,” those factors in addition to bone density that are important for strength and resistance to fracture.

In addition to osteoporosis, the Center sees patients with many metabolic bone diseases, including renal osteodystrophy, transplant bone disease, steroid osteoporosis, hyperparathyroidism, osteogenesis imperfecta and others.

Bone Deficiency: Bone Summit 2004
The Center, along with the Orthopaedic Research Center, organized and hosted an international conference attended by 187 participants from 12
countries and 17 states. This Summit brought together investigators, clinicians and industry to meet around issues of osteoporosis, skeletal repair, cell-based therapies for bone growth and skeletal imaging.

**Osteoporosis: Clinical Trials**

Numerous clinical drug trials are currently underway or completed at the Center for Osteoporosis and Metabolic Bone Disease. These include evaluation of the anabolic agent parathyroid hormone, rhPTH 1-84 and rhPTH 1-34, PTH in combination with raloxifene, and PTH as a treatment in patients with low bone mass who are on TPN. Use of novel dosing of an oral bisphosphonate, ibandronate, as well as evaluation of the intravenous bisphosphonate zolendronate in men and as an agent to prevent hip fracture are also ongoing.

**Osteoporosis: Basic Research**

The Center for Osteoporosis and Metabolic Bone Disease is a multidisciplinary clinic with participation of rheumatologists, endocrinologists and radiologists. In addition, the Center has strong ties to the Department of Biomedical Engineering, Department of Orthopaedic Surgery and the Orthopaedic Research Center where molecular mechanisms of bone formation, skeletal repair and bone growth using cell based therapies are active areas of basic and clinical research.
The new biologic agents which attenuate the effect of tumor necrosis alfa (TNF) have revolutionized the treatment of rheumatoid arthritis (RA). They are efficacious and safe compared to agents of past years. The anti-TNF drugs are particularly effective when combined with methotrexate, resulting in remission rates as high as 37% after one year. Although this remission rate is far superior to that seen with previous combination therapy, still more than half of our patients never achieve remission. There is room for improvement.

Our group has participated in trials of two promising new biological agents.

**CTLA4 IMMUNOGLOBULIN**

CTLA-4-Immunoglobulin (CTLA-4-Ig) blocks the second signal required for T-cell activation in an immune response. Among published studies, our group participated in a pilot, dose-finding, double-blind placebo controlled multicenter study of 214 patients. The agent was well tolerated and proved superior to placebo when given at 2 or 10 mgs/kg. We participated in a Phase III, multcentered, double-blind controlled trial of CTLA-4 Ig for patients whose response to etanercept or infliximab was not acceptable. CTLA-4 Ig 10 mgs/kg was added to the pre-existing anti-TNF therapy. Results of this trial have not yet been reported.

**RITUXIMAB**

Previous pathogenic models of RA have emphasized the role of the T-cell as a pivotal contributor to synovitis and eventual joint destruction. Contemporary models have demonstrated the unique participation of the B-lymphocyte, particularly in lymphoid follicle-like structures found in rheumatoid synovitis. Rituximab is a monoclonal antibody which attenuates B-cell activity. Small open studies in RA have suggested efficacy when it is combined with cyclophosphamide or methotrexate. We are currently enrolling patients in a large multicentered, double-blind controlled trial of rituximab added to methotrexate for patients who have failed to respond adequately to the combination of methotrexate and anti-TNF agents.

**EARLY ARTHRITIS CLINICS**

With the introduction of agents that may be capable of inducing remission and the availability of new diagnostic tools, including anti-cyclic citrullinated protein and magnetic imaging studies of the hands, early diagnosis of RA has been facilitated and the impetus to treat early and aggressively heightened. Our group is exploring strategies that assess the feasibility of early arthritis clinics for all patients who have the potential to develop erosive joint disease.

**GENERAL RHEUMATOLOGY**

From the perspective of general rheumatology, better understanding and efficacious treatment of fibromyalgia (FM) is a challenge. We participate in numerous double-blind controlled randomized multicenter trials for the treatment of FM.

