

Study allays concerns about endoscopic vein harvesting during heart surgery

July 31 2012

Using an endoscope to guide the removal of leg veins used in heart surgery is as safe as using large, ankle-to-groin incisions, according to a study by Duke University Medical Center researchers.

The data, published today in *JAMA*, shows the two procedures have similar <u>mortality rates</u> after three years. The endoscopic method has lower rates of infection and wound complications.

Today's study refutes previous findings linking the endoscopic method to higher rates of vein bypass <u>graft failure</u>, heart attack and death.

"Our study affirms the efficacy of endoscopic vein harvesting," says Peter K. Smith, M.D., chief of cardiovascular and thoracic surgery at Duke and the paper's senior author. "It allays the concerns of patients who have undergone endoscopic vein harvesting during coronary artery bypass, as well as the concerns of surgeons who prefer endoscopic vein harvesting for their patients."

Since the mid-1990s, surgeons have used endoscopes and tiny incisions at the ankle, knee and groin to remove leg veins during <u>coronary artery</u> <u>bypass surgery</u> (CABG). The minimally <u>invasive approach</u> caught on quickly because it resulted in shorter hospital stays, less perioperative discomfort, fewer incision-site complications and less scarring than open vein harvesting, which requires an incision that runs the length of the leg.

"<u>Coronary bypass</u> is among the most commonly performed procedures



worldwide," says Judson Williams, M.D., M.H.S., the study's first author and a Cardiothoracic Surgical Trials Network fellow at Duke. "This procedure is designed not only to prolong a patient's life, but to also improve their quality of life. Because of the importance of this operation, ensuring it can be done with the best <u>vascular grafts</u> is critically important."

Three years ago, an observational study of 3,000 patients called into question the safety of endoscopic vein harvesting. The U.S. <u>Food and</u> <u>Drug Administration</u> then commissioned the Duke researchers to study the long-term outcomes of endoscopic (EVH) versus open vein harvesting (OVH).

This FDA-sponsored observational study followed 235,394 Medicare patients undergoing CABG from 2003-2008 in 934 surgical centers participating in the Society of Thoracic Surgeons national database. About half (52%) were endoscopic cases. Baseline patient characteristics were balanced across both groups including age, body mass index, prevalence of vascular disease, and other risk factors such as smoking, diabetes and urgent care status.

After three years of follow-up, there were no significant differences in mortality between the two groups (13.2% for EVH vs 13.4% for OVH). There were also no statistical differences in heart attacks or revascularization (19.5% for EVH vs 19.7% for OVH). There was a significant difference in the 30-day rate for wound complication favoring endoscopic harvesting: (3.0% for EVH vs. 3.6% for OVH).

While several studies have questioned its safety, Smith says, "our study was done in a very large population, and was conducted in a diverse group of large and small community programs, as well as university and non-university affiliated centers. It's unlikely another result would occur if more patients were studied."



In addition to providing insight into this critically important clinical question, the study represented an important collaboration, said Williams, a surgical resident at Duke. "This is an exciting example of an opportunity to achieve post-market medical device surveillance through collaboration between the FDA, the Society of Thoracic Surgeons, the Duke Clinical Research Institute and the NIH-supported Cardiothoracic Surgery Clinical Trials Network. It demonstrates a new and powerful method to answer important clinical questions in the future."

More information:

JAMA. 2012;308[5]:475-484. *JAMA*. 2012;308[5]:475-484.

Provided by Duke University Medical Center

Citation: Study allays concerns about endoscopic vein harvesting during heart surgery (2012, July 31) retrieved 28 April 2024 from <u>https://medicalxpress.com/news/2012-07-allays-endoscopic-vein-harvesting-heart.html</u>

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