

PHILADELPHIA INTERNATIONAL MEDICINE® NEWS BUREAU

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For immediate release:

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Editors note: Research, new techniques and improved facilities by Philadelphia International Medicine hospitals and physicians may lead to new ways to treat some of our most challenging diseases. Below are just some examples from our hospitals

Temple University Hospital Launches New Protocol Designed to Explore the Reduction of Heart Attack Damage

Philadelphia – Temple University Hospital recently became the first in the world to participate in a clinical trial to determine if a new treatment regimen—performed during the first crucial moments after a heart attack—can minimize permanent heart damage, potentially reducing a patient's risk of future heart failure or death.

During the procedure, Temple interventional cardiologists Michael Brown, MD, and Jon George, MD, inserted a balloon into a male heart attack patient's aorta to help ease the stress on his heart as it struggled to keep pumping during the heart attack. As the balloon inflated and deflated, it assisted his heart in delivering more blood to the body as well as to the heart muscle itself—thereby potentially preserving heart muscle that otherwise would be lost. With the balloon in place, doctors then performed an immediate angioplasty to open the blockage that caused the heart attack.

While the intra-aortic balloon pump has been used since the 1970s to assist the heart in pumping the oxygenated blood to the body, this is the first time it is being tested as an intermediate step prior to an emergency angioplasty—which is the standard treatment for heart attack patients.

“This procedure may have the potential to minimize the impact of a heart attack and keep the heart strong,” said Interventional Cardiologist Riyaz Bashir, MD, who leads this clinical trial at Temple. Dr. Bashir reports that the procedure was successfully implemented and the patient is recovering nicely.

Over the next year, Temple will enroll additional patients to participate in the trial. Half the participants

will undergo the balloon procedure followed by an emergency angioplasty; and half will receive the standard treatment alone.

The Hospital of the University of Pennsylvania's Personalized Vaccine After Chemotherapy Improves Progression-Free Survival in Patients With Follicular Lymphoma

Although the majority of patients with follicular lymphoma initially respond to chemotherapy, the disease frequently recurs, eventually becoming resistant to available therapies. Patients treated with traditional chemotherapy followed by a personalized vaccine were found to have a 44 percent increase in progression-free survival compared with patients who responded to chemotherapy but received a control vaccine, according to research from the University of Pennsylvania School of Medicine.

Stephen J. Schuster, MD, associate professor in the division of Hematology/Oncology at Penn's Abramson Cancer Center, presented the results of the randomized, double-blind, phase III clinical trial at the annual meeting of the American Society of Clinical Oncology (ASCO). Patients who had a complete remission after chemotherapy lasting longer than six months received a vaccine prepared from their own freshly isolated tumor cells. Patients treated with the tumor-derived vaccine had a median time to relapse of 44.2 months compared with 30.6 months for patients treated with the control vaccine.

The personalized vaccine used in the current study included tumor-derived idiotypic protein—a protein unique to each lymphoma tumor—that is isolated from individual patient samples and linked to the hemocyanin protein from the keyhole limpet. It is injected simultaneously with an immune-stimulating agent called GM-CSF. The control vaccine included the keyhole limpet hemocyanin protein plus GM-CSF.

Idiotypic vaccines have been tested previously, however this is the first trial to show a statistically significant improvement in progression-free survival in follicular lymphoma patients treated with an idiotypic vaccine. Previous trials included patients who had partial or complete responses, whereas this trial only vaccinated patients who had no detectable tumor remaining after chemotherapy. Under these conditions, the investigators hypothesized that the vaccine could hold minimal residual disease in check.

“Whether the vaccine eradicated the disease that could no longer be seen on CT scan for patients in remission or just controlled minimal residual disease, remains to be determined,” Schuster says. “Even slowing the recurrence rate would be an amazing achievement because, in this study, we used this vaccine to improve patient outcomes after a single series of immunizations, and many vaccines require booster shots, which were not part of the original trial.”

When the trial started, chemotherapy was the standard of care for previously-untreated patients. Since that time, the standard of care has evolved to include chemotherapy plus the antibody rituximab (Rituxan®). Therefore, Schuster thinks a clinical trial should be launched to test whether adding a personalized vaccine to the current standard of chemotherapy and rituximab will improve patient outcome. “If indeed our trial is right that this approach leads to improvements in progression-free survival, then adding it to

even more effective therapies like chemotherapy plus Rituxan®, might result in even greater benefit,” Schuster says. “Combination therapies have been the paradigm in oncology resulting in greater successes with successive generations of therapies and cures for certain cancers.”

Although both rituximab and the tumor vaccine tested in this trial are immunologic agents, they work by different mechanisms. Rituximab is a mass-produced antibody designed to attack the type of cell that has gone awry in follicular lymphoma. By contrast, the newly-tested personalized vaccine induces the patients’ own immune systems to attack their tumors based on a protein that is uniquely expressed by their tumor cells. In addition to the immediate clinical results, the trial will provide an important opportunity for biomarker discovery in the future. Tumor samples were collected from all of the patients who enrolled in the trial. “This is a treasure trove of material,” Schuster says. “It is a rare opportunity to have outcomes data with the corresponding banked viable tumor cells and tumor infiltrating cells present for analysis. This is an opportunity for learning that cannot be passed up.”

Thomas Jefferson University Hospital’s Pre-emptive Treatment Helped Curtail Skin Toxicity Associated with Colon Cancer Drug

Edith Mitchell, MD, a clinical professor in the Department of Medical Oncology at Jefferson Medical College of Thomas Jefferson University, presented data from the STEPP (Skin Toxicity Evaluation Protocol with Panitumumab) trial, which was the first prospective study to compare pre-emptive and reactive skin treatment for skin toxicities related to panitumumab.

Skin toxicities are the most common adverse effects related to panitumumab (Vectibix) and cetuximab (Erbix), which are fully human monoclonal antibodies that target the epidermal growth factor receptor (EGFR). The toxicities affect approximately 90 percent of patients who receive panitumumab, and could include erythema, dermatitis, pruritus, pustules, rash, and hair and nail changes.

“Panitumumab and the other EGFR inhibitors are now key components to the treatment strategies for metastatic colorectal cancer,” Dr. Mitchell said. “But the majority of the patients who receive these agents suffer from skin toxicities, and for some patients, treatment must be interrupted or discontinued. If we can prevent or minimize these toxicities, it would be a significant advance in patient care.”

The researchers studied 95 patients receiving panitumumab in combination with irinotecan-based chemotherapy. The patients were randomized to receive pre-emptive skin toxicity treatment initiated 24 hours prior to the first dose of panitumumab, then given daily through week six, or reactive skin treatment after the skin toxicity developed. Forty-eight patients received the pre-emptive treatment, which included moisturizers, sunscreen, topical steroids and oral doxycycline.

The primary endpoint was the incidence of specific grade 2 or higher skin toxicities during the six week skin treatment period. In the six-week period, 29 percent of patients who received pre-emptive treatment

developed the skin toxicities, compared with 62 percent of the patients who did not receive pre-emptive treatment.

Quality of life was also assessed, using the Dermatology Life Quality Index. Patients who received the pre-emptive, prophylactic skin treatment regimen reported an improved quality of life.

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