Research Highlights

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Osteoporosis Treatment May Help Men Receiving Androgen-Deprivation Therapy

According to a study presented by the University of Pittsburgh Medical Center at the American Society of Clinical Oncology Prostate Cancer Symposium in February, men with prostate cancer who experience bone loss from androgen-deprivation therapy could benefit from weekly oral alendronate therapy.

The study included 112 men with prostate cancer who had an average age of 71. After an average of two years of androgen-deprivation therapy for prostate cancer, only 9% of the men had normal bone mass, whereas 52% had low bone mass and 39% developed osteoporosis. To study the effect of alendronate on the men, researchers randomized the men into two groups to receive either alendronate or placebo orally once a week. At the one-year follow-up assessment, bone mass in the spine and hips increased significantly ($p < 0.05$) in the men treated with alendronate (4.9% and 2.1% for spine and hips, respectively). By comparison, men in the placebo group had significant losses ($p < 0.05$) of bone mass in the spine and hips (1.3% and 0.7%, respectively). The therapy was well tolerated. The researchers concluded that because most men remain on androgen-deprivation therapy indefinitely, healthcare providers must assess bone mass and consider ways to prevent bone loss.

Nelson, J.B., Greenspan, S.L., Resnick, N.M., Trump, D.L., & Parker, R.A. (2006, February). *Once weekly oral alendronate prevents bone loss in men in androgen deprivation therapy.* Abstract presented at the American Society of Clinical Oncology Prostate Cancer Symposium, San Francisco, CA.

Adding Thalidomide to Myeloma Therapy Has Little Benefit

Melphalan-based high-dose therapy has been shown to improve the survival of patients with multiple myeloma. However, researchers did not know whether adding thalidomide, an agent with activity against advanced and refractory disease, to the therapy could further improve outcomes. The investigators assessed the outcomes of 668 patients who were randomized to receive two cycles of melphalan-based therapy prior to hematopoietic stem cell transplantation with or without thalidomide.

After a median follow-up period of 42 months, the complete response rate in the thalidomide group was 62%, significantly higher than the 43% rate noted in the control group ($p < 0.001$). Similarly, the five-year event-free survival rate in the thalidomide group also was higher, 56% versus 44% ($p = 0.01$). However, partly resulting from a lower response rate to salvage therapy, the addition of thalidomide did not improve overall survival; both groups had five-year overall survival rates of about 65%. The median survival period after relapse in the thalidomide group was 1.1 years, compared with a period of 2.7 years in the control group ($p = 0.001$). Additionally, deep vein thrombosis occurred in 34% of the thalidomide-treated patients compared with 18% of the controls ($p < 0.001$). The use of low–molecular-weight heparin did not eliminate the elevated risk. Other adverse events seen more frequently in the thalidomide group included peripheral neuropathy, syncope, bowel obstruction, tremor, and neutropenia.

Barlogie, B., Tricot, G., Anaissie, E., Shaugnessy, J., Rasmussen, E., van Rhee, F., et al. (2006). Thalidomide and hematopoietic stem-cell transplantation for multiple myeloma. *New England Journal of Medicine, 354,* 1021–1030.

Custom Chemotherapy Improves Survival Rates for Children With Bone Cancer

The Denver Clinic for Extremities at Risk has reported a 90% survival rate for children suffering from osteosarcoma, with more than 90% of patients avoiding amputation. Osteosarcoma is the most common form of bone cancer, and, historically, most children have been treated with amputation.

In two published studies, the Denver Clinic developed "custom chemotherapy" protocols for children with bone cancer. Using intra-arterial chemotherapy, doctors injected chemotherapy drugs directly into the tumor at a concentration five to nine times greater than the same drug administered via IV. Patients received IV and intra-arterial chemotherapy prior to surgery. Once the cancer was maximally killed, patients underwent surgical resection of the tumor. More than 90% of children were saved from amputation.

The Denver Clinic attributes its success to an ongoing multidisciplinary approach that develops unique treatment plans for each child. Although cancers of the bone are rare, the standard medical and surgical experience for children is difficult and often produces poor results, whereas customized chemotherapy regimens for osteosarcoma in children have saved limbs and lives.

Cullen, J.W., Jamroz, B.A., Stevens, S.L., Madsen, W., Hinshaw, I., Wilkins, R.M., et al. (2005). The value of serial arteriography in osteosarcoma: Delivery of chemotherapy, determination of therapy duration, and prediction of necrosis. *Journal of Vascular and Intervention Radiology, 16,* 1107–1119.

Ethnicity May Influence End-of-Life Care

An American Geriatric Society study investigated how people's ethnicity and cultural backgrounds affect preferences for end-of-life care. The study consisted of 73 people divided into 10 focus groups. Participants identified themselves as Arab Muslim, Arab Christian, Hispanic or Latino, African American, or Caucasian. They participated in exercises, listened to scenarios, and held discussions about end-of-life issues. All participants were aged 50 or older.

Among the findings were that all Arab Americans (Muslim and Christian) indicated that family members take care of the dying and that participants would not prefer to enter a nursing home as they near the end of their lives. They also did not want heroic measures taken to prolong life. Hispanic participants

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were concerned about dying with dignity. Hispanics were more likely than other groups to want to control their place of death, not want a feeding tube, and not have do-not-resuscitate orders.

African American men in the study did not want to burden their families with their care and would prefer staying in an intensive care unit or to have hospice care rather than being home under the care of family members. Caucasians were open to hospice care, hospitals, and nursing homes but generally expressed a preference to die at home. More than the other ethnic groups, Caucasians were likely to want to know what to expect about pain and other effects of their conditions.

