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RCTs: ‘Gold Standard’ for Medical Research Targets Improved Outcomes

For decades, prospective randomized clinical trials (RCTs) have been the “gold standard” for medical research. These studies randomly assign patients to one of two groups: half receive the standard treatment, and half undergo the experimental approach. As Associate Professor of Surgery Harish Lavu, MD, FACS, explains, randomly assigning patients helps eliminate even subconscious bias on the part of researchers. Dr. Lavu notes that while there is widespread agreement that RCTs are the best way to conduct research, these studies are complex and often costly. Funding often comes from institutional sources, government sponsored research grants, philanthropic organizations, or pharmaceutical companies.

“From conception to completion, a high-quality prospective RCT can take two to 10 years. By contrast, retrospective studies — in which researchers analyze an existing data set, such as a large collection of patient charts — are typically much faster and easier,” Dr. Lavu says. He adds that while retrospective studies can provide early findings suggesting that a new method may be beneficial or merits further investigation, the gold standard to test the hypothesis is often a full-scale RCT.

Jefferson’s Department of Surgery has a number of RCTs in various stages — including the HYSLAR (Hypertonic Saline) Trial and the Celiac Nerve Block trial for pancreatic cancer patients as well as a trial analyzing sternal pain after cardiac surgery.

The 264-patient HYSLAR Trial studied the type of fluid used during the Whipple procedure (pancreaticoduodenectomy). The standard approach is to administer Lactated Ringer’s solution for fluid replacement. The study hypothesized that with a more concentrated saline, surgeons could administer less fluid and improve outcomes.

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In our trial, surgeons used the standard amount of Lactated Ringer’s solution with half of the patients, while the other half received the concentrated form of intravenous fluids known as hypertonic saline," he says. "We found that with hypertonic saline, we were able to get patients through surgery and the recovery period with less total fluid administered. In fact, reducing fluid by several liters resulted in a 25-percent reduction in post-surgical complications such as edema and fluid build up in the lungs." Dr. Lavu and colleagues published the results in the September issue of Annals of Surgery.

From 2008 to 2013, Jefferson also enrolled pancreatic cancer patients in the Celiac Nerve Block Trial. All told, 485 individuals enrolled and have

forward to presenting our findings in December at the Annual Meeting of the Southern Surgical Association.”

In the Division of Cardiothoracic Surgery, an analysis of patients who underwent coronary artery bypass showed that compared to conventional sternal wire, rigid fixation using sternal plates led to a reduction in postoperative pain and shortened ventilation time, ICU stay and hospital stay. Hitoshi Hirose, MD, PhD, FACS, led the RCT that further investigated those outcomes — and confirmed a trend of shorter intubation time and lesser narcotic requirements with rigid fixation versus wire closure. These trials are just a sample of the gold-standard research at Jefferson. As Dr. Lavu notes, numerous other RCTs are ongoing and in development — including studies of vaccines and neoadjuvant treatment in both melanoma and pancreatic cancer and the efficacy of fibrin sealants to control blood loss during surgery.