

Outcomes₂₀₀₆

Taussig Cancer Center





Outcomes | 2006

Quality counts when referring patients to hospitals and physicians, so Cleveland Clinic has created a series of outcomes books similar to this one for its institutes and departments. Designed for a health care provider audience, the outcomes books contain a summary of our surgical and medical trends and approaches; data on patient volume and outcomes; and a review of new technologies and innovations. We hope you find these data valuable. To view all our outcomes books, visit Cleveland Clinic's Quality Web site at clevelandclinic.org/quality/outcomes.





Table of Contents |

Division Overview	5
Chairman’s Letter, Department of Hematologic Oncology and Blood Disorders	9
Chairman’s Letter, Department of Solid Tumor Oncology	10
Quality & Outcome Measures	
Hematologic Oncology and Blood Disorders	11
Solid Tumor Oncology	
Chairman’s Letter, Department of Radiation Oncology	26
Quality & Outcome Measures	
Radiation Oncology	27
Selected Disease Sites	34
Patient Experience	42
Innovations	44
New Knowledge	52
Staff Listing	62
Department Contacts How to Refer Patients	64
Locations	65
Cleveland Clinic Overview	66
Online Services	67
Cleveland Clinic Contact Numbers	68





Division Overview |

Derek Raghavan, M.D., Ph.D., FACP

Chairman, Cancer Division

Director, Taussig Cancer Center



Oncology patients and their families benefit from innovative, leading-edge cancer care arising from numerous research discoveries and extensive clinical experience. Patients and families also have access to a wide array of support services that help them cope with the challenges of cancer and its treatment. State-of-the-art diagnostic technology and the newest methods of treatment are offered, including pioneering surgical techniques and advanced radiation therapy, chemotherapy and bone marrow transplantation. An extensive research program gives patients access to a wide variety of clinical trials. The Taussig Cancer Center emphasizes continuum of care, which enhances overall quality of care for patients. This includes electronic medical recordkeeping, physician collaboration and access to the high quality care Cleveland Clinic patients have come to expect closer to their homes, thanks to the excellent services provided by Cleveland Clinic's regional campuses. In October 2006, oncologists from the Regional Medical Practice Division joined the Cancer Center Division, Department of Regional Oncology Practice. This move allowed implementation of clinical trials at all Cleveland Clinic cancer centers and facilitated further development of standards of care, leading to a much more symmetrical availability of clinical and research-based care across the Cleveland Clinic Cancer System. As they have only recently joined us, their outcomes will be included in future reports.

Clinical volumes are rising in the departments of Solid Tumor Oncology and Hematologic Oncology and Blood Disorders, as well as in the newly created Department of Regional Oncology Practice which treats a broad variety of neoplasms and hematologic disorders. All of the physicians are trained in disease-specific practices. In addition to treating a large number of patients with commonly diagnosed cancers, the medical team prides itself on its ability to treat patients with uncommon diagnoses.



Solid Tumor Oncology

Collaboration and teamwork have led to new discoveries and improved patient care. The breast cancer program received federal funding to join two multi-institutional trials in collaboration with Washington University and the renal cancer program is collaborating with The Ohio State University on federally funded clinical trials. In 2006, a team of Taussig Cancer Center researchers discovered a novel blood test can predict thyroid cancer more accurately than testing by fine needle aspiration biopsy. The Taussig Cancer Center and the Glickman Urological Institute combined forces and added key staff to expand the Cleveland Clinic's genitourinary oncology program.

The renal cancer program is refining and augmenting new therapies. Ronald Bukowski, M.D., Director of the Experimental Therapeutics Program, is co-principal investigator of a study that found sorafenib doubles the average progression-free survival in patients with advanced renal cell carcinoma. Phase III data from that study was recently published in the *New England Journal of Medicine*. Brian Rini, M.D., was awarded an NCI grant for translational science in renal cancer, working with James Finke, Ph.D., and Pierre Triozzi, M.D.

Major scientific and treatment advances continue to be made and patient care continues to improve, through increasing numbers of treatment choices, multidisciplinary management, innovations and second opinions.

Hematologic Oncology and Blood Disorders

For four of the past five years, the Bone Marrow Transplant team achieved 100% 30-day survival in autologous bone marrow transplantation by minimizing treatment-related morbidity. Several new studies under way are addressing the major long-term complication of disease relapse following autologous transplantation.

The Myeloma Program is coordinating three institutions (Cleveland Clinic, Mayo Clinic and the University of Arkansas) in a federally funded project to enroll patients with premalignant abnormalities in a study to determine whether chemotherapy can prevent disease progression. The Taussig Cancer Center is the coordinating center for the Bone Marrow Failure Disease Consortium of the NIH's Rare Diseases Clinical



Research Network, an initiative begun in 2006. Cleveland Clinic is one of only four participating medical centers in this consortium.

The Hematologic Oncology and Blood Disorders Department is extremely active in myriad clinical research projects. In 2006, our team presented more than 40 abstracts at the major international scientific meeting, the American Society of Hematology, which represented important clinical and scientific projects.

Department of Radiation Oncology

The Department of Radiation Oncology is among the busiest, largest and most technologically advanced clinical radiotherapy programs in the country. In 2006, Radiation Oncology had 90,000 patient visits to the main and regional campuses.

The department has a full range of therapeutic equipment and one of the most active brachytherapy programs in the United States. Along with intracavitary and intraluminal treatments now performed routinely throughout the country, Cleveland Clinic developed many novel approaches to brachytherapy and is among a handful of medical centers experienced in these techniques. The department developed special expertise in managing brain and spinal tumors and new treatment paradigms are being developed in radiation techniques for breast cancer and in the use of chemoradiotherapy for inoperable lung cancer. As a result, the department has been identified as an international training center for the Gamma Knife and Novalis equipment. Some of the best published survival figures have been achieved through the collaboration of Drs. David Adelstein in Solid Tumor Oncology and Jerrold Saxton in Radiation Oncology, as well as members of the Division of Surgery for locally advanced cancers of the head and neck and the esophagus.



Taussig Takes the Lead

Taussig Cancer Center is committed to continuing education for the medical staff; more than 750 participants undertook a variety of courses and symposia in 2006. The center is also committed to patient education. The Patient Resource Center took an estimated 5,000 calls and served 2,500 people seeking information on cancer.

Nationally prominent research and treatment programs are expanding in genitourinary cancer, hematological malignancy, breast cancer, melanoma, drug discovery and development, immunotherapeutics, brachytherapy, computerized radiation planning and delivery and other areas. Our team has participated in major scientific discoveries, including the introduction of new classes of drugs for the treatment of advanced kidney cancer, the development of first-in-man anticancer compounds, the refinement of radiotherapy techniques for prostate cancer to maintain efficacy with less toxicity and a series of significant laboratory observations. For these and other advances, and for the overall quality of patient care, Taussig Cancer Center is again rated by *U.S. News & World Report* as one of the top 15 cancer centers in the nation. Its ranking makes it the No. 1 cancer center in Ohio.

Taussig Cancer Center

Total Visits: 181,798

Total Admissions: 2,809

Total New Patients: 2,049

Total NCI Grants: 51

Total Outpatient Chairs: 60

Total Inpatient Beds: 75

Total Treatments: 35,576

Patient Resource Center:

More than 4,000 callers; 2,000 walk-ins

Derek Raghavan, M.D., Ph.D., FACP

Chairman, Cancer Division

Director, Taussig Cancer Center



Chairman's Letter |



Department of Hematologic Oncology and Blood Disorders

The Department of Hematologic Oncology and Blood Disorders continues to grow, while providing outstanding clinical services and innovative research into new treatments.

In 2006, volume in the Bone Marrow Transplant Program (BMT) increased with 149 transplants performed. Outcomes in BMT are unsurpassed by any program in the world; 30-day survival rates for all autologous transplants are 100%. Our related allogeneic 30-day survival rates are 100% and 100-day survival rates for related allogeneic transplants exceed 90%.

In 2006, the NIH launched an initiative to facilitate clinical research in rare diseases; we are the coordinating center for the Bone Marrow Failure Disease Consortium of this new network. Also in 2006, we pioneered the use of AMG-531, a small molecule that stimulates megakaryocytes and platelet production, in immune thrombocytopenia (ITP) which led to a *New England Journal of Medicine* article co-authored by Alan Lichtin, M.D.

Some staff members have taken leadership roles nationally and internationally. Anjali Advani, M.D., is principal investigator of a national clinical trial in acute lymphoblastic leukemia (ALL); Mikkael Sekeres, M.D., is principal investigator of a national clinical trial in elderly acute myelogenous leukemia (AML). John Sweetenham, M.D., was named to the Board of Trustees of the Leukemia and Lymphoma Society of the United Kingdom.

We are the largest accruing center in the world for the Leukemia and Lymphoma Molecular Profiling Project, a federally funded project studying genetic profiling in patients with these diseases. We continue to be active in a wide variety of clinical research projects, evidenced by the number of abstracts presented at the American Society of Hematology meetings in December. These projects and our focus on providing superior clinical care will help ensure our continuing growth and standing among the top cancer centers in the world.

Brian J. Bolwell, M.D.

Chairman, Hematologic Oncology and Blood Disorders &
Bone Marrow Transplant Program Director



Chairman's Letter |



Department of Solid Tumor Oncology

In 2006, the Department of Solid Tumor Oncology participated in major scientific discoveries, including the introduction of new classes of drugs to treat advanced kidney cancer. The renal cancer program is refining and augmenting new therapies recently described in the *New England Journal of Medicine*. Brian Rini, M.D., received an NCI grant for translational science in renal cancer and is working with James Finke, Ph.D., and Pierre Triozzi, M.D.

A number of our staff members, including Drs. Triozzi and Rini, secured peer-reviewed funding; Drs. Triozzi, Ram Ganapathi and Ernest Borden obtained R01 awards from the NCI. Other Cancer Center researchers also continue to secure new peer-reviewed funding, including Ronald Bukowski, M.D., and Jarek Maciejewski, M.D. Under Dr. Bukowski's leadership, the renal cancer program continues its collaboration with The Ohio State University on federally funded clinical trials, and additional funding was secured by Derek Raghavan, M.D., Ph.D., Vice Chair of the Genitourinary Program of the Southwest Oncology Group. The breast cancer program, under the leadership of G. Thomas Budd, M.D., received federal funding to join two multi-institutional trials in collaboration with Washington University. Also under Dr. Budd, Solid Tumor Oncology has full membership in the federally funded Southwest Oncology Cooperative Group.

Beyond our focus on groundbreaking research and excellent clinical care, we strengthened our commitment to the community through health screenings and educational programs. In 2006, our efforts included participation in the Colorectal Summit to kick off National Colorectal Cancer Awareness Month and provide leadership to the planning committee for Hoops 4 Health, an annual basketball tournament promoting prostate cancer awareness in minority communities. In addition, we continued offering well-attended support groups for patients and families coping with brain and breast cancer.