The limitations of the study are that it was based on focus groups so it allows researchers to develop only a hypothesis on which to base a larger, more sophisticated study. The researchers asked members of the public who represent different ethnic groups about their attitudes surrounding end-of-life care; thus, results reflect the attitudes and beliefs of healthy people, not those of patients with cancer. End-of-life care preferences vary not only by ethnicity but also according to socioeconomic status, educational level, age, gender, and religiosity. Researchers will need to control for those variables to better understand the independent role that ethnicity may have.

Although data on cultural preferences are limited, conversations about end-of-life care need to consider the culture and ethnic background of the people involved.

Duffy, S.A., Jackson, F.C., Schim, S.M., Ronis, D.L., & Fowler, K.E. (2006). Racial/ethnic preferences, sex preferences, and perceived discrimination related to end-of-life care. *Journal of American Geriatric Society, 54,* 150–157.

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Gamma Knife Radiosurgery Offers Long-Term Survival for Some Brain Metastases

Metastasis is a common problem in patients with cancer, and metastasis to the brain occurs in as many as 40% of malignancies. Gamma knife radiosurgery is a noninvasive method of removing brain tumors and metastatic cancer tissue. The current study provides evidence that gamma knife surgery can prolong survival of patients with brain metastases for at least 13 months, depending on tumor type.

Researchers from the University of Pittsburgh Medical Center looked at 44 patients from 1988–2000 who survived longer than four years after gamma knife radiosurgery for brain metastases. They compared them with a group of 100 patients who survived less than three months after gamma knife surgery for metastases to the brain. Clinical and treatment patterns responsible for their outcomes were assessed for differences. No differences existed in age, gender, percentage of lung or renal carcinoma or melanoma, or radiotherapy dose. Patients who survived longer than four years had mental function tests that were greater preradiosurgery, had fewer metastases, and had less disease involvement outside the brain than the group who survived less than three months. Despite traditional methods for predicting survival after brain metastasis, some patients continue to survive for many years, thus beating the odds of their disease.

Kondziolka, D., Martin, J.J., Flickinger, J.C., Friedland, D.M., Brufsky, A.M., Baar, J., et al. (2005). Long-term survivors after gamma knife radiosurgery for brain metastases. *Cancer, 104,* 2781–2791.

Low-Dose, Outpatient Regimen Is Safe and Effective in Treating Inoperable Metastatic Melanoma

Effective treatment for stage IV metastatic melanoma is unavailable. Death is often the result of brain metastases. Researchers have been investigating a new treatment regimen consisting of oral temozolomide; subcutaneous sargramostim (Leukine®, Berlex, Montville, NJ), a granulocyte macrophage–colony-stimulating factor; subcutaneous interferon-alpha2b; and subcutaneous recombinant interleukin-2 to treat advanced unresectable melanoma. The temozolomide treatment regimen was given orally, allowing patients to remain at home. Investigators reported that the drugs were well tolerated by patients in the study and appeared to protect against brain metastasis.

Thirty-one patients were enrolled. Four patients (13%) had a complete response, and four patients had a partial response. The median progression-free survival was 4.9 months, and the median overall survival was 13.1 months. Toxicities that developed were generally grade 1 or 2 and usually were managed easily.

Weber, R.W., O'Day, S., Rose, M., Deck, R., Ames, P., Good, J., et al. (2005). Low-dose outpatient chemobiotherapy with temozolomide, granulocyte-macrophage colony stimulating factor, interferon-alpha2b, and recombinant interleukin-2 for the treatment of metastatic melanoma. *Journal of Clinical Oncology, 23,* 8992–9000.

African American and Native Hawaiian Male Smokers Are More Susceptible to Lung Cancer

Previous studies have acknowledged the existence of ethnic and racial variation in the smoking-related risk of lung cancer. In this prospective, comparative study, the researchers extended earlier epidemiologic studies by examining incident cases of histologically different lung cancers in five ethnic and racially diverse groups of adult men and women (mean age for men = 60.1; women = 59.6) during an eight-year period (1993–2001). To answer the primary research question, investigators analyzed 1,979 cases of lung cancer (1,135 men and 844 women).

Sample participants were drawn from the population-based Multiethnic Cohort Study database (total potential = 183,813). The five ethnic and racially diverse groups were self-reported African Americans, Japanese Americans, Latinos, Native Hawaiians, and Caucasians.

Lung cancer risk was evaluated according to the number of cigarettes smoked per day (≤ 10, 11–20, 21–30, > 30), smoking status (former, never, current), and other variables. Despite the fact that 13% of the participants were employed in occupations that exposed them to carcinogens, findings supporting increased risk were not statistically significant. Not surprisingly, increased education correlated with a decreased risk of lung cancer.

Significant differences were found between cigarette smoking and the risk of incident lung cancer among the ethnic groups, lending support to prior findings that African Americans and Native Hawaiians are constitutionally more susceptible to the effects of tobacco carcinogens. The incidence of lung cancer is substantially higher among African Americans, Native Hawaiians, and Polynesians and lower among Japanese Americans, Hispanics, and Caucasians. The findings support the theory that ethnic and racial differences exist in smoking-associated risks of lung cancer.

Haiman, C.A., Stram, D.O., Wilkens, L.R., Pike, M.C., Kolonel, L.N., Henderson, B.E., et al. (2006). Ethnic and racial differences in the smoking-related risk of lung cancer. *New England Journal of Medicine, 354,* 333–342.

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