

NEW YORK-PRESBYTERIAN Oncology

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Spring 2005

Studies Seek To Prevent or Treat Cervical and Ovarian Cancers

Columbia and Weill Cornell investigators at NewYork-Presbyterian Hospital are now taking a leading role in a number of important clinical trials investigating treatment alternatives for various gynecologic cancers. These studies could provide answers to many nagging questions regarding the treatment and management of diseases such as ovarian and cervical cancers. The ultimate goal of these efforts is to coordinate the research at both centers of NewYork-Presbyterian Hospital to maximize the resources of the Hospital and its academic partners.

"We're on 2 campuses, but I think we would agree that our missions should be the same," said Thomas Caputo, MD. "We're both doing basic and clinical research as well as patient care."

Currently, at NewYork-Presbyterian Hospital/Columbia University Medical Center, a team led by Thomas Herzog, MD, is studying whether the addition of PET scans to the standard diagnostic method using CT scans will better detect metastatic disease. According to Dr. Herzog, cancer cells metabolize glucose faster than normal cells, and PET may be better able to observe the difference between cancerous and noncancerous cells. Another initiative will look at the role of vascular endothelial growth factor (VEGF) in ovarian cancers to see if these cancers can be prevented from

see Gynecologic, page 5

New Technology and Skill Revolutionize Prostate Surgery

Robotic prostatectomy is emerging as a safe and effective treatment option for men with prostate cancer, according to surgeons at NewYork-Presbyterian Hospital. Robotic removal of the cancerous prostate, when performed by skilled, experienced surgeons, offers substantial improvements over the standard open procedure, including a lower risk for bleeding and more rapid post-surgical recovery (Figure, page 7). "The outcomes related to the cancer itself are as good as [those of] open surgery, in part because of the magnification that we use," said David B. Samadi, MD.

Open surgery remains the gold standard for radical prostatectomy; newer procedures are based on the principles of anatomic prostatectomy. However, "there are advantages of robotic techniques that may benefit patients in early recovery," said Ash Tewari, MD. "The benefits to the patient include a shorter hospital stay, less pain, and less blood loss," he continued, adding that minimally invasive procedures are performed "looking over the shoulders of the giants of open prostatectomy. With experienced surgeons, cancer control could be comparable to [that of] the open procedure. However, the urinary continence and sexual function data are very early; we

see Prostatectomy, page 7



Photo courtesy of The Weill Cornell Robotic Surgery Institute.

The Robotic Surgery Institute in the Department of Urology at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. State-of-the art surgical systems have made prostate surgery safer, while improving outcomes.

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Researchers Seek To Learn the Role Of Race in Breast Cancer Outcomes

Two studies currently underway at NewYork-Presbyterian Hospital/Columbia University Medical Center are investigating the reasons why breast cancer mortality rates are higher among African-American women than among white women. Their findings could ultimately influence how patients from these different demographic groups are treated.

The US Centers for Disease Control and Prevention (CDC) estimates that 19,240 new cases of breast cancer will be diagnosed in African-American women in 2005. Although fewer African-American women younger than age 40 are diagnosed with breast cancer, the mortality rate in this population is 32% higher than the mortality rate in white women with breast cancer,

according to the CDC (Figure). Experts cite genetic, behavioral, and socioeconomic factors as reasons for this disturbing trend. Because breast cancer is the most common form of cancer and the second most common cause of cancer death among African-American women, it is important to understand why disparities exist and how doctors may best address them.

“African-American women have a significantly increased risk of dying from breast cancer on a stage-for-stage basis,” said Dawn L. Hershman, MD, MS. “Researchers have postulated that differences in tumor biology may account for some of the disparity in outcomes, but nobody has looked at differences in the initiation and completion of breast cancer treatment.”

