



## AMERICAN COLLEGE OF SURGEONS

## SURGERY NEWS

## Perioperative Risks From Resternotomy Defined

BY JEFF EVANS

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HOT SPRINGS, VA. — Cardiac injury that occurs with resternotomy may not increase the rate of perioperative death or morbidity, according to the results of an 11-year, single-center study.

But in the study of 56 cardiac injuries that occurred during 612 resternotomies, Dr. Irving L. Kron and his associates at the University of Virginia, Charlottesville, found that a history of more than three previous sternotomies was a significant, independent risk factor for having a cardiac injury.

Although resternotomy is a “huge part” of his practice and is increasingly used nationwide, the rate of cardiac injuries associated with it is “not well known... and the risk factors and outcomes are still unclear,” Dr. Kron said at the annual meeting of the Southern Surgical Association.

The 612 resternotomies in the study comprised 8% of the total 7,872 adult cardiac procedures performed during 1995-2006 at the University of Virginia. Dr. Kron and his colleagues included any injury to the heart, great vessels, mammary arteries, or previously placed grafts during sternotomy and initial dissection for bypass, but excluded pediatric patients and adult patients who underwent resternotomies for heart transplant.

Most of the reoperations were coronary artery bypass grafts (250) or valve repairs (231), and most injuries that occurred during resternotomy damaged a bypass graft (26) or the right ventricle (12). The investigators defined cardiac injury as an injury to either a bypass graft or the right ventricle, said Dr. Kron, an ACS Fellow who is chair of the department of surgery and head of the division of thoracic and cardiovascular surgery at the university. About 90% of the 612 resternotomies were performed with chest cannulation, which he described as

one of their biases in the study.

In a multivariate analysis, both the receipt of a fourth sternotomy and the presence of hyperlipidemia were associated with significantly higher odds of experiencing cardiac injury during resternotomy. The presence of hyperlipidemia as a risk factor for cardiac injury probably relates to the fact that it was a “marker for vascular disease in general,” Dr. Kron said.

Mortality was similar among those who suffered a cardiac injury (9%) and those that

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did not (10%). Patients who had an injury to a bypass graft also were no more likely to die than were those without a cardiac injury, although Dr. Kron suspected that “this may be a type II error.”

The 11 patients who experienced catastrophic hemorrhaging “required some form of alternate cannulation,” but none died.

The patients who were placed on cardiopulmonary bypass prior to undergoing sternotomy to try to reduce the incidence of cardiac injury had no better injury rate than did those who did not undergo bypass, the investigators found.

Dr. Thoralf M. Sundt of the Mayo Clinic, Rochester, Minn., a discussant at the meeting, pointed out that because the patients in the study were not randomized to receive cardiopulmonary pass, he could just as easily argue that the treatment of patients who were thought to be at highest risk for cardiac injury during resternotomy on bypass during the operation “actually reduced their risk to the baseline risk” of other patients undergoing repeat sternotomy. ■

## High-Dose Chemo Prolongs Pancreatic Cancer Survival

BY FRAN LOWRY

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ORLANDO — Adjuvant chemoradiation with cisplatin, 5-fluorouracil, and interferon- $\alpha$  for resected pancreatic cancer increased the 18-month overall survival in 53 of 79 patients but at a price—severe grade 3/4 toxicity in virtually all who received the treatment.

The protocol was initially tested in 53 patients at Virginia Mason Medical Center, Seattle, between 1995 and 2001. The median survival was 39 months, the 2-year survival was 51%, and 5-year survival was 41%, Dr. Vincent J. Picozzi of Virginia Mason said at a meeting on gastrointestinal cancers sponsored by the American Society of Clinical Oncology.

This prompted the current, phase II multicenter American College of Surgeons Oncology Group (ACOSOG) Z05031A2 trial, Dr. Picozzi said.

Accrual was initially set at 93 patients but was halted at 89 patients at 2 years, after concerns about the high toxicity rate prompted the data safety monitoring board to recommend that recruitment be stopped.

