Research Highlights

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Breast Cancer Treatment Outcome Is Unaffected by Marital Status

During the October 2005 annual meeting of the American Society for Therapeutic Radiology and Oncology held in Denver, CO, researchers reported that marital status had no significant effect on relapse-free survival. Results were reported from a study involving 2,143 women with early-stage breast cancer treated with lumpectomy and radiation from 1984–2003. The women were divided into one of four groups reflecting their marital status: married (63%), single (10%), divorced (10%), and widowed (18%). Age, rather than marital status, was found to have a significant effect on relapse-free survival. Women aged 40–70 had better survival rates. Physical and biochemical status were important, whereas social status was not found to be a significant factor. Women with HER2-positive sensitivity have worse prognoses and may benefit from more aggressive treatment strategies, such as tamoxifen.

Hayes, S., Freedman, G.M., Li, T., Ross, E., Anderson, P., & Andre, K. (2005). An analysis of outcome based on marital status in early stage breast cancer patients undergoing breast conservation therapy. *International Journal of Radiation Oncology, Biology, Physics, 63*(Suppl. 1), S433–S434.

Single Men With Metastatic Prostate Cancer Are Not Likely to Seek Retreatment

The Radiation Therapy Oncology Group at Fox Chase Cancer Center in Philadelphia, PA, found that single men with metastatic prostate cancer were less likely to receive retreatment with radiation therapy for bone pain than their married counterparts. In an attempt to evaluate outcomes based on marital status, data were analyzed from men and women with symptomatic bone metastasis resulting from either prostate or breast cancer. Patients were randomly selected to receive either 10 radiation treatments of 30 Gy each or a single dose of 8 Gy. Researchers reported that women lived longer than men (11.8 months versus 7.8 months) regardless of the treatment protocol. Married men, and all women in the study who received 8 Gy, sought retreatment more readily than single men. All patients who received 10 treatments of 30 Gy were significantly less likely to return for retreatment. A tendency for single men not to receive retreatment also was realized. Researchers perceived the difference in retreatment rates likely resulted from single men having less social support. Developing strategies such as nurse follow-up and patient navigators to help them through the healthcare system was recommended. Knowing that single male patients are unlikely to return, the investigators also recommended that a more aggressive first treatment be given.

Konski, A.A., DeSilvio, M., Hartsell, W., Watkins-Bruner, D., Coyne, J., Scarantino, C., et al. (2005). Continuing evidence for poorer treatment outcomes for single male patients: Re-treatment data from RTOG 97-14. *International Journal of Radiation Oncology, Biology, Physics, 63*(Suppl. 1), S192.

Colonoscopy Often Is Inaccurate in Localizing Colorectal Cancer

According to a report in the October issue of the *Archives of Surgery,* colonoscopy is very sensitive in detecting colorectal cancer but often fails to correctly localize the malignancy. The sensitivity of the colonoscopy procedure in detecting colon cancer is reported to be 85%–95%, but the accuracy in localizing tumors is unclear. Researchers reported that precise tumor localization is important for preoperative planning. Researchers investigated the accuracy of localizing tumors by analyzing data from 314 patients having surgical resection for colorectal cancer from 2000–2003. The location of the tumor was identified incorrectly in 49 (21%) of the patients. In 27 cases, a different operation from the one initially planned was needed. An alternative to the surgical approach was required in 10 additional cases.

The researchers determined that having a previous colorectal procedure increased the odds of inaccurate localization more than fourfold. The study also showed that the accuracy rate for localization was higher if the colonoscopy was performed by a surgeon rather than another physician. The data suggest that surgery may be unnecessarily prolonged, excessive amounts of bowel may be resected, trocars may be placed inappropriately, or the lesion may be missed altogether if colonoscopy is the only method used for tumor localization.

Piscatelli, N., Hyman, N., & Osler, T. (2005). Localizing colorectal cancer by colonoscopy. *Archives of Surgery, 140,* 932–935.