Dr. Hershman and Alfred I. Neugut, MD, PhD, Columbia researchers at NewYork-Presbyterian Hospital, have received a \$10 million grant from the US Army Medical Research Acquisition Activity Division of the Department of Defense to create a Breast Cancer Center of Excellence. According to Drs. Neugut and Hershman, the Center will study 900 black and 900 white cancer patients who are already enrolled in previously existing cancer studies. The study participants will be interviewed about their overall cancer treatment experience, including referral to oncologists, adherence to recommended chemotherapy, cultural and personal values, and their perceptions of the physician-patient interaction. The treating oncologists will also be interviewed to determine their attitudes toward various treatment options.

“Identifying the barriers to optimal treatment will enable us to intervene to reduce racial disparities and to improve survival for all women with breast cancer,” said Dr. Neugut, principal investigator of the Breast Cancer Center of Excellence. In a previous study analyzing patients in the Henry Ford Health System in Detroit, Drs. Hershman and Neugut and colleagues determined that incomplete treatment of breast cancer is common among black women. In this study, only 68% of black patients completed all prescribed cycles of adjuvant chemotherapy, compared with 76% of white patients. According to Dr. Hershman, the aim of the new grant is to understand all of the factors that may contribute to suboptimal treatment.

In another study currently under way at NewYork-Presbyterian/Columbia, Kathie-Ann Joseph, MD, MPH, will examine African-American patients with ductal carcinoma in situ (DCIS), a cancer of the cells lining the milk ducts. It is believed that African-American women with DCIS are more likely than white women to present with estrogen receptor (ER)-negative tumors. Consequently, they derive comparatively little benefit from tamoxifen therapy. ER-negative patients with DCIS experience more

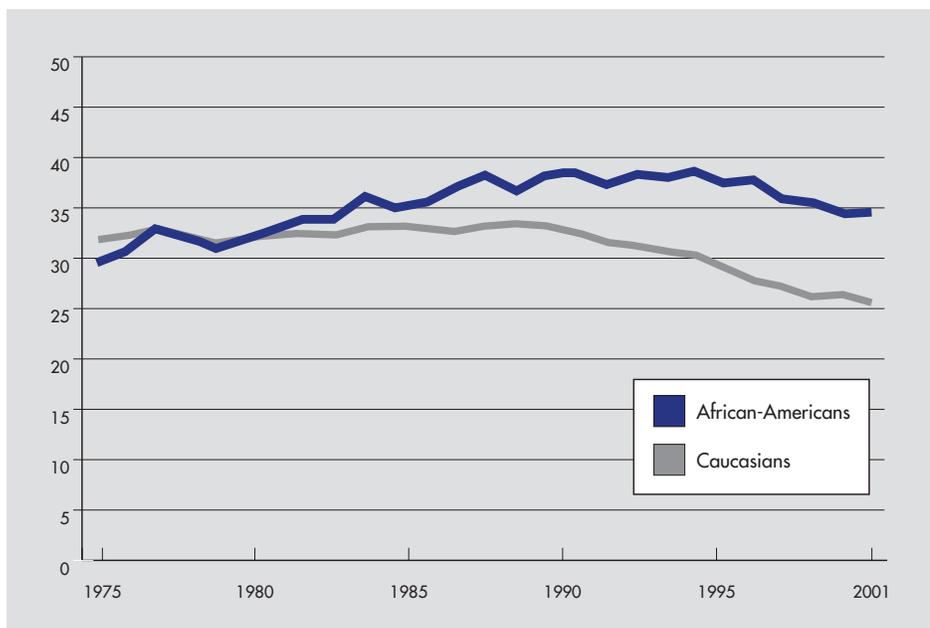


Figure. Trends in death rates for female breast cancer, 1975-2001.*

*Rates are per 100,000 population and age-adjusted to the 2000 US standard population, and are 2-year moving averages.

Source: US Mortality Public Use Data Tapes, 1969-2001, National Center for Health Statistics, Centers for Disease Control and Prevention, 2004.

recurrences of breast cancer, possibly because ER-negative tumors are not affected by tamoxifen.