These are only a few of the many projects, programs and activities in which our department was involved in 2006 that demonstrate our continuing commitment to excellence in research and patient care and to making strides in improving community health.

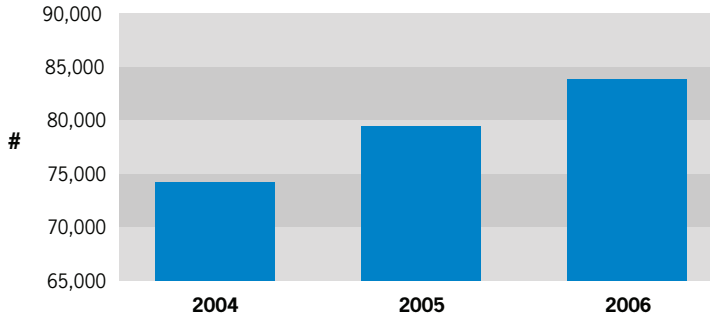
Robert Dreicer, M.D.

Chairman, Solid Tumor Oncology

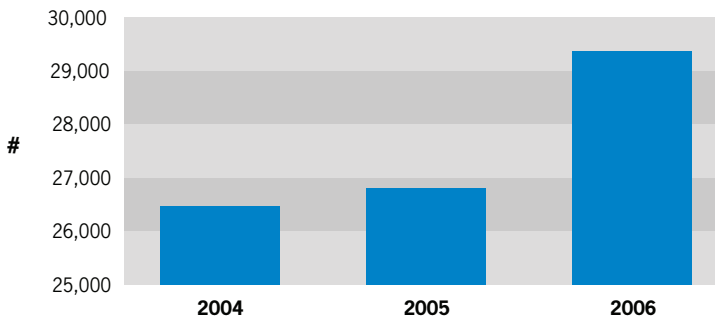


Quality & Outcome Measures |

Hematology & Medical Oncology Outpatient Visits



Hematology & Medical Oncology Treatment Center Patient Visits

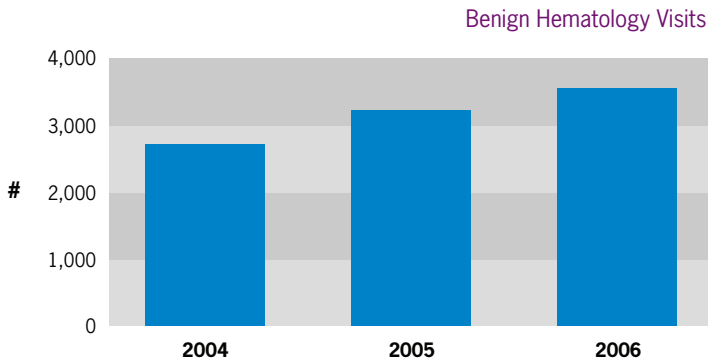


The entire nursing team in our outpatient treatment facility is certified in the administration of chemotherapy. These nurses are trained to address the clinical as well as psychosocial needs of each individual patient.



Benign Hematology Program

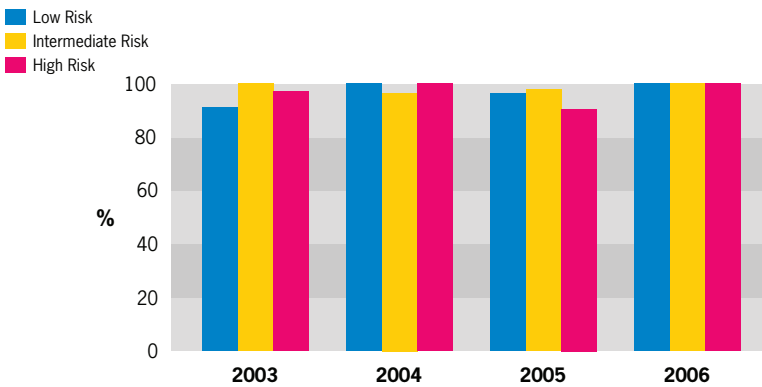
This section of the Department of Hematology includes several practitioners. The section works closely with the Translational Research Program within the Taussig Cancer Center. Our collaboration with internal researchers as well as pharmaceutical sponsors places us in a unique position in the treatment of orphan diseases. Together with Cleveland Clinic Children's Hospital and the Genomic Medicine Institute, we have embarked upon a Lysosomal Storage Disorder Clinic. This clinic and other initiatives provide an excellent teaching environment for future hematologists. The area of benign hematology co-sponsors a variety of educational conferences with the Departments of Pathology and Vascular Medicine. This program also offers consultative services to all Cleveland Clinic inpatients with hematological abnormalities.



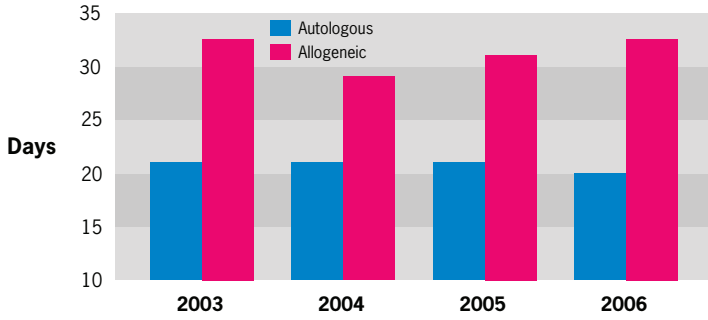
Bone Marrow Transplant Program (BMT)

The Cleveland Clinic Bone Marrow Transplant Program is internationally recognized as a leader in the field. Autologous, allogeneic, non-myeloablative, bone marrow, peripheral stem cell, and umbilical cord blood transplants are performed for patients with leukemias, lymphomas and other hematological malignancy and bone marrow failure states. As one of the most productive clinical research programs in the world, our clinical outcomes are superb. In 2006, 30-day survival for autologous transplantation was 100% and 100-day survival was 100%. In allogeneic transplantation, over 90% of patients were high risk at the time of transplant. Despite this, 30-day survival rate was 94% and 100-day survival rate was approximately 80% for the entire group of patients. These results are unsurpassed in the world.

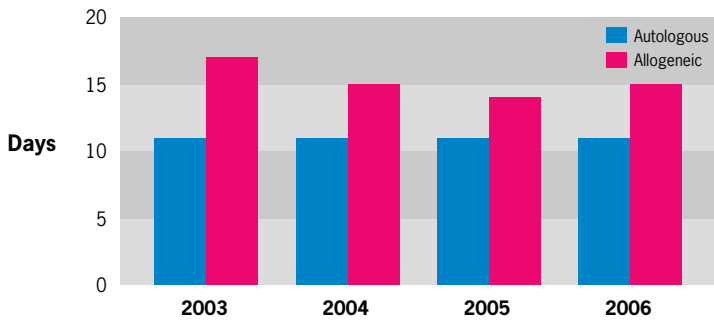
Autologous BMT: 100-day Survival Rate



Length of Stay

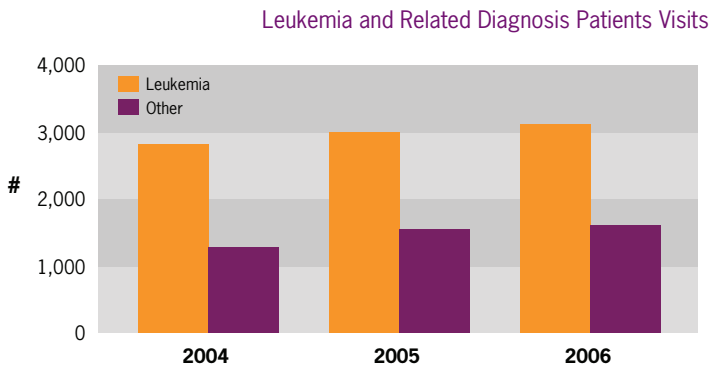


Engraftment

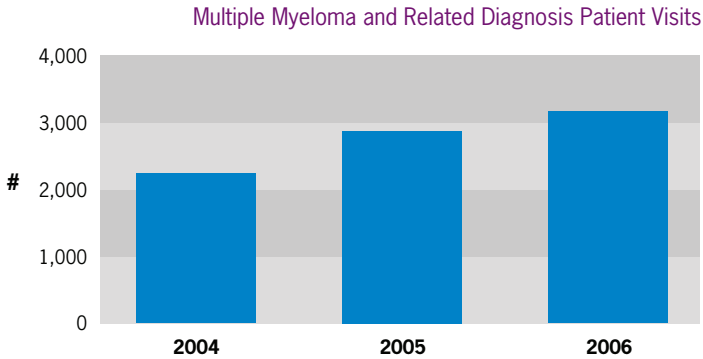


Acute Leukemia Program

The Acute Leukemia Program is one of the largest in Ohio and provides multidisciplinary care to patients. Patients with acute leukemia are managed on a dedicated inpatient oncology unit by a team of staff physicians, nurses, residents and doctors of pharmacy, providing a level of expertise not usually available at smaller institutions. Separately, the newly created Chronic Leukemia and Myeloma Program gives patients access to innovative treatment approaches and exciting new medicines. All patients benefit not only from the special expertise of our physicians, but also from the close collaboration with the Bone Marrow Transplant Program.



Multiple Myeloma Program

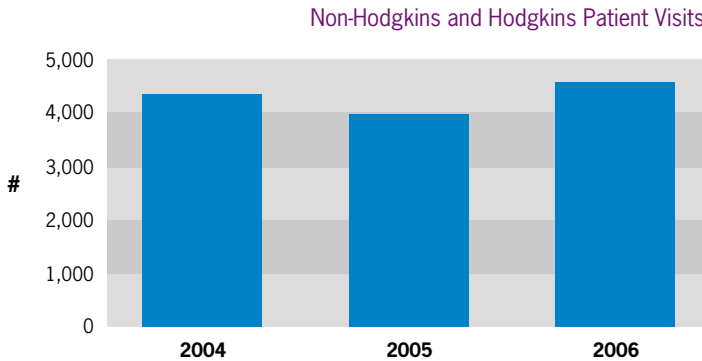


The Plasma Cell Dyscrasia and Multiple Myeloma Programs were created in 1996 as a multidisciplinary and multifaceted approach to the research and treatment of multiple myeloma and related disorders. In 2006 the program incorporated chronic leukemia and is now the Chronic Leukemia and Multiple Myeloma Program. The program integrates patient care and clinical research with basic laboratory investigational activities, following the model of collaborative medical practice, research and education. The Chronic Leukemia and Multiple Myeloma Program sees more than 450 new consult appointments per year.