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Deformities such as these are uncommon in the modern era of rheumatology. (x-ray from a patient in 1979)
One of the unique features of pediatric rheumatology at The Cleveland Clinic is that it is part of the Department of Rheumatic and Immunologic Diseases, and not Pediatrics, as in most academic centers in the United States. There are important advantages to this arrangement. Most pediatric rheumatology practices are in small units consisting of one or two physicians, thereby being limited in services and facilities offered. As part of the Department of Rheumatic and Immunologic Diseases we share the nursing, allied medical professionals, logistic and research staff of the Department. Many rheumatic diseases common in adults are rare in children (including many types of vasculitis and systemic sclerosis). Clinical cooperation and sharing of expertise between pediatric and adult rheumatologists specializing in these entities improve the care of children with these rare diseases. We also share the expertise of the bone center in the management of osteoporosis, which is often seen in children with rheumatic diseases, especially those treated with steroids. Due to the reputation of the Clinic, many of our patients are referred from states outside of Ohio and other countries.

Rheumatic diseases are less common in children than adults. The most common chronic rheumatic disease is juvenile idiopathic (formally rheumatoid) arthritis with a prevalence of about 1:1000 children. Based on data that radiographic joint damage is usually seen within two years of disease onset (earlier by MRI) and that most children with arthritis continue with disease into adulthood, we treat these children aggressively with early use of methotrexate and new “biologic” medications in children not responsive to methotrexate.

We collaborate with other pediatric services at the Clinic, primarily orthopaedics, ophthalmology, nephrology and other subspecialties necessary for treating children with rheumatic conditions. We run a common clinic with the Section of Pediatric Infectious Diseases in evaluating and treating children with unexplained periodic fever syndromes. Genetic mutations have been identified for many of these syndromes leading to a greater understanding and more effective treatment.

We work closely with The Cleveland Clinic Children’s Hospital for Rehabilitation. This collaboration enables us to use their services for rehabilitation of children with arthritis and pain syndromes, particularly reflex sympathetic dystrophy or severe fibromyalgia.

There is a national shortage of pediatric rheumatologists, so it is crucial to teach the principles of the discipline to pediatricians and adult rheumatologists who may encounter these children in localities where pediatric rheumatology services are not available. Since we are part of the Department of Rheumatic and Immunologic Diseases, adult rheumatology fellows are exposed to pediatric rheumatology more than in most training programs.

Current research projects include both industry sponsored and original research. We participate in trials of new medications for the treatment of juvenile arthritis. Newer medicines for the treatment of juvenile arthritis are necessary since 10-20% of children do not respond to methotrexate or “biologic” agents. We actively participate in national research networks, necessary for effective research in pediatric rheumatology.

For more information, please contact Philip Hashkes, M.D., M.Sc., at 216/444-3250.
The Clinical Immunology Section of the Department of Rheumatic and Immunologic Diseases carries out a number of programs in a wide array of immunologic conditions. The section, headed by Dr. Leonard Calabrese, concentrates its efforts in three main areas, each with a component of clinical care and research. These areas are 1) immunodeficiency disorders 2) chronic viral illnesses and 3) chronic fatigue syndrome.

**Immunodeficiency Disorders**
Within the section, a large number of adults with primary and secondary immune deficiencies is evaluated and treated. The main concentration of energy and resources is directed at programs of integrated care and research in HIV disease. Dr. Calabrese, who has a joint appointment in the Department of Infectious Diseases, is actively involved in day-to-day patient care as well as research in HIV disease. He has been doing so since 1983 and was included in the 80 physicians and researchers considered pioneers in the HIV epidemic, described in Voices from the Epidemic; an oral history (Oxford Press 2000). Together with Elizabeth Kirchner, M.S.N., N.P., a certified HIV specialist, they care for a large number of patients with HIV disease within the multi-specialty HIV clinic at The Cleveland Clinic. This clinic, which brings together clinical immunologists, infectious disease specialists, nurse practitioners, infectious disease pharmacists, social workers and other allied personnel, is part of the AIDS Clinical Trial Group (ACTG). The ACTG is a system of centers involved in clinical trials affording the most cutting edge research protocols for treatment as well as investigations of pathophysiology and the numerous co-morbidities and toxicities found in the disease.

In addition to the ACTG protocols, the multispecialty HIV clinic is involved with a number of investigator designed initiatives, which emphasize the study of HIV-associated rheumatic diseases. Since 1989, Dr. Calabrese has prospectively followed a cohort now of more than 400 HIV infected patients. He and his team have found that, with the introduction of combination antiretroviral therapy and the attendant decrease in mortality, there has been a dramatic change in the pattern of rheumatic complications. Other projects include therapeutic and pathophysiologic studies in metabolic bone disease as well as studies of psychosocial issues affecting adherence to medications.