Dr. Joseph will study samples from 80 black women and 80 white women diagnosed with DCIS in the past 10 years. She will determine the ER and progesterone-receptor (PR) status of these samples and analyze the effectiveness of tamoxifen in both ER-positive and ER-negative patients. Because 40% of black women with breast cancer are diagnosed with invasive forms of the disease that are ER-negative, according to Dr. Joseph, these data could lead doctors to question whether tamoxifen therapy is the most helpful approach for their African-American patients. Most US hospitals do not routinely test DCIS patients for hormonal status, but if Dr. Joseph is successful in proving the prevalence of ER-negative cancers among black patients, this policy may be reconsidered in the interest of providing appropriate breast cancer therapy as quickly as possible.

“We know that African-American women have the worst survival rates of any ethnic group, even if they participate in clinical trials and receive excellent care,” Dr. Joseph said. “We need to try different strategies to treat cancer that is not hormonally dependent.”

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NewYork-Presbyterian Oncology

is a publication of the Cancer Centers of NewYork-Presbyterian Hospital. The Cancer Centers are at the forefront of cancer screening and diagnosis, and basic science and clinical research. The Cancer Centers serve over 6,500 new cancer patients each year, who receive state-of-the-art multidisciplinary care. The Cancer Centers include the Herbert Irving Comprehensive Cancer Center at NewYork-Presbyterian Hospital/Columbia University Medical Center and the Weill Cornell Cancer Center at NewYork-Presbyterian Hospital/Weill Cornell Medical Center, which are respectively comprised of faculty from the Columbia University College of Physicians and Surgeons and the Weill Medical College of Cornell University.

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New Chemotherapy Regimens Promise Enhanced Treatment of AML

Weill Cornell investigators at NewYork-Presbyterian Hospital are taking the lead role in developing new chemotherapy drugs for the treatment of leukemia, chronic myelodysplasia, and chronic myeloproliferative disorders. These promising approaches focus on molecular and protein targets and anti-angiogenic therapy.

According to Eric Feldman, MD, the

Center for Leukemia and Myeloproliferative Disorders at NewYork-Presbyterian Hospital/Weill Cornell Medical Center is currently involved in several Phase I and II clinical trials and, in many instances, the first human studies of novel chemotherapy regimens. One major area of research involves identifying new antibodies or small molecules that are directed against molecular or protein targets abnormally expressed in leukemic cells.

In line with this approach, the Center recently completed a Phase II trial of tipifarnib, an oral farnesyltransferase inhibitor that “has been the most successful treatment to date among the new, nonchemotherapy drugs we have been investigating,” Dr. Feldman said. Tipifarnib works by inhibiting the Ras protein as well as other proteins involved in signal transduction. Up to 30% of patients with acute myelogenous leukemia (AML) and myelodysplastic leukemia have a mutation of the gene encoding the Ras protein, according to Dr. Feldman. Ras is activated through the process of farnesylation.

“If you inhibit the enzyme, Ras is no longer an active protein in the cell,” Dr. Feldman explained. “We think Ras, as well as other signal transduction proteins that require farnesylation, are important in the signal for cell proliferation and cell survival for

leukemic cells.”

The tipifarnib study, sponsored by the National Institutes of Health, was designed to evaluate the drug in older patients (aged 65 years and older) with acute AML. More than 142 patients participated from a number of sites, including NewYork-Presbyterian/Weill Cornell, during the yearlong trial. In all, 30% of the patients in the study responded to treatment with tipifarnib; the drug was also well tolerated, with minimal toxicities reported (Figure). The response rates were favorable, said Dr. Feldman, particularly when compared with those of more toxic regimens.

“It’s possible that this drug will be approved by the FDA, based on this Phase II trial for elderly patients with AML, for whom no other reasonable treatment exists,” Dr. Feldman said.

Another promising area of research involves the use of anti-angiogenic therapy, currently being investigated by Dr. Feldman’s team in conjunction with Shahin Rafii, MD, at the Ansary Center for Stem Cell Therapeutics at NewYork-Presbyterian/Weill Cornell. According to Dr. Feldman, Dr. Rafii’s lab findings indicate that pro-angiogenic proteins, such as vascular endothelial growth factor (VEGF), are significant “drivers” of leukemic cell growth.