Lymphoma Program

The Lymphoma Program employs the newest treatments, including chemotherapeutic drugs, recombinant biologic agents, monoclonal antibodies and high-dose chemotherapy with autologous or allogeneic peripheral blood stem cell or bone marrow transplantation. Our physicians and scientists are also investigating new, more reliable methods to determine lymphoma diagnosis and prognosis. This includes an international multi-center trial for which Cleveland Clinic is the lead institution in patient accrual.

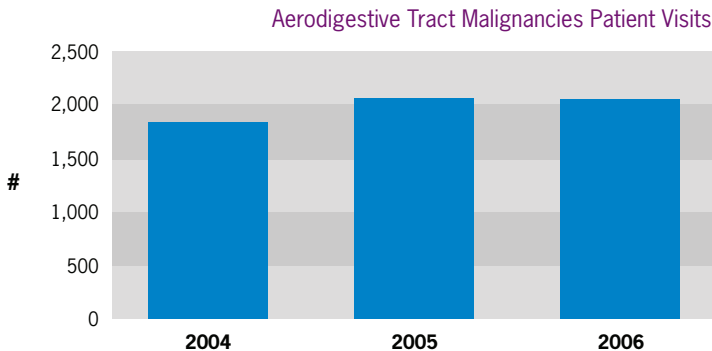


Solid Tumor Oncology

Aerodigestive Tract

Close interdisciplinary cooperation is the hallmark of the Upper Aerodigestive Tract Malignancy Program. Patients with head and neck cancer are routinely evaluated by all members of our multidisciplinary team of surgeons, radiation therapists, medical oncologists, dentists, dietitians and speech pathologists. This collective input results in the best treatment recommendations and facilitates administration of complex, but highly effective, therapies. This team approach in head and neck cancer achieved long-term survival in 65% of patients with advanced disease, a group that historically had these outcomes in only 30% to 40% of cases. Current clinical investigation is directed towards the optimal integration of these treatment modalities in disease management.

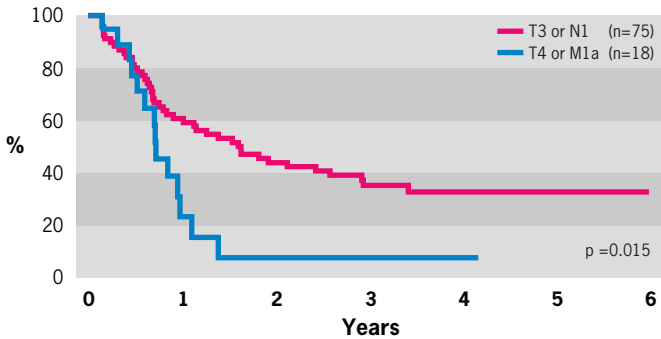
Clinical investigation of esophageal cancer focuses on refining clinical staging to better define appropriate treatment approaches. All patients with this disease undergo rigorous pretreatment staging with endoscopic ultrasound and PET/CT scanning. Patients with early stage tumors (T1-2N0) undergo primary surgical resection with excellent results. Patients with locoregionally advanced diseases historically had very poor long-term survivals, predominately due to locoregional failures. Using aggressive multimodality treatments, locoregional control can now be achieved in more than 85% of patients with a dramatically improved survival. Current research efforts are also exploring the role of newer targeted therapies to further improve this treatment success.



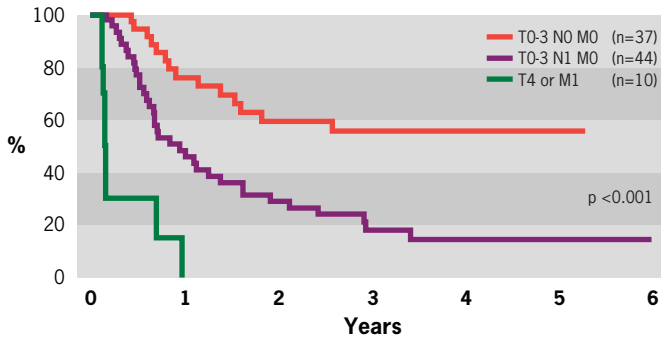


Taussig Cancer Center

This is a series of patients treated with chemoradiotherapy and surgery between 1999-2003 for locoregionally advanced esophageal cancer.



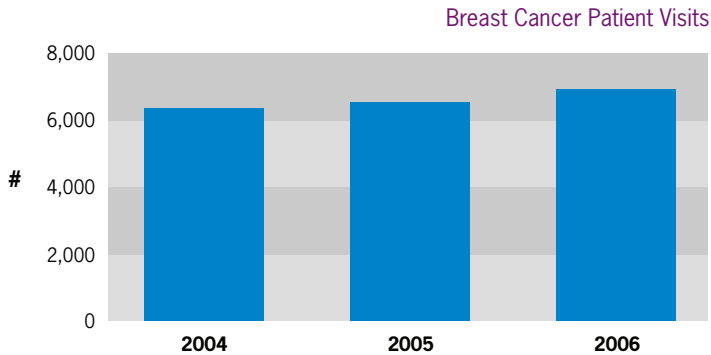
Projected freedom from recurrence by pathologic stage, *i.e.* after induction chemoradiotherapy and surgery. Clearly, patients who had a lower stage at the time of surgery also had a better prognosis. In the best subgroup (approximately 40% of patients), 3-year freedom from recurrence was 56%.



Projected freedom from recurrence by pre-treatment clinical stage. Not surprisingly, patients with earlier (T3 or N1) disease had better outcomes.



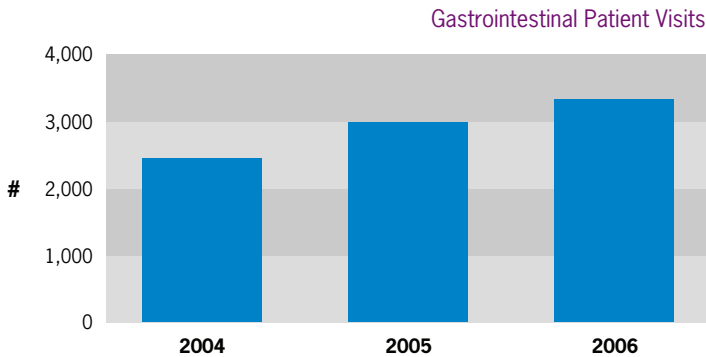
Breast Cancer



New patients with advanced breast cancer are generally seen initially in the Taussig Cancer Center's Medical Oncology Department. New patients with early breast cancer are generally first seen in the multidisciplinary breast clinic. Patients receive the benefit of surgical, radiation oncology and medical oncology opinions regarding the best approach to their disease. A unified treatment plan is developed for each patient. These plans are consistent with national and international standards. Many patients are eligible for clinical trials sponsored by the National Cancer Institute, pharmaceutical firms or a Cleveland Clinic investigator.



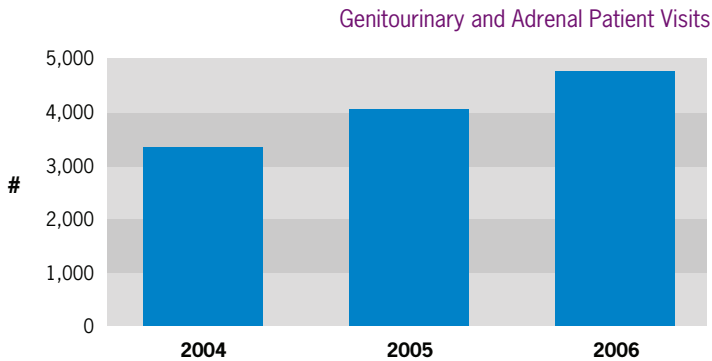
Gastrointestinal



The Medical Oncology program for gastrointestinal cancers is a multidisciplinary program for patients with stomach, pancreas, liver, gallbladder, bile duct and large and small bowel cancers. Rare cancers, such as neuroendocrine tumors and anal cancers, are also seen. Treatment requires careful and close collaboration with a number of departments: Colorectal Surgery, General Surgery, Gastroenterology, Interventional Radiology and Radiation Oncology. Treatment regimens include adjuvant therapies for surgically resected tumors at risk for recurrence and systemic therapies for incurable advanced tumors. Patients are offered a variety of clinical trials, from large randomized trials sponsored by the National Cancer Institute, cooperative group trials and industry-sponsored trials, and/or institutional local trials of experimental drugs. Patients can also elect to receive standard-of-care therapies administered with the latest state-of-the-art techniques. Close collaboration with the Genomics Institute provides genetic counseling.



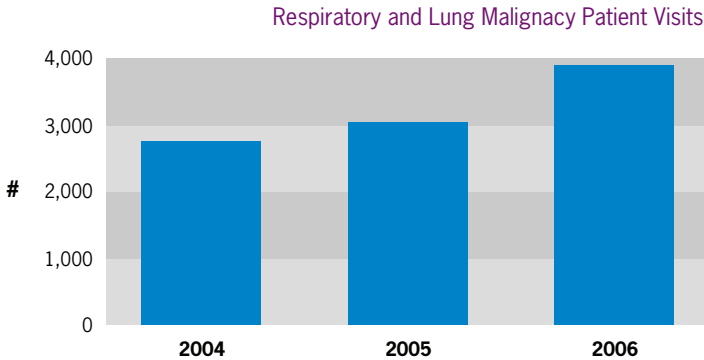
Genitourinary



The genitourinary (GU) medical oncology program has ongoing multidisciplinary clinics with colleagues from the Glickman Urological Institute and the GU section of the Department of Radiation Oncology. In addition to clinical and translational research efforts, there is a major emphasis on medical education of medical oncology fellows and urology and radiation oncology residents in interdisciplinary management of GU neoplasms. This program has resulted in pivotal studies of international importance, including major contributions to the development of novel new therapies for advanced renal cell carcinoma and the development of the neoadjuvant model to test novel systemic therapy agents for prostate cancer. Major areas of ongoing clinical research include novel agents in renal cancer, therapy for PSA in prostate cancer and integrating novel agents in advanced bladder cancer.