Recurrence Rate Is Not Increased by Delaying Surgery Following Prostate Biopsy

To allow postbiopsy inflammation to resolve, surgeons generally wait at least two months after a prostate biopsy before performing surgery. Investigators tested the safety of the practice by examining nearly 4,000 consecutive patients who had a radical prostatectomy within one year following the diagnosis of prostate cancer. The time between biopsy and prostatectomy did not predict biochemical recurrence when evaluated by multivariant analysis, as either a continuous variable or a dichotomous variable divided at three months. To further evaluate, researchers performed additional reviews using patients considered at high risk for biochemical recurrence. For those reviews as well, researchers determined that the time between biopsy and radical prostatectomy did not predict biochemical recurrence after surgery. The researchers reported that most men do not delay surgery longer than six months if they are considering immediate treatment, but some men opt for active surveillance and delay treatment for months or years. Studies continue to follow these patients to determine whether their decision to wait influences their outcomes.

The importance of taking the time to obtain the information needed to make a well-informed decision about what patients need

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was stressed. The decision should be based on the individual cancer as well as patients' age, state of health, and personal preferences. The key finding was that taking the time to collect that information would not have a negative impact on patient outcomes.

Boorjian, S.A., Bianco, F.J., Scardino, P.T., & Eastham, J.A. (2005). Urological oncology: Does the time from biopsy to surgery affect biochemical recurrence after radical prostatectomy? *British Journal of Urology International, 96,* 773–776.

Epoetin Alfa Increases Red Blood Cell Levels in Chemotherapy-Related Anemia

A prospective, randomized trial in 55 U.S. clinical sites, recently compared the efficacy of epoetin alfa (Procrit®, Ortho Biotech Products, Bridgewater, NJ) to that of darbepoetin alfa (Aranesp®, Amgen Inc., Thousand Oaks, CA) in an open-label comparison. Chemotherapy-induced anemia can have debilitating effects on patients with cancer. Procrit and Aranesp have been approved by the U.S. Food and Drug Administration and are widely used in the treatment of the common chemotherapy complication. The primary efficacy end point was the percentage of patients demonstrating an increase in hemoglobin (Hgb) of greater than 1 g/dl by week 5 of therapy. Previous studies have demonstrated that an earlier rise in Hgb for patients with chemotherapy-induced anemia leads to better outcomes such as a noticeable Hgb response (> 2 g/dl), improved perceived quality of life, reduction in the number of blood transfusions, and the need for overall lower dosages of erythropoietic therapy than patients demonstrating no response or a later response to therapy.

Eligible patients were anemic (Hgb ≤ 11 g/dl) men and women aged 18 years or older who had solid tumor malignancies and were scheduled to receive cyclic chemotherapy for at least 12 weeks. Lung and breast cancers were the most common. Patients had to have a life expectancy of at least six months and adequate renal, hepatic, and hematologic functions (not the result of transfusion). Patients were excluded if they had received any erythropoietic agent within three months, they had anemia resulting from factors other than cancer and chemotherapy, they had received more than two prior chemotherapy regimens, or radiation was included in the treatment plan. Eligible patients were randomized 1:1 to receive either Procrit (starting dose of 40,000 U, subcutaneously, once weekly) or Aranesp (starting dose of 200 mcg, subcutaneously, every two weeks). The patients were further randomized by study site and chemotherapy type (platinum versus nonplatinum based). Study treatment was administered for as long as 16 weeks, and dosing changes were made based on patient response in accordance with recommendations made by the National Comprehensive Cancer Network and the American Society of Clinical Oncology and American Society of Hematology guidelines. Quality of life was assessed using two reputable assessment tools.