The researchers are investigating whether the inhibition of VEGF or its receptors can be effective in treating several forms of leukemia. They are using small molecules, such as PTK787, or antibodies directed against the receptor—such as the new humanized anti-VEGF receptor 2 antibody—to attempt to inhibit the activity of these proteins.

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— Eric Feldman, MD

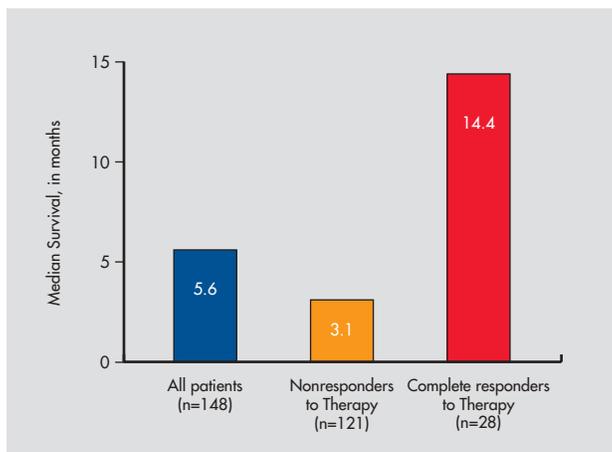


Figure. Median survival in elderly AML patients treated with tipifarnib.

Source: Lancet JE, Gotlib J, Gojo I, et al. Tipifarnib in previously untreated poor-risk AML of the elderly: updated results of a multicenter phase 2 trial. Presented at the 2004 annual meeting of the American Society of Hematology. December 4-7, 2004. San Diego, Calif. Abstract 874.

acquiring the blood vessels necessary to grow and spread.

Similarly, at NewYork-Presbyterian Hospital/Weill Cornell Medical Center, Dr. Caputo is investigating a screening program for ovarian cancer that involves extracting and assaying DNA by polymerase chain reaction and endonuclease digestion, then examining the samples for the presence of mannose-binding lectin (MBL), a component of the innate immune system with antimicrobial and anticancer activity. "Polymorphisms in the MBL gene are associated with production of an unstable protein and decreased levels of MBL. We believe that women with gynecologic malignancies would have an elevated rate of MBL gene polymorphisms," said Dr. Caputo.

Dr. Herzog, who came to NewYork-Presbyterian/Columbia in August 2004, is part of the Gynecologic Oncology Group (GOG), the large cooperative research group sponsored by the National Cancer Institute. He's a primary investigator in the largest ovarian cancer trial worldwide, GOG 182, a study evaluating the efficacy of newer cytotoxic agents in the treatment of the disease. One of his main goals, to make NewYork-Presbyterian/Columbia a GOG institution, is close at hand.

"Women with ovarian and cervical cancers will have access to clinical trials offering the newest treatments available," said Dr. Herzog.

"It would be a tremendous advantage to do away with the cone biopsy. Morbidity and complications from cone biopsy have serious consequences for many women."

—Thomas Caputo, MD

Dr. Caputo, meanwhile, participates in the New York GOG, a local consortium. He is leading another treatment-related study. In this study, after diagnosis of carcinoma in situ 3 dysplasia, subjects receive either 3 doses of a vaccine, made from a protein subjected to heat shock, or 3 doses of the vaccine plus an immunotherapeutic agent called HSP E7. All patients have a cone biopsy at the end of therapy to determine whether

those treated only with the vaccine have a decreased recurrence of dysplasia.

"It would be a tremendous advantage to do away with the cone biopsy," said Dr. Caputo. "Morbidity and complications from cone biopsy have serious consequences for many women."

In addition, Dr. Caputo and his team are spearheading research on consolidation chemotherapy, a unique and controversial approach to treating patients whose ovarian cancer is in complete remission. Upon remission, patients begin standard therapy with paclitaxel and carboplatin, followed by a round of topotecan, an alternate chemotherapy drug. The object is to reduce recurrences of advanced cancer and increase long-term control and cure rates.