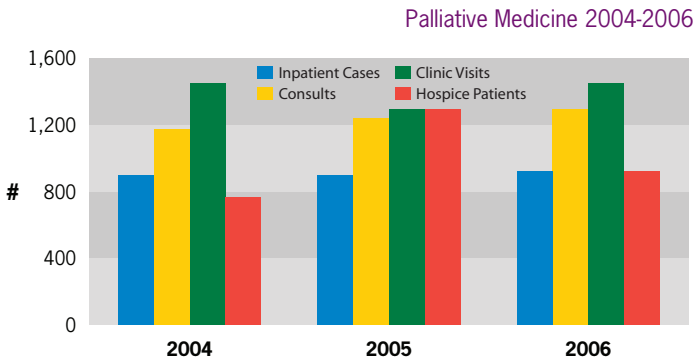
Lung and Respiratory Malignancies



Lung cancer is the most common cause of cancer mortality throughout the world. Optimal management of lung cancer is dependent upon proper identification and staging of the tumor. Physiologic assessment is also an important component of pretreatment evaluation, especially when lung resection is contemplated. Treatment options for patients with lung cancers include a combination of chemotherapy, radiotherapy and surgery. Outcomes of patients with lung cancers are largely dependent on treatment decisions tailored to individual patients. Comprehensive medical evaluations are conducted for lung cancer patients to reach the best treatment decisions. This approach has resulted in improved outcomes for patients with lung cancer. For example, long-term survival in locally advanced non-small cell lung cancer is between 35% and 40% which compares favorably to the national average. Many clinical trials employing novel drugs are currently open for patient accrual at the Cleveland Clinic Taussig Cancer Center.



Palliative Medicine Program



Patients with cancers often have unrelieved symptoms and significant physical difficulties during their illnesses. The specially trained staff of the Harry R. Horvitz Center for Palliative Medicine at the Cleveland Clinic Taussig Cancer Center coordinates the complex medical care for patients as they face the physical and psychological challenges associated with their illnesses.



Chairman's Letter |



Department of Radiation Oncology

In 2006, the Department of Radiation Oncology did an excellent job meeting its clinical responsibilities and pursuing research goals. Overall, patient satisfaction surveys ranged from good to excellent, with the strongest areas in the thoracic, CNS and GU programs. Our department renovated its facilities, upgraded its technologies and integrated the main campus and satellite facilities to better serve patients and their families.

The Department led the largest brain metastases trial for women with breast cancer, an international study that enrolled 368 women from North and South America and Europe. One industry trial resulted in seven abstracts at the ASTRO meeting; the staff submitted numerous publications on prostate cancer and brain tumors of which 57 were either accepted or published in 2005-2006.

Our Residency Training Program continues to be among the most highly regarded in the country. During training, residents are exposed to the full range of human malignancies and treatments. Residency candidates are required to apply through ERAS and, following interviews, two are selected through the National Resident Match Program. For the past five years, the percentage of residents passing the Board the first time is 100%.

A cone-beam CT linear accelerator and a large-bore CT simulator are new technologies for more customized treatments acquired by the department this year. In addition, educational opportunities are being expanded and multidisciplinary programs and translational research efforts are being developed to improve outcomes for cancer patients.

Greater access to innovative clinical trials, expansion of educational opportunities, development of multidisciplinary programs and development of translational research will help lead to better outcomes. These and other attributes and accomplishments are moving us toward our goal of becoming one of the best known and most respected radiation oncology departments in the country.

John H. Suh, M.D.

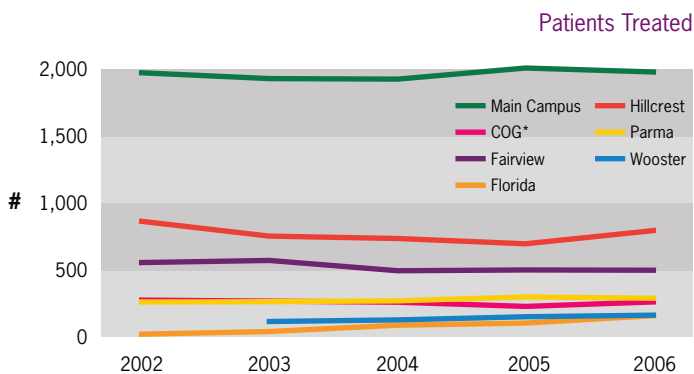
Chairman, Radiation Oncology



Quality & Outcome Measures |

Radiation Oncology

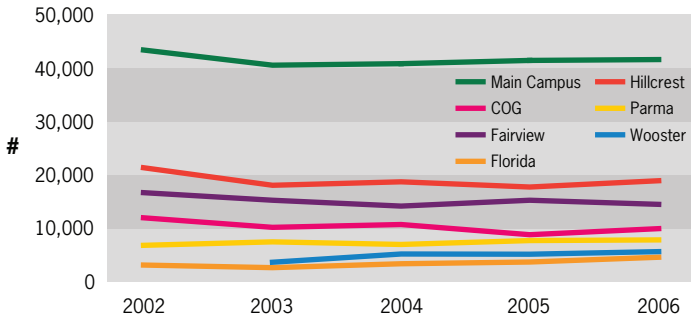
The Department of Radiation Oncology offers a full complement of therapeutic equipment and advanced technologies for treating a wide range of solid and hematologic cancers: lung, breast, prostate, head and neck, lymphoma, gastrointestinal, brain tumor, and multiple myeloma, as well as bone marrow and stem cell transplantation. The department is one of the most active brachytherapy programs in the United States. Along with intracavitary and intraluminal treatments now performed routinely throughout the country, Cleveland Clinic developed many novel approaches to brachytherapy and is among a handful of medical centers experienced in these techniques. The department developed special expertise in managing brain and spinal tumors and new treatment paradigms are being developed in radiation techniques for breast cancer and in the use of chemoradiotherapy for inoperable lung cancer. The department initiates and actively participates in Cleveland Clinic in-house protocols and is a full member of two national collaborative groups: Southwest Oncology Group (SWOG) and Radiation Therapy Oncology Group (RTOG). Of interest, in 2006, the department was one of the top 10 accruing centers for RTOG clinical trials.



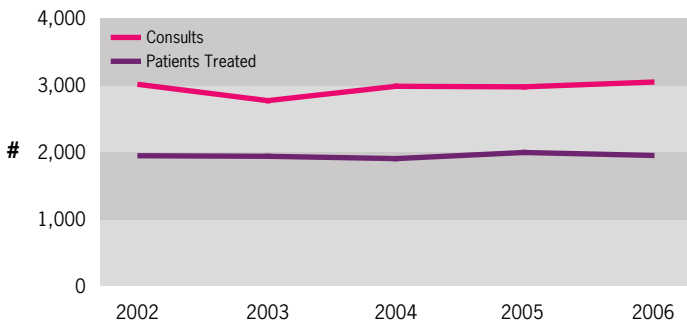
*Community Oncology Group



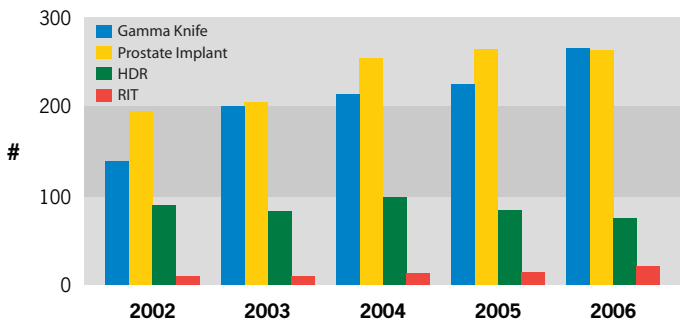
Patient Visits



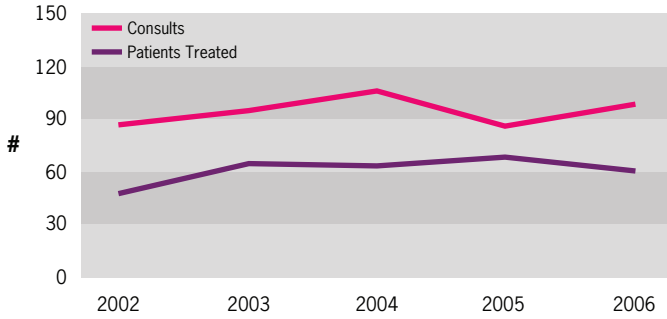
Consults and Patients Treated – Main Campus



Special Procedures – Main Campus



Non-Hodgkin's Lymphoma

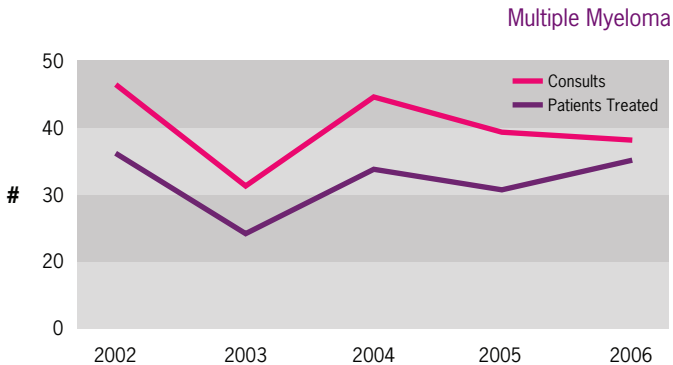


Hodgkin's Lymphoma



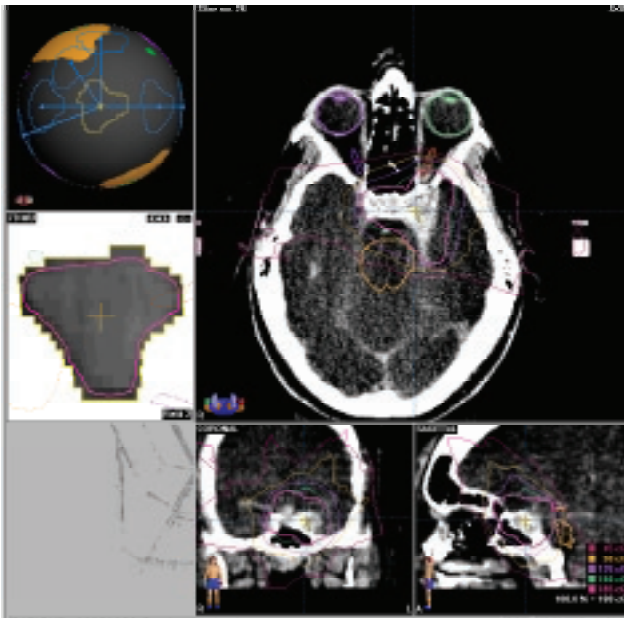
Hematopoietic Diseases and Multiple Myeloma

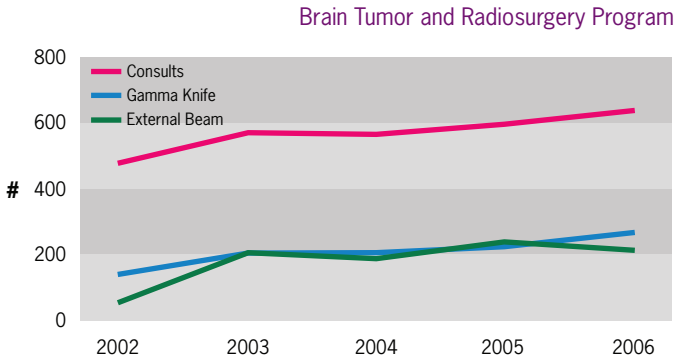
The Department is a recognized leader in highly focal beam technologies, including those specifically adapted for the treatment of hematopoietic diseases. These technologies consist of conformal external beam treatment, intensity modulated radiation therapy (IMRT), positron emission tomography (PET) scan, directed external beam radiotherapy, total body irradiation (TBI) and biologically targeted radiotherapy including radio-immunotherapy (RIT). Cleveland Clinic has one of the most advanced clinical programs in bone marrow and stem cell transplantation. A significant proportion of patients undergoing stem cell transplantation receive total body irradiation as a component of their preparative regimen.



