

After Mastectomy, Breast Reconstruction Typically Requires More than One Operation

BY KURT SAMSON

Women who undergo a breast reconstruction procedure after a mastectomy typically require at least one or two additional operations, according to data reported at the American Society of Breast Surgeons Annual Meeting.

Amanda Roberts, MD, a clinical research fellow at the University of Toronto Health Network, said at a news briefing that women can expect to have the first re-operation usually within seven months, followed by another at a later point. Some women, however, require multiple repeat procedures, which carry the potential risk of complications, often serious.

The researchers, who titled the study “Once Is Rarely Enough: A Population-Based Study of Reoperations After Postmastectomy Breast Reconstruction,” said they believed it to be the first long-term retrospective population-based review of data on post-mastectomy breast reconstruction (PMBR) re-operation rates, including both planned and unplanned procedures.

In the study, which used administrative and cancer registry databases in Ontario, the primary group included women ages 18 to 65 who underwent prophylactic or therapeutic mastectomy between April 1, 2002, and March 31, 2008, followed by an immediate or delayed PMBR within three years.

Overall 3,972 women underwent primary mastectomy and PMBR, and 3,506 (88%) required at least one reoperation during an average follow-up of 5.1 years, while an average of 35 percent had at least one additional procedure and 26 percent underwent one additional surgery.

In all, 9,353 procedures were performed during the 5.1-year follow-up period, 42 percent of which were anticipated and 37 percent that were not. A total of 610 women underwent three additional procedures and 763 had four or more.

Better Informed Decisions

“Breast reconstruction can improve quality of life for some women, but excessive repeated procedures can increase morbidity and mortality as well as result in a decline in quality of life and greater health care utilization and associated costs,” Roberts said.

“We hope this study will help patients and their physicians make better informed decisions about breast reconstruction options.”

The investigators categorized repeat procedures as anticipated, unanticipated, second oncologic breast surgery, a combination of these, or unclassified operations. While some re-operations were expected, unanticipated procedures were often emergency operations or those requiring revision of the PMBR, Roberts said.

Though the analysis of second oncologic breast procedures included

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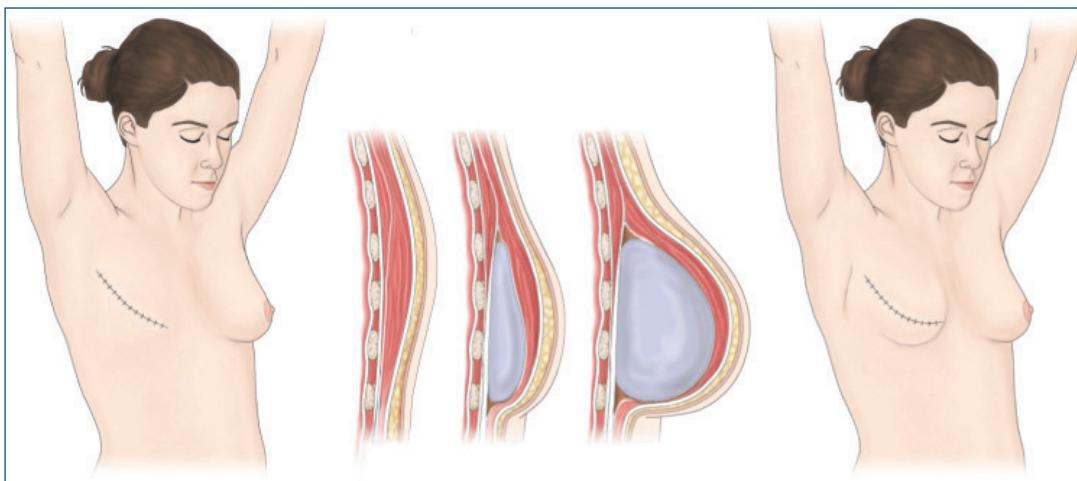
She said she and her colleagues are now looking to conduct a prospective study of potential long-term consequences in women who undergo repeated PMBR procedures.

Nipple-Sparing as Safe as More Radical Procedures

In another study reported at the meeting, researchers reported that mastectomies sparing the nipple and surrounding envelope appear to be as safe as more radical procedures in many patients.

Lucy De La Cruz, MD, Chief Surgery Resident at the University of Miami’s Miller School of Medicine, presented the findings of what was the largest meta-analysis of studies to date on this

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From: Timby and Smith, *LWW*, 2013, adapted from American Society of Plastic and Reconstructive Surgeons, *Breast Reconstruction: Helping You Become Whole Again*

prophylactic therapy, the study was not designed to evaluate procedures that were primarily related to skin or scar-related issues, she added.

Future Research

Procedures for secondary breast cancer issues were reported in 658 women (7%), and one percent were due to a combination of issues. “Future research should compare implant versus tissue-based PMBR and immediate versus delayed PMBR, and will hopefully be able to better identify factors that contribute specifically to unanticipated procedures,” Roberts said.

“As surgeons, we want patients to have the best data with which to make informed decisions on reconstruction, but often they are not told about how

alternative to traditional radical mastectomy procedures.