"This approach provokes debate in the field about type and number of drugs, no drugs, or other ways of monitoring patients, such as a 'second-look' operation," said Dr. Caputo. "Most of us used to do second-look operations routinely, but we believe it is an advantage to the patient not to have another surgery."

Dr. Herzog's team is also interested in looking at the molecular genetics of ovarian cancer. With specimens from their tumor bank, they will examine gene expression and design clinical interventions based on the tumors' genetic profiles in the search for new therapeutic strategies and drugs. It is on this latter project that Drs. Herzog and Caputo hope to collaborate. Noted Dr. Herzog, "We'll be developing designs for clinical interventions based on the genetic profile of these tumors. The goal, of course, is to come up with new strategies, new drugs, and new agents for treatment."

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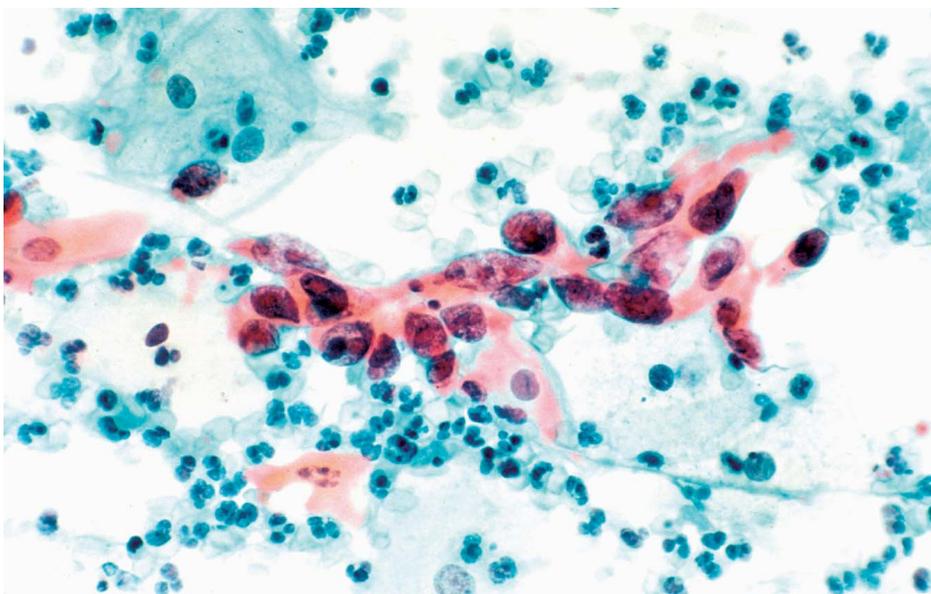


Photo Courtesy of the National Cancer Institute

Figure. A histologic section showing specifically squamous cell carcinoma in the cervix (Papanicolaou's stain).

Demographics and Disease: Researchers Explore the Risk Factors of Retinoblastoma

Manuela Orjuela, MD, ScM, a pediatric oncologist at Morgan Stanley Children's Hospital of NewYork-Presbyterian/Columbia University Medical Center, is collaborating with researchers at several institutions in Mexico and the United States in an effort to trace the causes of nonfamilial retinoblastoma in children. Maternal environmental exposures, particularly during pregnancy, are among the suspected etiologic factors.

"There is a variety of work that suggests that nonfamilial retinoblastoma evolves from an event in utero," said Dr. Orjuela. "We are involved in a series of studies, including case-control analyses, which may provide better insight into specific risk factors."

Although retinoblastoma is the most common intraocular malignancy in children, it is relatively rare. The incidence is about 1 in 16,000 births, or about 300 cases in the United States per year. The average age at diagnosis is 18 to 24 months, but the onset of malignancy is believed to be much earlier. An inherited genetic abnormality has been identified in familial cases, but it is estimated that these account for fewer than 10% of the total cases of retinoblastoma. Sporadic cases, which may have a similar genetic abnormality, appear to account for the remainder. Epidemiologic evidence suggests that sporadic cases are slightly more prevalent in geographic regions with poorer economic resources, but this relationship is not absolute.