Brain Tumor and Radiosurgery Program

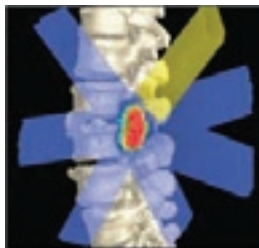
The Neuro-Oncology program in the Department of Radiation Oncology in conjunction with the Brain Tumor and Neuro-Oncology Center offers state-of-the-art treatments for patients with brain and spinal cord tumors. Technologies include Gamma Knife, intensity-modulated radiotherapy (IMRT) and image-guided radiation therapy (IGRT). The Gamma Knife radiosurgery program, the first in Ohio, is clinically very active and participates in a number of clinical trials. Enrollment into clinical trials is an important aspect of the program. We are recognized for our participation in national and international trials.



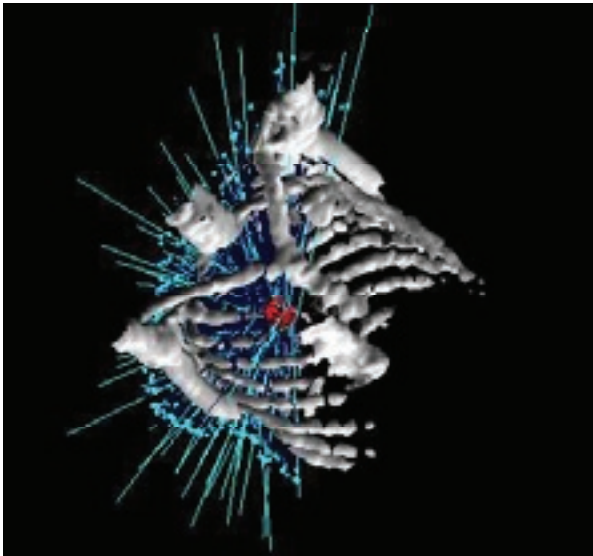
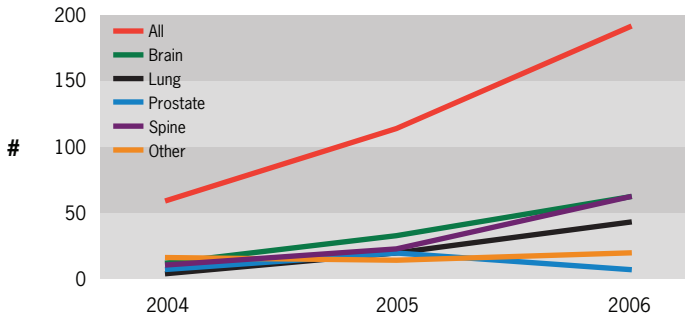


Novalis Image-Guided Radiation Therapy

Shaped-beam therapy, a form of image-guided radiation therapy (IGRT), emits doses shaped to closely fit the target from whatever direction the beam is oriented. This technique is called stereotactic body radiotherapy (or extracranial radiosurgery) and is currently being evaluated to determine its optimal role in cancer management. The Novalis Shaped-Beam Therapy System is currently being utilized to treat patients with many cancer types, including spine, kidney, brain and early-stage lung cancer and in patients not eligible for surgery.



Disease Sites Treated by Novalis



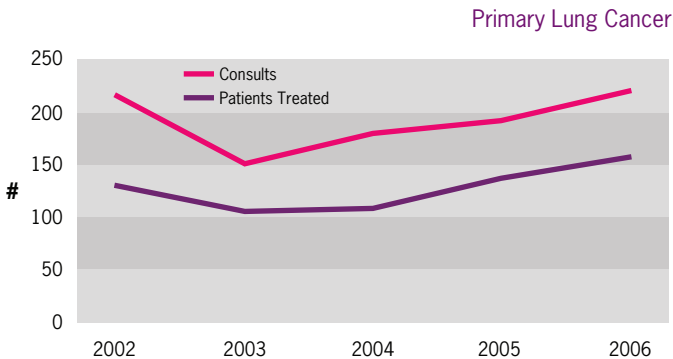
Outcomes for Selected Disease Sites

In addition to being one of the busiest radiation oncology centers in the country, our survival rates are better than the national average. The following shows outcomes for the treatment of selected specific diseases.

Lung

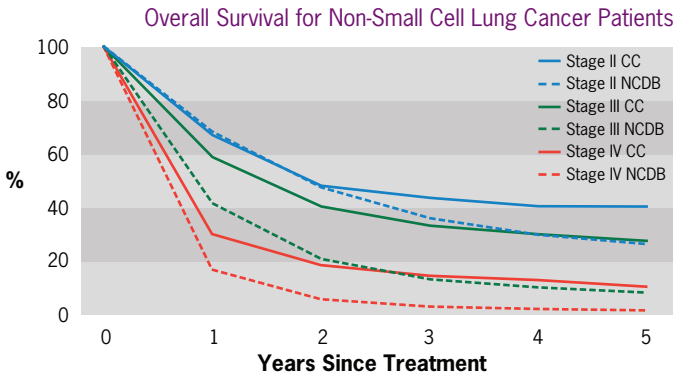
The multidisciplinary thoracic program is a clinical trials-driven service developed in collaboration with surgical and medical oncologists and offers individualized treatment plans for patients with chest malignancies. The program actively participates in Cleveland Clinic in-house protocols and is a full member of two national collaborative groups: Southwest Oncology Group (SWOG) and Radiation Therapy Oncology Group (RTOG). Of interest, the department is one of the leading accruals for RTOG lung clinical trials.

Novalis Shaped Beam Therapy for Lung Cancer



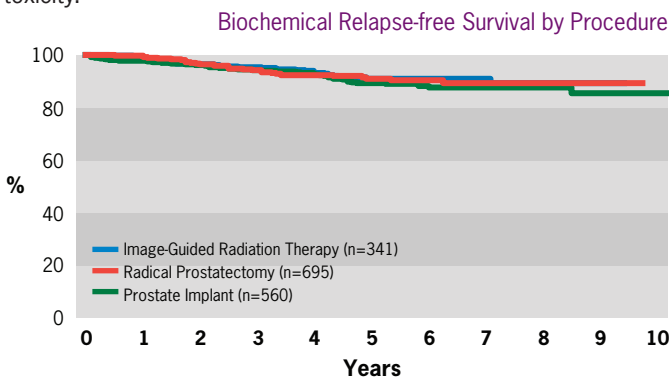
Overall Survival for Non-Small-Cell Lung Cancer Patients

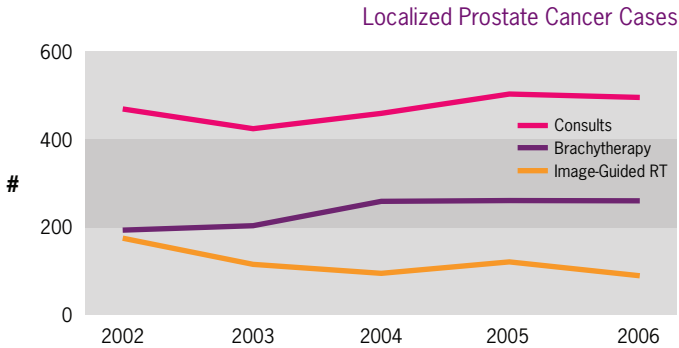
Standard for lung cancer outcomes: National Cancer Data Base (NCDB) reported in AJCC Cancer Staging Manual, sixth edition, 2002.



Prostate Cancer

The Department offers innovative state-of-the-art care for patients with prostate cancer. Image guidance for radiation therapy delivery enhances cancer outcomes and reduces treatment-related morbidity. Cleveland Clinic's (CC) prostate brachytherapy program is one of the largest in the country. The program has also been subjected to rigorous quality control reviews and continues its growth in number of patients served and innovative approaches to treatment to reduce post-treatment toxicity.





Overall Survival for Prostate Cancer Patients by Risk Group

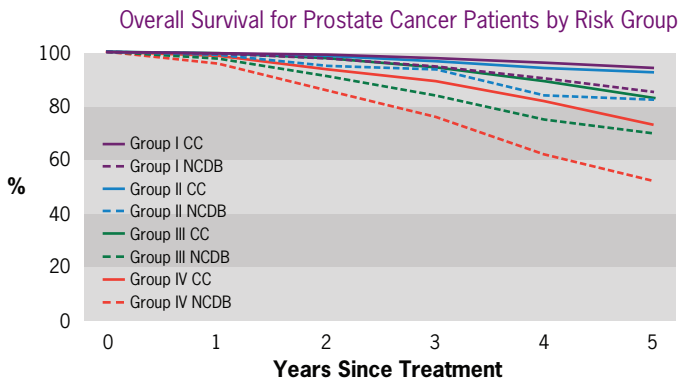
Standard for prostate cancer results: RTOG, Roach M, et al. Four prognostic groups predict long-term survival from prostate cancer following radiotherapy alone on radiation therapy oncology group clinical trials. International Journal of Radiation Oncology Biology Phys 2000;47:609-615.

