

Breast implant surgery is safe in outpatient settings

A preliminary analysis of data collected on 246,552 breast implant procedures performed in facilities accredited by the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) in Gurnee, IL, shows a high level of safety for patients undergoing the procedure in outpatient settings.

These procedures were for reconstructive or aesthetic purposes, and adverse events were reported in only one in 143 procedures performed, or less than 1% (0.7%) of the time.

The data for the study were collected through an Internet-based quality improvement and peer review program in which AAAASF facilities participate. Analysis was performed upon 913,154 surgical procedures entered by surgeons participating in the program.

Breast implantation, for reconstructive or aesthetic purposes, was performed in 27% of the studied cases, yielding 246,552 breast implant procedures analyzed.

Unanticipated complications of surgery were divided into two categories: early and late-occurring events. The early occurring events were complications that might occur with any operative procedure such as bleeding, infection, or cardiovascular irregularities associated with anesthesia.

The early events occurred within one month of the date of the operative procedure. Late events included capsular contracture, deflation of implants, loss of implants through extrusion, and miscellaneous events.

A total of 1,730 significant complications included mild postoperative nausea or light-headedness after surgery, were reviewed. This represents an incidence of one in 143 procedures performed, or 0.7%. There were 1,059 patients who had hematomas or one in 233 procedures performed. There were no deaths associated with hematoma formation.

Other early complications included infection, wound breakdown, and pneumothorax. There were 142 patients hospitalized for management of these conditions. Two patients died, one from a pulmonary embolism five days after surgery, and the other from an asthmatic attack 12 hours after surgery.

These two events represent complications that can follow any type of surgery, says **Geoffrey Keyes**, MD, lead researcher of the study and chairman of the AAAASF quality improvement and peer review committee. "These complications were not specific to breast surgery," he adds.

The most common late-occurring event was deflation of an implant. That occurred in 173 patients or one in 1,425 procedures. Another late-occurring event included capsular contracture, which was reported in 141 procedures or one in 1,749 of the breast implant procedures performed.

While the preliminary analysis of the data suggests a high safety level for breast augmentation surgery, a more in-depth analysis is planned, according to Keyes. "The study should be ready for publication within the next six months," he adds.

In other breast surgery news, a Food and Drug Administration advisory panel voted to allow the Santa Barbara, CA-based Mentor Corp. silicone breast implant back on the market with conditions to monitor the safety of the product. Another silicone implant, manufactured by Inamed in Santa Barbara, CA, was not recommended for return to market until more research on the product is completed.

(Editor's note: At press time, the FDA is considering the recommendation, but no time frame for a final decision has been set.)