**Chronic Viral Illness**
The Clinical Immunology Section has also focused increasing efforts on the evaluation and treatment of patients infected with hepatitis C virus (HCV). HCV is the most common bloodborne infection in the United States and poses a major public health problem. HCV infects nearly one-third of all HIV-
infected patients and is particularly aggressive in that population. In addition to being a leading cause of liver disease, HCV is associated with a wide variety of extra-hepatic rheumatic and immunologic manifestations, especially vasculitis. Dr. Calabrese is interested in further understanding why only some patients are afflicted with these immunologic complications and finding new and better therapies for both the virus as well as its immunologic manifestations. (Vassilopoulos D, Calabrese LH. Hepatitis C virus infection and vasculitis: Implications of antiviral and immunosuppressive therapies. *Arthritis and Rheumatism* 46:585-597, 2002.)

Investigators from the Lerner Research Institute performing neurophysiologic studies as part of a three year Department of Defense grant to investigate veterans with Gulf War Syndrome and patients with chronic fatigue syndrome done jointly with Dr. Calabrese.
The Department includes the Center for Vasculitis Care and Research which was initiated by Dr. Hoffman, who served as its Director through 2004. Dr. Carol Langford, from the National Institutes of Health, assumed responsibility as Director of the Center in August 2004. Several other faculty within the Department have special expertise in vasculitis and participate in providing care for vasculitis patients and enrolling patients in multicenter studies. The Center enjoys numerous visiting faculty, on sabbatical, from throughout the world who come to study and participate in clinical trials and basic research. Extensive collaborations with other departments have been established to bring complementary skills to both service and research, e.g., Dr. Stanley Hazen, Dr. Marie-Luise Brennen, (Diagnostic Cardiology and Cell Biology), Dr. Tom Hamilton and Dr. Rula Hajj-Ali (Immunology), Dr. Richard Prayson (Pathology), Drs. Kosmorsky, Perez, Perry and Lowder (Ophthalmology), Dr. Rob Lorenz (ENT) and others.

The Center also has thrived because of collaborative relationships with longstanding partners at the Mayo Clinic, Johns Hopkins and Boston University. Secondary collaborations have been developed with more than 30 other centers when it has been necessary for large randomized controlled trials. During the past 10 years, the Center and its collaborators in the United States and abroad have led some of the first randomized controlled trials in vasculitis and are currently conducting randomized controlled trials using biologic agents. Unprecedented studies are ongoing with agents that block TNF, IL1 and B cell propagation. Linked to clinical trials are studies that evaluate the genetic predisposition and susceptibility to a variety of vasculitides. In collaboration with colleagues at the University of Alabama, the first genetics repository using immortalized cell lines has been established and will be made available to geneticists throughout the United States to further evaluate disease susceptibility profiles. All of these studies are NIH funded or investigator initiated and funded with industry partners. Listed at left is a sample of recent and ongoing studies.

**Center for Vasculitis Care and Research**

Carol Langford, M.D., M.H.S.
Director, Center for Vasculitis Care and Research

The Department includes the Center for Vasculitis Care and Research which was initiated by Dr. Hoffman, who served as its Director through 2004. Dr. Carol Langford, from the National Institutes of Health, assumed responsibility as Director of the Center in August 2004. Several other faculty within the Department have special expertise in vasculitis and participate in providing care for vasculitis patients and enrolling patients in multicenter studies. The Center enjoys numerous visiting faculty, on sabbatical, from throughout the world who come to study and participate in clinical trials and basic research. Extensive collaborations with other departments have been established to bring complementary skills to both service and research, e.g., Dr. Stanley Hazen, Dr. Marie-Luise Brennen, (Diagnostic Cardiology and Cell Biology), Dr. Tom Hamilton and Dr. Rula Hajj-Ali (Immunology), Dr. Richard Prayson (Pathology), Drs. Kosmorsky, Perez, Perry and Lowder (Ophthalmology), Dr. Rob Lorenz (ENT) and others.