Group 1: Gleason Score (GS) = 2-6 and T1-2 NX

Group 2: GS = 2-6 and T3 NX or GS = 2-6 and N+ or GS = 7 and T1-2 NX

Group 3: GS = 7 and T3 NX or GS = 7 and N+ or GS = 8 and T1 -2 NX

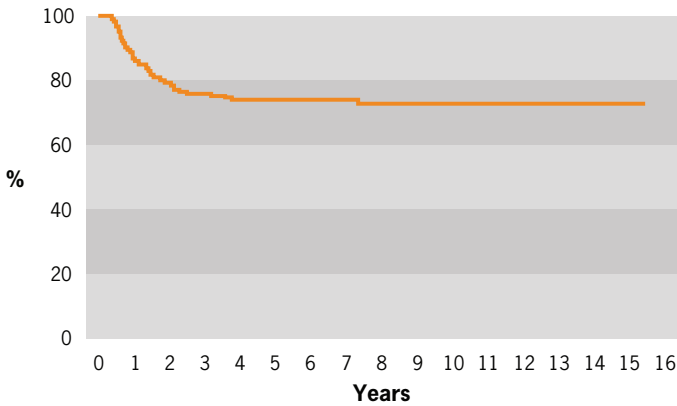
Group 4: GS = 8-10 and T3 NX or GS = 8 and N+



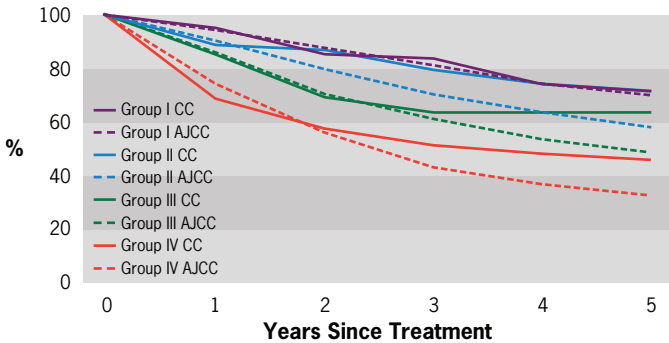
Head and Neck

Radiation therapy is frequently used in combination with surgery or chemotherapy or as a single-modality treatment. For many Cleveland Clinic patients, multimodality approaches increase local regional control, cure and improve quality of life issues associated with the treatment of head and neck tumors. Many advanced lesions treated by a non-surgical approach receive combined radiation and chemotherapy. The data show excellent local regional control and improvement in survival.

Freedom from Recurrence for Head and Neck Cancer Patients Treated with Combined Radiation Therapy/ Chemotherapy

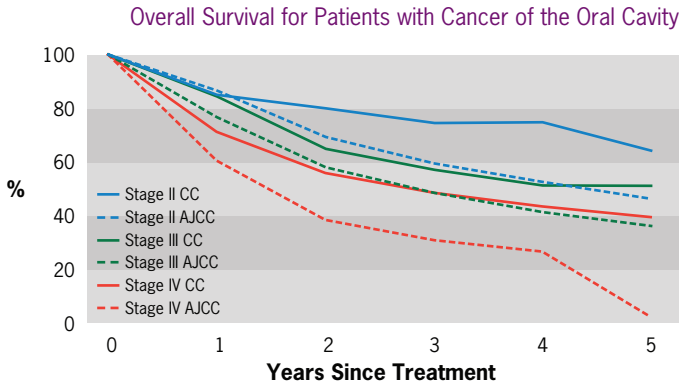


Overall Survival for Patients with Cancer of the Larynx

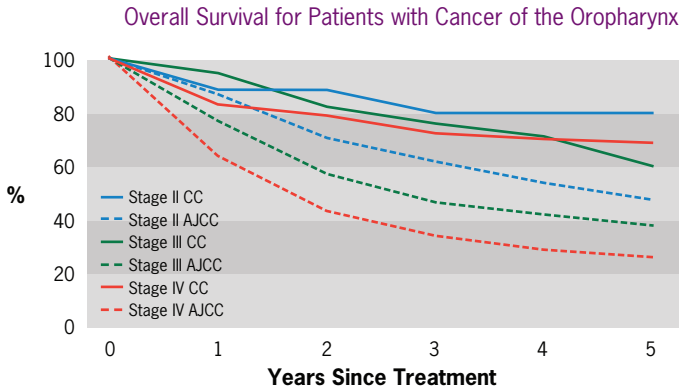


Standard for all head-and-neck cancer outcomes American Joint Committee on Cancer: Cancer Staging Manual, sixth edition, 2002. (AJCC)



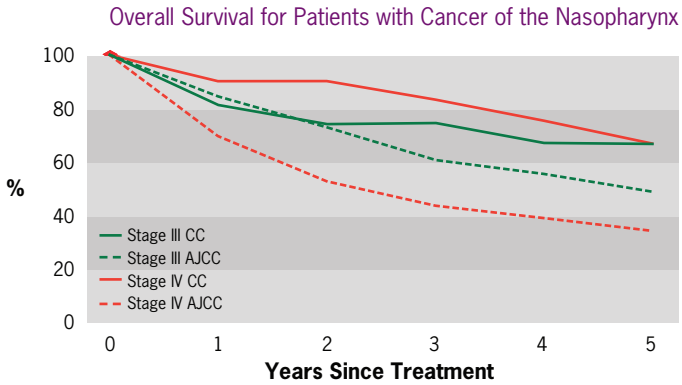


Standard for all head-and-neck cancer outcomes American Joint Committee on Cancer: Cancer Staging Manual, sixth edition, 2002.



Standard for all head-and-neck cancer outcomes: American Joint Committee on Cancer: Cancer Staging Manual, sixth edition, 2002.



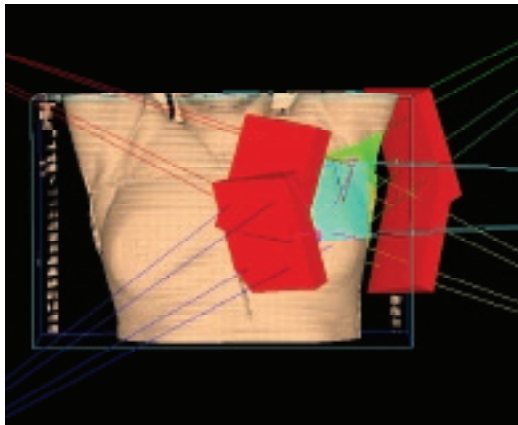


Standard for all head-and-neck cancer outcomes: American Joint Committee on Cancer Cancer Staging Manual, sixth edition, 2002.

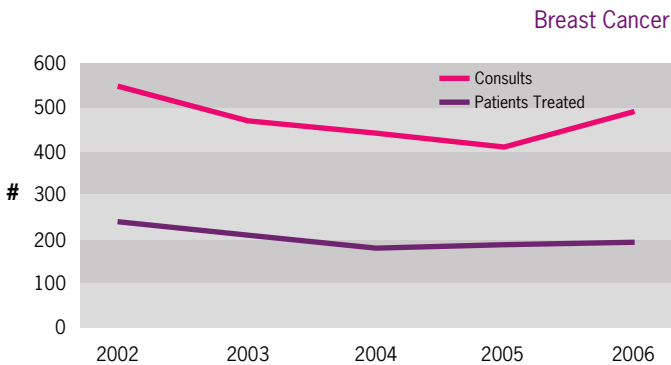


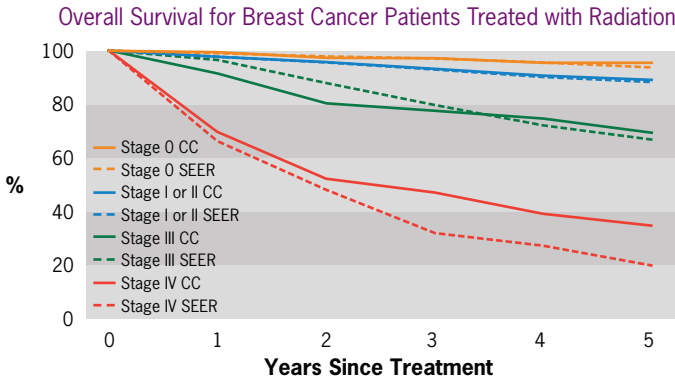
Breast

Radiation oncologists actively participate in the multidisciplinary Breast Center where patients are seen along with surgeons and medical oncologists in a single location. This arrangement is convenient for patients and allows the closest possible collaboration among the physicians in developing an integrated treatment plan.



**3D Plan for
Partial Breast
Irradiation**

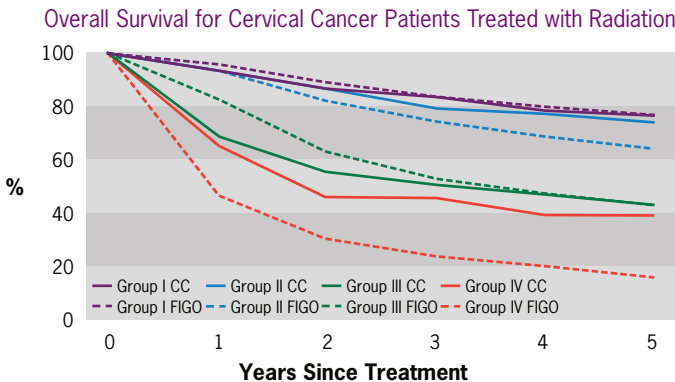




Standard for breast cancer outcomes: Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute, 1983-1998, reported in American Joint Committee on Cancer: Cancer Staging Manual, sixth edition, 2002.

Gynecological Cancers

The Gynecologic Program in the Department of Radiation Oncology is characterized by close cooperation with the gynecologic oncology staff. Treated gynecologic tumor sites are vulva, vagina, cervix, uterine body and uterine adnexa. Standard treatment employs high-dose-rate brachytherapy and external beam radiotherapy.

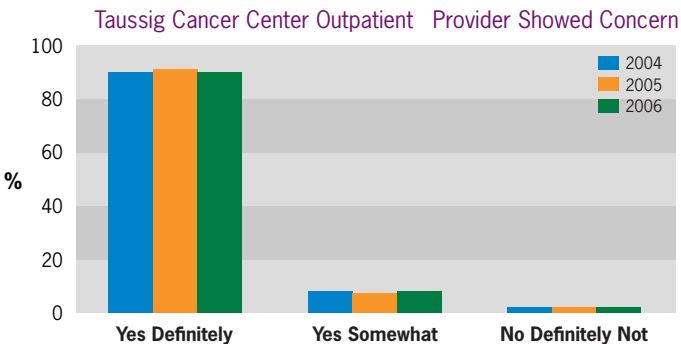
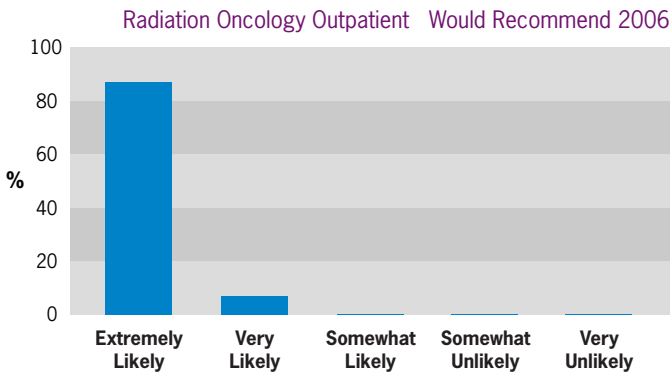
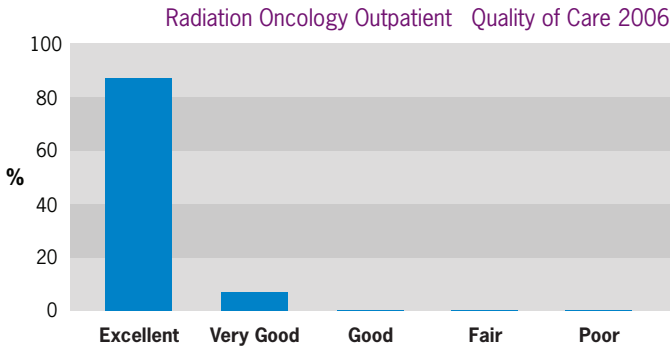


