Use of surgically implanted antibiotic sponge does not reduce rate of sternal wound infections

August 17 2010

Contradicting previous study results, insertion of a sponge that contains the antibiotic gentamicin at the time of surgical closure following cardiac surgery did not reduce the rate of sternal wound infections after 3 months, compared to patients who did not receive the intervention, according to a study in the August 18 issue of *JAMA*.

"Despite the use of prophylactic systemic antibiotics, postoperative sternal wound infection continues to be a serious problem after cardiac surgical procedures, especially in the increasing population of patients with diabetes and/or obesity. Sternal wound infection is associated with significant suffering, additional expense, lengthened hospital stay, and increased mortality," the authors write. The gentamicin-collagen sponge, a surgically implantable topical antibiotic, is currently approved in 54 countries, and to date, more than 2 million sponges have been used to treat more than 1 million patients outside the United States across a broad range of clinical indications. A large trial in Sweden reported in 2005 that the sponge reduced surgical site infection by 50 percent in cardiac patients.

Elliott Bennett-Guerrero, M.D., of the Duke Clinical Research Institute, Duke University Medical Center, Durham, N.C., and colleagues conducted this phase 3, randomized controlled trial to confirm previous data regarding use of the gentamicin-collagen sponge and a reduction in sternal wound infections, and to support regulatory approval in the

United States. The trial included 1,502 cardiac surgical patients at high risk for sternal wound infection (diabetes [n = 1,006], body mass index greater than 30 [n = 1,137], or both) who were enrolled at 48 U.S. sites between December 2007 and March 2009. Patients were randomized to either insertion of 2 gentamicin-collagen sponges between the sternal halves at surgical closure (n = 753) vs. no intervention (control group: n = 749). All patients received standardized care including prophylactic systemic antibiotics.

The researchers found no significant difference in sternal wound infections in patients randomized to the gentamicin-collagen sponge group (63/753; 8.4 percent) compared with patients in the control group (65/749; 8.7 percent). No significant differences were observed between the sponge group and the control group, respectively, in superficial sternal wound infections (6.5 percent vs. 6.1 percent), deep sternal wound infection (1.9 percent vs. 2.5 percent) or rehospitalization for sternal wound infection (3.1 percent vs. 3.2 percent).

"These findings directly contradict the data previously available on the efficacy of this technology in wound infection prevention," the authors write.

Regarding why their findings are in such contrast to those of the Swedish study, the researchers add that there were important differences between the studies, including several important quality-control measures that were not incorporated in the previous study, as well as ethnic and regional differences, that may have produced differing results.

"In conclusion, despite approval of the gentamicin-collagen sponge in 54 countries outside of the United States and positive results from a large Swedish trial, our large multicenter U.S. trial did not find the gentamicin-collagen sponge to be effective at preventing sternal wound infection in the setting of cardiac surgery."

Provided by JAMA and Archives Journals