The Center also has thrived because of collaborative relationships

**Projects**

Pathogenesis of WG. Analysis of cytokine gene polymorphisms
Investigators: Yihua Zhou, DeRen Huang, Gary Hoffman

Utilization of infliximab therapy in giant cell arteritis
Investigators: Karen Rendt, Gary Hoffman

Utilization of anti-TNF therapy in Takayasu’s arteritis
Investigators: Gary Hoffman, Patrick Liang

Molecular and genomic analysis of vessel wall in GCA
Investigators: Rula Hajj-Ali, Gary Hoffman

Wegener’s Granulomatosis Etanercept Trial (WGET)
Investigators: Gary Hoffman, John Stone (PI-Hopkins)

Wegener’s Granulomatosis Genetic Repository (WGGER)
Investigators: Gary Hoffman, Jeffrey Edberg (PI-UAB), John Stone (Hopkins)

Search for Infectious Etiology of Wegener’s Disease
Investigators: Gary Hoffman, Herbert Virgin, (Wash U-PI), John Stone (Hopkins)

Short Term Cyclophosphamide followed by alternative therapy in WG
Investigators: Alexandra Villa Forte, Gary Hoffman

Rituximab in ANCA-Associated Vasculitis
Investigators: John Stone (Hopkins), Ulrich Specks (Mayo) – PI’s; Gary Hoffman, Carol Langford, site PI’s

Vasculitis Clinical Research Consortium
Investigators: Peter Merkel (PI-BUMC), Carol Langford, site PI; Gary Hoffman, site co-PI

Vasculitis Outcome Measures
Investigators: Gary Hoffman, site co-PI Development and Validation; Carol Langford, site PI

Utility of rituximab in HCV-associated cryoglobulinemia
Investigators: Leonard Calabrese, Carol Langford

Surrogate markers of disease activity in vasculitis
Investigators: Gary Hoffman, Stanley Hazen, Marie-Luise Brennen, Carmen Gota

The Center has derived great benefits from multidisciplinary collaborations, such as in studies of surrogate markers. Pictured are Drs. Hazen and Brennen (Diagnostic Cardiology) and Drs. Gota and Hoffman (Rheumatology).
Dr. Soumya Chatterjee directs scleroderma research in the Department of Rheumatic and Immunologic Diseases. He joined the Department in January 2004. Dr. Chatterjee trained in rheumatology in England before moving to the United States in 1996. Formerly, he was a rheumatology faculty member at Wayne State University, where his mentor, Dr. Maureen Mayes, inspired his interest in scleroderma.

Dr. Chatterjee has been involved in the following research projects:

1. An NIH/NIAMS sponsored randomized, double-blind, placebo-controlled multi-center phase II trial of oral type I bovine collagen (CI) as a toleragen in scleroderma.

2. A double-blind, randomized, placebo-controlled study of 122 patients at 17 centers in Europe and North America, to assess the effect of Bosentan on the prevention of ischemic digital ulcers in systemic sclerosis (RAPIDS 1).

3. A double-blind randomized placebo-controlled study looking at the efficacy of Bosentan in patients with interstitial lung disease associated with systemic sclerosis [BUILD-2].

   Bosentan, an orally active dual endothelin receptor antagonist, has been shown to antagonize the deleterious effects of endothelin, e.g., vasoconstriction, hypertrophy, fibrosis and inflammation. It is FDA-approved for the treatment of severe pulmonary arterial hypertension (PAH).

4. Dr. Chatterjee is establishing a scleroderma database that will collect data on patients who are followed by CCF physicians in internal medicine and the various sub-specialties. Data will be used to conduct epidemiologic, translational and outcomes research and help in recruitment of patients for future trials.

5. Endothelial dysfunction plays an important role in the pathogenesis of vasculopathy in scleroderma. Dr. Chatterjee is collaborating with the basic scientists at the CCF Lerner Research Institute to evaluate the microcirculation in scleroderma and the effect of various pharmacologic interventions on microcirculatory blood flow.
Education is a cornerstone of The Cleveland Clinic’s overall mission, and members of our department are extremely active in multiple areas of medical education. Several of our physicians serve the American College of Rheumatology, performing work on behalf of the Board of Directors and many committees, including medical education, annual meeting planning, professional meeting planning, workforce training and research. A number of our faculty and one of our fellows repeatedly serve in “Meet the Professor” sessions during the national ACR annual meeting.