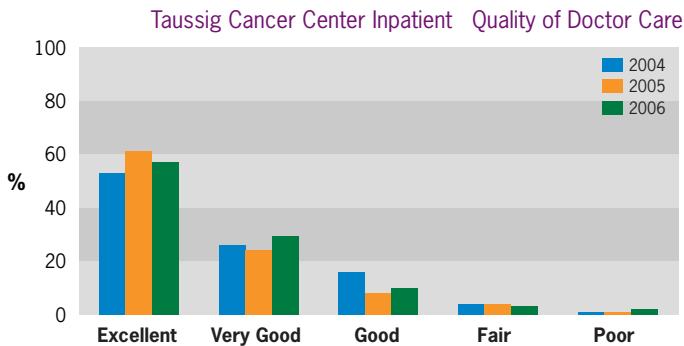
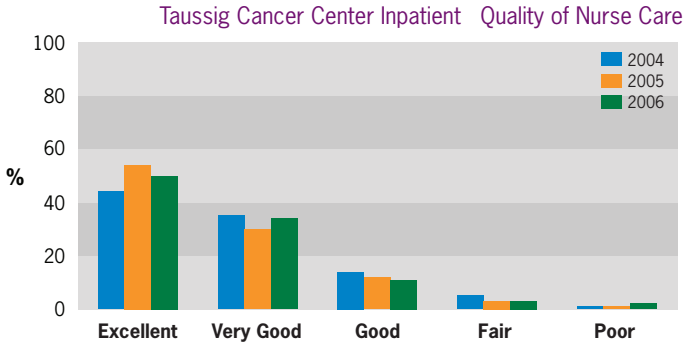
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Patient Experience

We ask our patients about their experiences and satisfaction with the services provided by our staff. Although our patients are already indicating we provide excellent care, we are committed to continuous improvement.





A Note regarding H-CAHPS, the New National Standard for Reporting Hospital In-Patient Experience of Care:

The service excellence data displayed above shows results from an external patient experience survey administered for Cleveland Clinic.

A new national standard patient experience survey instrument called H-CAHPS was instituted across the country on October 1, 2006. Public reporting of initial results on CMS's Hospital Compare website is anticipated in late 2007. Accordingly, Cleveland Clinic outcomes booklets will transition to reporting H-CAHPS inpatient service excellence results in 2007.



Innovations |

Cancer Fertility Protocol

The Taussig Cancer Center is the first in the United States to formally adopt a structured protocol to inform all age-appropriate cancer patients of their reproductive risks and fertility treatment options. In 2005, this protocol was developed in collaboration with Fertile Hope, a national nonprofit organization. We currently screen 100% of the intended population.

New Patient Chemotherapy Class

In 2006, chemotherapy classes were initiated as part of the education process for patients receiving treatment at the Taussig Cancer Center. Implementation was based upon national research showing patients educated about their disease and its treatment feel less anxious and are better prepared to face the treatment process. The chemotherapy class has been incorporated into all new patient schedules and into the schedules of existing patients who have had changes to their chemotherapy regimen. Chemotherapy class is led by oncology nurses and offers a general overview of what to expect in the scheduling and treatment process, as well as information related to parking, nutrition, pharmacy options and the many other services provided at the Cancer Center. Patients are also given more complex information related to the drugs used in their treatment plan, including side effects. Drug information is customized to each patient, according to the individual's planned course of treatment. Education is also related to interpretation of the patient's laboratory results and recognition of neutropenia, anemia and thrombocytopenia. Patients learn how to recognize important signs/symptoms to report to their physician to ensure their safety throughout the continuum of care.

Research into New Drug for Renal Cell and Gastrointestinal Stromal Tumor Cancer (GIST)

Cleveland Clinic was the lead institution to enroll patients in the phase 3 randomized study of SU011248 versus Interferon-alpha as first line systemic therapy for patients with metastatic renal carcinoma. Cleveland Clinic was a contributing institution in the phase III randomized, double-blind, placebo-controlled study of SU011248 in the treatment of patients with Imatinib Mesylate (Gleevec)-resistant or intolerant malignant gastrointestinal stromal tumor.



As a result of the studies, in 2006, the U.S. F.D.A. approved Sunitinib Maleate (Sutent/Pfizer) for treatment of both gastrointestinal stromal tumor after disease progression on, or intolerance to, Imatinib Mesylate, and for renal cell cancer. It was the first time the agency simultaneously approved a new oncology product for two indications.

Sutent is a tyrosine kinase inhibitor which received a priority review and was approved in less than six months. It works through multiple targets to deprive tumor cells of the blood and nutrients needed to grow. Sutent and other new targeted therapies are expanding options for patients with limited alternatives.

According to the American Cancer Society, about 32,000 new cases of advanced kidney cancer and 5,000 cases of GIST are diagnosed each year. Sutent was approved for the treatment of patients with gastrointestinal stromal tumors whose disease progressed or who were unable to tolerate treatment with Gleevec, the current treatment for GIST patients. While studying the treatment in patients, researchers conducted an early (interim) analysis of data that showed Sutent delayed the time for tumors or new lesions to grow in patients with this rare type stomach cancer. Specifically, the median time-to-tumor progression for patients treated with Sutent was 27 weeks, compared to six weeks for patients who were not treated.

In contrast to the approval for GIST, based on the drug's ability to delay tumor growth, approval of Sutent for treating kidney cancer was based on the drug's ability to reduce the size of tumors in patients. An overall response rate ranging from 26% to 37% was found in patients with metastatic kidney cancer whose tumors progressed following cytokine-based therapy.

In the GIST clinical trial, significant clinical benefit was determined through an early interim analysis of data, thereby allowing researchers to convert all patients in the trial to treatment. For Renal Cell Carcinoma indication, the FDA used an accelerated approval process. The FDA worked with the product sponsor to offer an expanded access program prior to approval, making the product available to patients not enrolled in a clinical trial.



Hematologic Oncology Research

AMG-531

Cleveland Clinic helped pioneer the use of AMG-531, a small molecule that stimulates megakaryocytes and platelet production, in immune thrombocytopenic purpura (ITP). This research was described in an October 2006 *New England Journal of Medicine* article co-authored by Alan Lichtin, M.D., of the Department of Hematologic Oncology and Blood Disorders. For chronic ITP, an autoimmune disorder in which antiplatelet autoantibodies cause platelet destruction, most treatments act by decreasing platelet destruction; however, relapse is common when these agents are discontinued.

Evidence that platelet production is suboptimal in many patients with ITP suggests increased platelet production may be effective in managing the disorder. In a Phase III study, trial participants with ITP received AMG-531, a thrombopoiesis-stimulating protein. Overall, a platelet count of at least 50,000 per cubic millimeter was achieved in seven of 12 patients, including three with counts exceeding 450,000 per cubic millimeter. Increases in the platelet count were dose-dependent. AMG 531 caused no major adverse events and increased platelet counts in patients with ITP.

BMS-354825

Cleveland Clinic participated in a national Phase III randomized clinical trial testing the drug Dasatinib (Sprycel) in patients with myelogenous leukemia. These trials led to FDA-accelerated approval of Dasatinib in June 2006 for use in treating adults with chronic phase, accelerated phase, or myeloid or lymphoid blast phase chronic myeloid leukemia with resistance to or intolerance of prior therapy, including Imatinib Mesylate (Gleevec).

In addition, the FDA granted regular approval of Dasatinib for use in treating adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance to, or intolerance of, prior therapy.



Novel Blood Test for Thyroid Cancer

A novel blood test was found to more accurately predict thyroid cancer and improve patient management than the current use of fine needle aspiration biopsy. Results of the study by the team led by clinical pathobiologist Manjula Gupta, Ph.D., endocrinologist Sethu Reddy, M.D., and endocrine surgeons Allan Siperstein, M.D., and Mira Milas, M.D., were published in the *Journal of Clinical Endocrinology & Metabolism*.

A significant number of FNABs show overlapping pathology to make or rule out conclusively a cancer diagnosis which can lead to unnecessary removal of harmless nodules. Thyroid cancer patients are monitored for recurrence using serum thyroglobulin measurement, the sensitivity of which may be compromised by interference with thyroglobulin autoantibodies and thyroid hormone suppression therapy. Researchers found thyroid cancer cells can be detected in the bloodstream by amplifying TSH receptor or thyroglobulin message ribonucleic acid by reverse transcription polymerase chain reaction with the use of a carefully designed primer pair. The team evaluated the blood test to determine whether it could distinguish accurately between benign and malignant cells before a nodule was surgically removed. Preoperatively, the team tested 72 patients, 36 with benign disease and 36 with thyroid cancer (25 with no thyroid surgery and 11 with recurrent disease) and compared the results with FNAB results. Diagnostic sensitivity was 73% and specificity, 81%; 39% of FNAB samples were considered indeterminate to test accurately for cancer. TSHR mRNA, however, correctly classified 77% of indeterminate FNAB samples, enhancing the accuracy of FNAB from 61% to 89%. The combined sensitivity of FNAB and RT-PCR was 95%; specificity was 83% (positive and negative predictive values were 84% and 95%, respectively). The test has 100% sensitivity and 98% specificity in detecting residual/recurrent disease.



Smart Drugs for Lung Cancer

New therapies for lung cancer under investigation include clinical trials of the smart drug Bevacizumab (Avastin), originally approved by the FDA for advanced colon cancer. This antibody binds to the vascular endothelial growth factor, leading to interrupted blood vessel growth in tumors. Preliminary results of Avastin with chemotherapy have shown improvement and increased survival in some patients. Cleveland Clinic researchers are also exploring adding Avastin earlier, combining it with different targeted agents, or targeting different receptors in cancer cells. In addition, patients can live more normal lives because these new agents do not have side effects typical of chemotherapy.

Radiation Oncology Cancer Detection and Treatment Radiotherapy Devices for Prostate Cancer

Arul Mahadevan, M.D., Director of Clinical Research in Radiation Oncology, and his team pioneered the use of 3-D transabdominal ultrasound to track the position of the prostate during or between treatments with intensity-modulated radiation therapy. The system compares ultrasound images with previous images to track prostate shift and compensate for its movements. The department is investigating if the same goal can be achieved by using tiny transponders implanted in the prostate and activated by an electromagnetic field which would provide real-time tracking of the radiation therapy target during treatment. In addition, radiation oncologist Jay Ciezki, M.D., is the lead investigator of a Phase I clinical trial of a prostatic urethral stent to prevent or eliminate urinary obstructive symptoms following prostate seed implantation to treat localized prostate cancer.