The outcome of the study indicated no noticeable differences in the number of patients who were discontinued from the study or the number of patients who had their doses of medication increased. However, by week 5 of the study, the percentage of patients who achieved an Hgb increase of 1 g/dl or more, not attributable to the use of blood transfusion, was 47% in the Procrit group versus 32.5% in the Aranesp group. The findings were statistically significant in favor of Procrit. In addition, the proportion of patients who achieved an Hgb increase of 1 g/dl or more or 2 g/dl or more by week 9 or by study end was consistently higher in the Procrit group. By study end, 57.7% of patients receiving Procrit compared with 41.8% of those receiving Aranesp had an increase in Hgb of at least 2 g/dl. The time to Hgb response was found to be 40% higher in patients receiving Procrit than those treated with Aranesp. The mean number of blood transfusions given to study participants was significantly lower in the Procrit group. The quality-of-life assessments found that a positive correlation exists between Hgb level and quality-of-life scores. The researchers concluded that epoetin alfa (Procrit) demonstrated an earlier hematologic response in patients with chemotherapy-induced anemia and required less intensive (not less frequent) blood transfusion therapy.

Waltzman, R., Croot, C., Justice, G.R., Fesen, M.R., Charu, V., & Williams, D. (2005). Randomized comparison of epoetin alfa (40,000 U weekly) and darbepoetin alfa (200 µg every 2 weeks) in anemic patients with cancer receiving chemotherapy. *Oncologist, 10,* 642–650.

Paclitaxel, Carboplatin, and Etoposide Improve Survival From Small Cell Lung Cancer

Researchers from the Minnie Pearl Cancer Research Network developed the triplet therapy of paclitaxel, carboplatin, and oral etoposide (PCE) to use in the treatment of extensive-stage small cell lung cancer to improve survival rates of that patient population. Until now, the standard chemotherapy for patients with the disease was the use of a platinum (either cisplatin or carboplatin) plus etoposide. Therefore, the triplet was considered a reasonable standard, likely to be at least efficacious as, if not more so than, etoposide and cisplatin.

The patient population consisted of 120 people with previously untreated extensive-stage small cell lung cancer. The study was performed at 29 affiliate Minnie Pearl Cancer Research Network participating sites. Exclusion criteria were mixed histology, congestive heart failure or history of myocardial infarction within three months, and history of prior malignancy within five years (with the exception of nonmelanoma skin cancer or cervical carcinoma in situ). Eligible patients were randomly assigned to receive either paclitaxel and topotecan (PT) or the triplet drug therapy of PCE. Patients received as many as eight cycles of either chemotherapy regimen. Treatment courses for both groups were repeated every 21 days. Patients who were diagnosed as having brain metastasis were treated with whole brain radiotherapy concurrently with the beginning of chemotherapy. Patients hospitalized for febrile neutropenia required a 25% dose reduction for all drugs during subsequent courses. Patients who required platelet transfusions or experienced bleeding episodes associated with thrombocytopenia received 75% doses of all drugs during subsequent courses. Patients who developed severe, acute hypersensitivity reactions did not receive further doses of the offending agent. Patients developing other grade 3 or 4 nonhematologic toxicities, with the exception of alopecia, nausea, or vomiting, had further treatment held until the toxicity resolved to grade 2 or less, then received treatment with a 75% dose of the drugs for the remainder of their therapy. All patients received standard supportive care, including blood and platelet transfusions, antiemetics, and antibiotics. Cytokines were not used during the first course of treatment, but use during subsequent courses was at the discretion of the investigator.

The primary focus of the investigation was the rate of tumor response and time to progression. The secondary focus of the investigation was overall survival. The overall response rate showed a significant advantage for PCE (78%) over PT (48%). The progression-free survival rate at one year was 14% with the PCE regimen versus 8% with the PT regimen. Overall survival comparing the two drug therapies showed no significant differences.

Greco, F.A., Thompson, D.S., Morrissey, J.B., Burris, H.A., III, Spigel, D.R., Joseph, G., et al. (2005). Paclitaxel/carboplatin/etoposide versus paclitaxel/topotecan for extensive-stage small cell lung cancer: A Minnie Pearl Cancer Research Network randomized, prospective phase ii trial. *Oncologist, 10,* 728–733.

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