Members of our faculty are frequently invited visiting professors both nationally and internationally. Our physicians also have provided literature beyond that linked to research, serving as journal reviewers, journal and book authors and sitting on numerous editorial boards.

A key goal of the department includes training the next generation of rheumatologists. Consequently, we emphasize our faculty’s role in being leaders in medical education at a departmental, institutional and international level.

Our two-year fellowship accommodates five to six fellows (two to three per year). An option for a third post-graduate year is available and linked to acquiring either an MPH or MSc degree. Fellows have rotations in metabolic bone disease, pediatric rheumatology, orthopaedics, spine, podiatry, the vasculitis clinic and musculoskeletal radiology. We offer a one-year vasculitis fellowship for exceptional board-eligible or board-certified rheumatologists who have a primary interest in clinical or basic science research aspects of inflammatory vascular disease.

In addition, all residents in the Clinic’s Internal Medicine program rotate through the Department of Rheumatic and Immunologic Diseases.

Department members are playing a vital role in the new Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Drs. Leonard Calabrese, Chad Deal and Brian Mandell are deeply involved in providing the immunology and musculoskeletal curricula.

Research is a crucial component of our mission. The department is one of four major medical centers across the country involved in a Vasculitis Clinical Research Consortium, part of the NIH’s Rare Diseases Clinical Diseases Network. The consortium is fostering and facilitating clinical investigation in the vasculitides, which has been a major area of interest in our department.

Currently, the department’s research group is recruiting for numerous clinical trials. Several areas of interest include rheumatoid arthritis in adults and children, osteoporosis, HIV, hepatitis C, cryoglobulinemia, scleroderma, giant cell Arteritis, Wegener’s granulomatosis, microscopic polyangiitis and Takayasus’s arteritis. Translational research is ongoing in vasculitis, especially in regards to studies of surrogate markers of disease activity, pathogen discovery, genetic profiles of susceptible patients and gene expression analyses of targeted vessels in an attempt to identify substrate vulnerability to disease.

Dr. Hoffman, chairman of the Department of Rheumatic and Immunologic Diseases, can be reached directly at 216/445-6996 or 800/553-5056, ext. 56996.
The Rheumatology Research Support Group (RRSG) helps develop, plan and administer all clinical research projects within the Department of Rheumatic and Immunologic Diseases. RRSG includes Debora J. Bork, Research Administrator; Sonya Crook, R.N., Research Nurse; Tiffany Clark, C.N.P., Research Nurse Practitioner; Sharon Farkas, R.N., Research Nurse; Elizabeth Kirchner, C.N.P., Research Nurse Practitioner. The research nurses in the RRSG are experts in clinical research, having been involved in clinical trials for many years. They can take a study from start to finish. During the study, they plan and implement patient recruitment strategies, educate potential study participants, schedule and perform patient visits and complete data collection forms.

Tiffany Clark, C.N.P., is a co-investigator and study coordinator for the vasculitis research projects in the Department.

Elizabeth Kirchner, C.N.P., has provided clinical research support for HIV studies, including those sponsored by the AIDS Clinical Trials Group (ACTG). Her contributions include collaborative relationships with colleagues in Infectious Diseases and the ACTG unit at the Case Western Reserve University School of Medicine.

Debora Bork provides administrative oversight for the entire Department’s research efforts. She is a liaison with study sponsors and a consultant providing advice regarding study design and operational issues.

The group has many ongoing clinical trials in several different subspecialty areas including rheumatoid arthritis in adults and children, osteoporosis, scleroderma, large vessel vasculitis, microscopic polyangitis, Wegener’s granulomatosis, cryoglobulinemia and hepatitis. The Department is one of four major medical centers involved in the Vasculitis Clinical Research Consortium, a part of NIH’s Rare Diseases Clinical Diseases Network. The Department Chairman is also the founder of the International Network for the Study of Systemic Vasculitides. Basic and translational research has focused on immune susceptibility profiles, target organ vulnerability in vasculitis, as well as biochemical mediators and surrogate markers of vessel injury.
Department of Rheumatic and Immunologic Diseases: Selected Recent Publications


Recent Books and Symposiums:


The Cleveland Clinic is an independent, not-for-profit, multispecialty academic medical center. It is dedicated to providing quality specialized care and includes an outpatient clinic, a hospital with more than 1,000 staffed beds, an education division and a research institute.

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