Stereotaxis for Lung Cancer

Based on the same principle used in Gamma Knife brain surgery, stereotaxis employs multiple rays at differing angles, each trained on a single pinpoint target, against which their combined energy is exceptionally powerful. The Cancer Center's Novalis system produces stereotactic radiation strong enough to accomplish in three to five treatments in one week what would take standard radiation seven to 10 weeks of



treatment. Novalis offers superior accuracy in establishing the target frame by matching CT scan coordinates with infrared markers placed on the patient's skin for reference, creating a virtual tumor image similar to time-lapse photography. Techniques are used simultaneously to restrict breathing motion during treatment, enhancing accuracy. Novalis thus gives real-time confirmation of the patient's tumor position, confirming the target was hit accurately and radiation was delivered.

Spinal Radiosurgery

The Department of Radiation Oncology treated its first patient with spinal radiosurgery in February 2006. The Novalis image-guided program permits treatment of lesions near critical structures, including spinal lesions.

Enrollment in clinical trials is an important aspect of the program. The Department of Radiation Oncology is recognized for its participation in national and international trials. National collaborative group trial participation includes the Radiation Therapy Oncology Group and New Approaches to Brain Tumor Therapy.

Bronchoscopic Catheter

Gregory M. Videtic, M.D., and colleagues in Pulmonary Medicine received a 2006 Cleveland Clinic Innovations Award for "Bronchoscopic Catheter for the Implantation of Fiducial Markers, Flexible Bronchoscopy and Aspiration Needle." Patients treated with stereotactic body radiotherapy for lung cancer often have severe underlying lung abnormalities, making both biopsies and implantation of fiducial markers (used to track tumor movement during radiotherapy) a high-risk procedure. Working with pulmonary medicine, Dr. Videtic designed a new flexible needle system and modified fiducial markers which can be placed in the lungs using a bronchoscopic approach. The new method allows better placement of fiducial markers while reducing the risk to patients.



Memokath Urethral Stent

Jay P. Ciezki, M.D., and Samuel Chao, M.D., have an institutional Investigational Device Exemption for the Memokath urethral stent. The most common short-term complication after prostate brachytherapy is urinary retention. The Memokath urethral stent is used prophylactically in patients undergoing prostate I-125 seed implants for prostate cancer to assess its effect on reducing urinary symptoms after brachytherapy. Cleveland Clinic is the only site in the United States approved by the FDA to use this device for this indication. A Phase I study has been completed and a multicenter Phase III trial is being developed.

Calypso 4D Localization System

Arul Mahadevan, M.D., is the site principal investigator for the Calypso 4D Localization System. One of the most challenging problems in radiation therapy is the inability to track tumors in real-time during treatment. The Calypso 4D Localization System uses implanted transponders and global positioning technology to track tumors up to 10 times per second during treatment without adding ionizing radiation. Cleveland Clinic participated in pivotal studies leading to FDA approval of the device for prostate cancer. New trials involving the Calypso system are being developed by Cleveland Clinic. This new real-time tracking device will contribute significantly to future treatment advances, even beyond treating prostate cancer.



Center for Hematology Oncology Molecular Therapeutics (CHOMT)

Cleveland Clinic researchers have identified new molecules with antitumor effects, developed collaborative ties with biotechnology companies, begun training more young scientists and expanded their base of financial support. CHOMT investigators are building on advances in molecular biological techniques and applying them to new pharmacological, immunological, biological and cellular approaches to therapeutics and diagnostics.

Researchers identified more than 300 interferon-stimulated genes that influence apoptosis, immune responses and angiogenesis; showed combining IFNs with anti-estrogens or with retinoids results in enhanced anti-tumor effects in cell culture and in xenograft models; focused their research on improving the ability to break immunologic tolerance and deal with tumor escape phenomena, examining methods of studying dendritic cell subpopulations and methods of targeting and activating dendritic cells in patients with cancer. Researchers are using a novel assay to identify activated circulating dendritic cells, a cellular target for CSF-1GM function that leads to enhanced immune recognition. Clinical trials are under way to apply novel methods of assessing dendritic cell function in patients with prostate cancer. In addition, researchers conducted translational investigations of the pathophysiology of bone marrow failure syndromes, including aplastic anemia, paroxysmal nocturnal hemoglobinuria, myelodysplastic syndromes and related diseases. Researchers employed molecular methods of T cell receptor analysis to identify and characterize autoimmune T cell clones and conducted research into developing an antibody that might be predictive of therapeutic response to topoisomerase II inhibitors, a DNA replication enzyme. Novel agents for treating cancer are being evaluated in Phase I and Phase II trials.



New Knowledge |

Selected Publication Highlights

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Department Contacts | How to Refer Patients

The Helen Meyers McLoraine Patient Resource Center is the gateway to the Taussig Cancer Center.

The McLoraine Patient Resource Center is located in the northeast corner of the Taussig Cancer Center. It offers information and resources to cancer patients and their friends and families. Resources also are available to staff members. The McLoraine Patient Resource Center is staffed by two clinical nurse specialists and an administrative coordinator who assist in providing information and answering questions.

Available resources include:

Free pamphlets and informational brochures

Computer terminals for searches

A room for nurse/patient discussions, subcutaneous self-injection teaching, and educational video viewing

Listings and registrations for support groups and other patient-related events

Listings of resources, such as wigs, transportation, and lodging

The McLoraine Patient Resource Center is open from 8 a.m. to 5 p.m. Monday through Friday. The Cancer Answer Line, 1.866.223.8100 or 216.444.7923 is available from 8 a.m. to 5 p.m. Monday through Friday for:

Telephone triage program (Cancer Answer Line)

Appointment scheduling of all outside new patient referrals

Prevention and screening programs

Development and distribution of educational material

Bone Marrow Failure Clinic

The Bone Marrow Failure Clinic of the Taussig Cancer Center is a subspecialty clinic with expertise in aplastic anemia, myelodysplasia, single-lineage cytopenias, paroxysmal nocturnal hemoglobinuria, large granular lymphocytic leukemia and other immune-mediated hematologic diseases.

The Bone Marrow Failure Clinic offers collaborations and referrals to Leukemia, Lymphoma and Myeloma Programs of Cleveland Clinic Taussig Cancer Center.

Jarek Maciejewski, M.D., Ph.D., is a leading expert in the area of bone marrow failure syndromes. Our clinic provides a full diagnostic spectrum and access to the most advanced treatments. Appointments can be made for second opinions and consultations. Patients can obtain insightful information about their disease, its prognosis, standard and experimental therapies, and also, if needed, referrals to leading experts in appropriate areas of hematology.

For appointments and information, please contact:

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If you are in need of more information related to appointment scheduling during the hours of 8 a.m. to 5 p.m. please contact us by calling 216.444.6833.

Radiation Oncology

For Radiation Oncology appointments, call 216.444.5571 or 1.800.223.2273 (ext. 45571).



Cleveland Clinic Overview |

Cleveland Clinic, founded in 1921, is a not-for-profit academic medical center that integrates clinical and hospital care with research and education. Today, 1,700 Cleveland Clinic physicians and scientists practice in 120 medical specialties and subspecialties.

Cleveland Clinic's main campus, with 41 buildings on 130 acres in Cleveland, Ohio, includes a 1,000-bed hospital, outpatient clinic, subspecialty centers and supporting labs and facilities. Cleveland Clinic also operates 13 family health centers, eight community hospitals, two affiliate hospitals, and a medical facility in Weston, Florida.

At the Cleveland Clinic Lerner Research Institute, hundreds of principal investigators, project scientists, research associates and postdoctoral fellows are involved in laboratory-based research. Total annual research expenditures exceed \$150 million from federal agencies, non-federal societies and associations, and endowment funds. In an effort to bring research from bench to bedside, Cleveland Clinic physicians are involved in more than 2,400 clinical studies at any given time.

In September 2004, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University opened and will graduate its first 32 students as physician-scientists in 2009.

For more details about Cleveland Clinic, visit clevelandclinic.org



Online Services |

eCleveland Clinic

eCleveland Clinic uses state-of-the-art digital information systems to offer several services, including remote second opinions through a secure Web site to patients around the world; personalized medical record access for patients; patient treatment progress access for referring physicians (see below); and imaging interpretations by the Department of eRadiology's subspecialty trained academic radiologists. For more information, please visit eclevelandclinic.org.

DrConnect

Online Access to Your Patient's Treatment Progress

Whether you are referring from near or far, our new eCleveland Clinic service, **DrConnect**, can streamline communication from Cleveland Clinic physicians to your office. This new online tool offers you secure access to your patient's treatment progress at Cleveland Clinic. With one-click convenience, you can track your patient's care using the secure **DrConnect** Web site. To establish a **DrConnect** account, visit eclevelandclinic.org or e-mail drconnect@ccf.org.

MyConsult

MyConsult Remote Second Medical Opinion is a secure, online service providing specialist consultations and remote second medical opinions for more than 600 life-threatening and life-altering diagnoses. **MyConsult** remote second medical opinion service allows you to gather information from nationally recognized specialists without the time and expense of travel. For more information, visit eclevelandclinic.org/myconsult, e-mail eclevelandclinic@ccf.org or call 800.223.2273, ext 43223.



Cleveland Clinic Contact Numbers |

How to Refer Patients

24/7 Hospital Transfers or Physician Consults
800.553.5056

General Information

216.444.2200

Hospital Patient Information

216.444.2000

Patient Appointments

216.444.2273 or 800.223.2273

Medical Concierge

Complimentary assistance for out-of-state patients and families
800.223.2273, ext. 55580, or email: medicalconcierge@ccf.org

International Center

Complimentary assistance for international patients and families
216.444.6404 or visit www.clevelandclinic.org/ic

Cleveland Clinic in Florida

866.293.7866

www.clevelandclinic.org



Cleveland Clinic is determined to exceed the expectations of patients, families and referring physicians. In light of this goal, we are committed to providing accurate and timely information about our patient care.

Through participation in national initiatives, we support transparent public reporting of healthcare quality data and participate in the following public reporting initiatives:

- Joint Commission Performance Measurement Initiative (www.qualitycheck.org)
- Centers for Medicare and Medicaid (CMS) Hospital Compare (www.hospitalcompare.hhs.gov)
- Leapfrog Group (www.leapfroggroup.org)
- Ohio Department of Health Service Reporting (www.odh.state.oh.us)

In addition, this publication was produced to assist patients and referring physicians in making informed decisions. To that end, information about care and services is provided, with a focus on outcomes of care. For more information, please visit the Cleveland Clinic Quality Web site at clevelandclinic.org/quality.



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Cleveland Clinic is a not-for-profit multispecialty academic medical center. Founded in 1921, 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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