If identified early in its course, retinoblastoma is treatable. Mortality is about 15% and generally occurs only

when the cancer has metastasized. However, the morbidity includes loss of vision in the affected eye or blindness if retinoblastoma is bilateral. Bilateral disease is observed in about one third of cases.

Although the molecular changes underlying the development of the disease are well documented, very few studies have been undertaken to examine what factors may be contributing to these molecular changes, in part because of the low incidence of the disease. Dr. Orjuela is interested in interactions between maternal and fetal environmental factors and genetic susceptibility. Since 2003, she has been the principal investigator of a study funded by the American Cancer Society and the National Institutes of Health to examine suspected environmental insults in the context of genetic susceptibility. Based on early results from the study, even a relatively common infection, such as with human papillomavirus, may play a role.

Another environmental factor of interest is maternal diet. Further data from Dr. Orjuela's work are expected later this year.

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—Manuela Orjuela, MD, ScM

"One of the advantages of the collaboration with researchers in both the United States and Mexico is the opportunity to compare differences and similarities in environmental exposures in very different settings and populations," Dr. Orjuela noted. The institutions with which she is currently collaborating in Mexico are the Hospital Infantil de Mexico, the Universidad Nacional Autonoma de Mexico, the Instituto Mexicano de Seguro Social, and the Instituto Nacional de Salud Publica.

Even if specific environmental factors are isolated as contributing to retinoblastoma, Dr. Orjuela does not anticipate the introduction of screening [see Retinoblastoma, page 8](#)

Retinoblastoma has served as an important model for the understanding of molecular oncogenesis. A better understanding of the risk factors associated with its occurrence may eventually lead to opportunities for earlier detection and, ultimately, for prevention.

Prostatectomy

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should wait for the data to mature.”

According to Dr. Samadi, outcomes following robotic prostatectomy at NewYork-Presbyterian Hospital/Columbia University Medical Center compare very favorably with what can be achieved with the open procedure. He has performed hundreds of these procedures and is one of the few urologic surgeons in the world trained in both laparoscopy and uro-oncology.

“Because we have extensive experience in laparoscopy, oncology, and robotic surgery,” he said, “patients can really experience the benefits of robotic prostatectomy and a rapid recovery of both continence and potency. The majority of our patients go home in 1 day, the catheter is removed on day 3 or 4, and the patient is back to work in 1 week.”

Outcomes are similarly positive for patients treated at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. According to Dr. Tewari, 98% of patients undergoing robotic prostatectomy go home within 24 hours, and up to 96% of patients have no urine control issues within 6 months. The rate of return of potency at 6 months is approximately 82%.

Historically, radical prostatectomy was performed through a large incision 4 to 5 inches in length; with robotic systems, only 5 tiny keyhole incisions are required, resulting in less pain, a smaller chance of bleeding, and a significant decrease in recovery time. Recent studies suggest robotic surgery may reduce the risk for postsurgical impotence.

While the benefits of robotic prostatectomy are substantial, the procedure is not right for everyone, said Mitchell C. Benson, MD. “We are not applying the same surgical procedure to all patients,” he noted. “Some patients are definitely better treated with robotic surgery, and some with open surgery. The trick is to have the ability to perform both well, and to know which patients benefit most from which procedure.”

In Dr. Benson’s hands, the risk for serious incontinence following radical open surgery in low-risk patients (eg, prostate-specific antigen [PSA] <10

ng/mL) is 0.16%, with a 2% to 3% chance of mild daily stress incontinence. “Our outcome in urinary incontinence and potency preservation is excellent,” Dr. Benson said. “Patients should be aware of the options and receive the procedure that is right for them.”