She and her colleagues conducted a statistical analysis of 19 studies published from 2004 to 2015 that involved a total of 5,393 patients, 2,013 of which involved nipple-sparing mastectomy.

The team also performed a comprehensive database review of appropriate peer-reviewed studies published between 1991 and 2014, with two reviewers independently screening and selecting those with the most rigorous data.

“Our hypothesis was that in the setting of breast cancer, nipple-sparing mastectomy is as safe as skin-sparing or modified radical procedures, and the data clearly supports this,” she said. However, the small benefit shown for nipple-sparing mastectomy in the

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collected literature “should be taken very lightly.”

According to the collective data, nipple-sparing mastectomy was found to be at least as safe as more radical mastectomies in terms of both overall and disease-free survival. The team also evaluated nipple-areolar recurrence.

Oncological Safety

“Oncological safety has been a concern due to the potential for residual glandular breast tissue to harbor future cancer,” De La Cruz said at the news briefing. The rate of occult malignancy in the nipple and areola area averaged 11.5 percent, she reported.

From a total 18 studies, 2,332 patients met the inclusion criteria. The average follow-up was 44.7 months, and the mean patient age was 46. Among the women, 403 procedures were prophylactic and 2,135 were therapeutic.

The most common pathology in the latter was invasive ductal carcinoma. Most patients had stage I disease and 268 patients had positive lymph nodes.

The average overall survival, disease-free survival, and nipple-areolar recurrence rates were 96.3, 90.9, and 1.3 percent, respectively. Subgroup analyses of therapeutic or prophylactic procedures included eight studies with 1,476 patients who were followed for an average of 68.5 months.

The most common pathology was invasive ductal carcinoma in therapeutic cases and the most common presentation was evenly distributed between stages I and II cancer. Moreover, 179 patients tested positive for lymph node involvement.

Combined, the therapeutic and prophylactic group included 10 studies involving 856 women followed for an average of 25.7 months. In both groups, invasive ductal carcinoma was also the most prevalent pathology, with a majority of patients having stage I disease and 89 having positive lymph nodes.

Overall survival was 93 percent in the therapeutic subgroup, while disease-free survival was 84.2 percent—lower than in the combined subgroup, where the rates were 99.0 and 96.2 percent, respectively. Nipple-areolar recurrence was found to be more common in the therapeutic group (2.6%) than in the combined group (0.4%).

Significant Differences in Subgroup Analyses

While the study confirmed the oncologic safety of nipple-sparing nipple-sparing mastectomy, the subgroup analysis showed significant differences in outcomes between therapeutic and combined therapeutic/prophylactic procedures, De La Cruz reported. In addition, she noted, women with larger breasts are typically not good

candidates for the nipple-sparing procedure.

Future studies are needed to better stratify patients based on each woman’s indication for nipple-sparing mastectomy, she added, while prospective data registries, especially the Nipple Sparing Mastectomy Registry, will help better characterize outcomes.

The moderator of the news briefing, Julie Margenthaler, MD, Associate Professor in the Division of Endocrine and Oncologic Surgery at Siteman Cancer Center in St. Louis, noted that less than five percent of women across the country currently undergo nip-

ple-sparing mastectomy, but among surgeons with such experience, the procedure is likely offered to some 20 to 30 percent of women who are considered to be candidates.

Cost Considerations

Regarding cost, De La Cruz said that although nipple-sparing mastectomy is expensive, the cost is not much more than skin-sparing procedures. Moreover, she said that in her experience, insurance coverage is about the same.

An observational study published last year in *Plastic and Reconstructive*

Surgery (2014;133:496-506) reported generally good results in women who underwent prophylactic nipple-sparing mastectomy due to a high genetic risk of breast cancer. The researchers examined outcomes after performing 500 of the procedures in 285 women between 2007 and 2012.

Almost all the patients underwent immediate breast reconstruction—most often with implants—and reconstruction with implants was completed at the same time as the mastectomy in 60 percent. Most of the others underwent a two-stage procedure that

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Cancer-Related News from the CDC

Tobacco Use Among Middle & High School Students

By René A. Arrazola, MPH; Tushar Singh, MD, PhD; Catherine G. Corey, MSPH; Corinne G. Husten, MD; Linda J. Neff, PhD; Benjamin J. Apelberg, PhD; Rebecca E. Bunnell, PhD; Conrad J. Choiniere, PhD; Brian A. King, PhD; Shanna Cox, MSPH; Tim McAfee MD; and Ralph S. Caraballo, PhD, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; Epidemic Intelligence Service, CDC; and Center for Tobacco Products, FDA

Tobacco use and addiction most often begin during youth and young adulthood.^{1,2} Youth use of tobacco in any form is unsafe.¹ To determine the prevalence and trends of current (past 30-day) use of nine tobacco products (cigarettes, cigars, smokeless tobacco, e-cigarettes, hookahs, tobacco pipes, snus, dissolvable tobacco, and bidis) among U.S. middle (grades 6-8) and high school (grades 9-12) students, CDC and the Food and Drug Administration analyzed data from the 2011-2014 National Youth Tobacco Surveys (NYTS).