Dr. Picozzi noted that the chemoradiation regimen was dose dense and dose intense. Six to 8 weeks after pancreaticoduodenectomy, patients received external beam radiation at a dose of 4500 to 5400 Gy given in 25 fractions over 5 weeks and chemotherapy with continuous-infusion 5-FU (200 mg/m<sup>2</sup> daily on days 1-35), weekly intravenous bolus cisplatin (30 mg/m<sup>2</sup> daily on days 1, 8, 15, 22, and 29), and subcutaneous interferon- $\alpha$  (3  $\times$  10<sup>6</sup> U on days 1-35).

Chemoradiation was followed by two cycles of 5-FU follow-up. The primary study end point was median survival of at least 18 months from the

start of chemoradiotherapy, or 20 months from surgery in at least 65% of study patients.

Despite the observed overall grade 3 and 4 toxicity rate of 96%, there were no toxic deaths. Of the 89 patients who were enrolled in the study, 80 were evaluable. Follow-up results are pending in one of these patients, Dr. Picozzi said.

Grade 3 and 4 neutropenia and thrombocytopenia were significantly higher in ACOSOG Z05031 than in the pilot trial at Virginia Mason (39% and 12% vs 14% and 4%, respectively). There was only one documented incidence of febrile neutropenia.

Grade 3/4 gastrointestinal toxicity was similar to that seen at Virginia Mason. Nausea was most common, followed by anorexia, dehydration, diarrhea, stomatitis, and vomiting.

The patients in this trial had characteristics that would be considered “somewhat adverse” by the standards of other clinical trials looking at adjuvant therapy for pancreatic cancer, Dr. Picozzi said.

A total of 86% had stage 3 primary tumors, 41% had tumors greater than 3 centimeters in size, 46% had tumors with poorly differentiated histology, 75% were node positive, and 25% were margin positive.

“We met our primary end point, with 67% of patients remaining alive. Toxicity was significant, but we feel if we can find ways to reduce it, we will be able to carry this concept further,” Dr. Picozzi said in an interview.

He noted that this study adds to the existing phase II data suggesting the potential value of an intense approach in resected pancreas cancer. Further study is ongoing within the ACOSOG.

Dr. Picozzi disclosed no financial conflict of interest. ■

## Gastric Bypass Helped Cut Hypertension in 65% of Obese Patients

HUNTINGTON BEACH, CALIF. — In a study of 95 morbidly obese patients with hypertension, 46% had complete resolution of their hypertension and another 19% showed some improvement 12 months after laparoscopic Roux-en-Y gastric bypass surgery, Dr. Marcelo W. Hinojosa reported at the Academic Surgical Congress.

It's well known that when obese patients lose weight, their hypertension often improves, and when they have gastric bypass surgery, they usually lose weight.

So it's reasonable to assume that when obese patients have gastric bypass surgery, their hypertension will probably improve. The study data provided evidence supporting these relationships.

All of the patients in the retrospective study were taking at least one antihypertensive medication, and 40% were on two or more. Their mean age was 47 years at the time of surgery, and their mean body mass index was 47 kg/m<sup>2</sup>.

As expected, the surgery resulted in significant weight loss.

Within 1 month after the surgery, patients had lost an average of 23% of their excess weight, and that increased to 66% at the end of 12 months.

Dr. Hinojosa and his colleagues at the University of California, Irvine, defined complete resolution of hypertension as a systolic blood pressure less than 140 mm Hg and diastolic pressure less than 80 mm Hg without the use of any antihypertensive medication. They defined improvement as maintaining that pressure or less while decreasing

the requirement for antihypertensives.

Within 1 month, the average blood pressure declined from 139.8/79.9 to 123.3/75.3, a significant difference. At 12 months, the group showed evidence of further decline, with an average blood pressure of 120.0/71.3.

At 1 month, 25% of the patients had complete resolution of their hypertension, and 36% showed some improvement. The proportion showing complete resolution increased to 41% at 6 months and 46% at 12 months.

The proportion showing some improvement was 21% at 6 months and 19% at 12 months.

The patients had experienced hypertension for an average of about 6 years. Patients with a disease duration of less than 4 years were significantly more likely to have complete resolution of their hypertension than were those whose disease lasted longer.

Dr. Hinojosa declared that he had no relevant financial relationships associated with this study.

—Robert Finn