Meanwhile, NewYork-Presbyterian Hospital surgeons continue to make meaningful contributions to research in the field of robotic prostatectomy. Dr. Tewari is actively studying strategies for nerve visualization during the procedure; another area of interest is the development of preprocedural 3-dimensional reconstructions that may provide a better “road map” of the pelvis anatomy. Dr. Tewari cautioned that there have been no randomized studies comparing various techniques. Therefore, any comparative observations are at best hypothesis-generating and cannot be construed as a benefit of a particular procedure. Still, some preliminary findings suggest that the accuracy of robotic surgery results in a decreased positive margin rate compared with open prostatectomy.

“Positive margin rate is a short-term measure, but it is a surrogate marker for cure,” said Douglas Scherr, MD. “To that end, robotics has been very beneficial to us here. With great resolution and optics, we are able to see things we would not

see through an open approach. “The procedure has evolved over time. We have perfected a technique that has been beneficial for our patients.”

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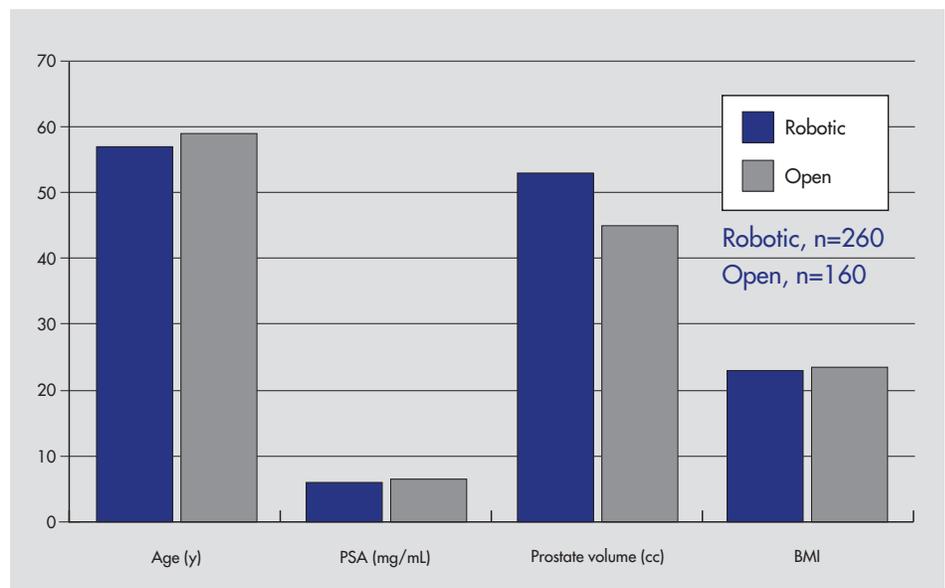


Figure. Comparison of baseline parameters in patients undergoing robotic prostatectomy versus open radical retropubic prostatectomy.

PSA, prostate-specific antigen; BMI, body mass index [kg/m²]

Source: Tewari A, Srivasatava A, Menon M, et al. A prospective comparison of radical retropubic and robot-assisted prostatectomy: experience in one institution. *BJU Int.* 2003;92:205-210.

Retinoblastoma

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programs. Because of the low incidence of this malignancy, a population-based approach to early detection is not appropriate. However, the isolation of environmental factors could heighten awareness among physicians managing populations at risk, fostering a greater index of suspicion for earlier diagnosis and better outcomes. Currently, a variety of diseases can be mistaken for retinoblastoma, such as *Toxocara canis* infection and persistent hypertrophic primary vitreous, which may delay diagnosis and increase the risk for an adverse outcome.

Retinoblastoma has served as an important model for the understanding of molecular oncogenesis. A better understanding of the risk factors associated with its occurrence may eventually lead to opportunities for earlier detection and, ultimately, prevention.

Although the molecular changes underlying the development of [retinoblastoma] are well documented, very few studies have been undertaken to examine what factors may be contributing to these molecular changes, in part because of the low incidence of the disease.

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Upcoming CME Programs

NewYork-Presbyterian Hospital, Columbia University College of Physicians and Surgeons and Weill Medical College of Cornell University are sponsoring a Continuing Medical Education program on the topic of Prostate Cancer in 2005.

Please visit www.nypcancer.org for future announcements pertaining to registration information and a specific course outline.

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