In 2014, e-cigarettes were the most commonly used tobacco product among middle (3.9%) and high (13.4%) school students. Between 2011 and 2014, statistically significant increases were observed among these students for current use of both e-cigarettes and hookahs, while decreases were observed for current use of more traditional products, such as cigarettes and cigars, resulting in no change in overall tobacco use.

Consequently, 4.6 million middle and high school students continue to be exposed to harmful tobacco product constituents, including nicotine. Nicotine exposure during adolescence, a critical window for brain development, might have lasting adverse consequences for brain development,¹ causes addiction,³ and might lead to sustained tobacco use. For this reason, comprehensive and sustained strategies are needed to prevent and reduce the use of all tobacco products among youths in the United States.

NYTS is a cross-sectional, school-based, self-administered, pencil-and-paper questionnaire administered to

U.S. middle and high school students. Information is collected on tobacco control outcome indicators to monitor the impact of comprehensive tobacco control policies and strategies⁴ and inform FDA's regulatory actions.⁵

A three-stage cluster sampling procedure was used to generate a nationally representative sample of U.S. students who attend public and private schools in grades 6 to 12.

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use that excludes kreteks (sometimes referred to as clove cigarettes).

Information is collected on tobacco control outcome indicators to monitor the impact of comprehensive tobacco control policies and strategies⁴ and inform FDA's regulatory actions.⁵ A three-stage cluster sampling procedure was used to generate a nationally representative sample of U.S. students who attend public and private schools in grades 6 to 12. This report includes data from four years of NYTS (2011-2014), using an updated definition of current tobacco use that excludes kreteks (sometimes referred to as clove cigarettes). Of 258 schools selected for the 2014 NYTS, 207 (80.2%) participated, with a sample of 22,007 (91.4%) among 24,084 eligible students; the overall response rate was 73.3%. Sample sizes and overall response rates for 2011, 2012, and 2013 were 18,866 (72.7%), 24,658 (73.6%), and 18,406 (67.8%), respectively. Participants were asked about current (past 30-day) use of cigarettes, cigars (defined as cigars, cigarillos, or little cigars), smokeless tobacco (defined as chewing tobacco, snuff, or dip), e-cigarettes, hookahs, tobacco pipes (pipes), snus, dissolvable tobacco (dissolvables), and bidis. Current use for each product was defined as using a product on at least one day during the past 30 days. Tobacco use was categorized as "any tobacco product use," defined as use of one or more tobacco products and "two or more tobacco product use," defined as use of two or more tobacco products. Data were weighted to account for the complex survey design and adjusted for nonresponse; national prevalence estimates with 95 percent confidence intervals and population estimates rounded down to the nearest 10,000 were computed. Estimates for current use in 2014 are presented for any tobacco use, use of two or more tobacco products, and use of each tobacco product, by selected demographics for each school level (high and middle). Orthogonal polynomials were used with logistic regression analysis to examine trends from 2011 to 2014 in any tobacco use, use of two or more tobacco products, and use of each tobacco product by school level, controlling for grade, race/ethnicity, and sex and simultaneously assessing for linear and nonlinear trends. A p-value <0.05 was considered statistically significant. SAS-Callable SUDAAN was used for analysis.

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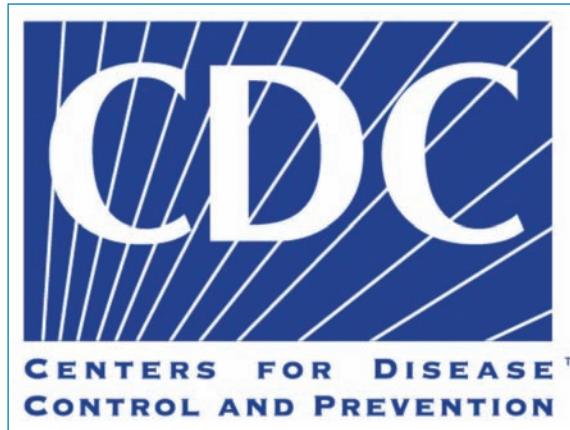
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Results

In 2014, a total of 24.6 percent of high school students reported current use of a tobacco product, including 12.7 percent who reported current use of two or more tobacco products. Among all high school students, e-cigarettes (13.4%) were the most common tobacco products used, followed by hookahs (9.4%), cigarettes (9.2%), cigars (8.2%), smokeless tobacco (5.5%), snus (1.9%), pipes (1.5%), bidis (0.9%), and dissolvables (0.6%).

Among high school non-Hispanic whites, Hispanics, and persons of non-Hispanic other races, e-cigarettes were the most used product, whereas among

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"25 percent of high school students reported current use of a tobacco product, including 13 percent who noted current use of two or more."

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included tissue expansion to increase the amount of skin available for implant-based reconstruction.

In all, the complication rate was about 12 percent, and the most common complications were necrosis of part of the nipple or the skin used for reconstruction purposes. Subsequent cancer in the nipple area was found in another four percent of patients, yet even including these cases the natural nipple in the final

reconstruction was maintained in more than 90 percent of the cases.

"Our review demonstrated that nipple-sparing mastectomy and immediate reconstruction has a high rate of success and a low rate of complications," the researchers wrote.

"We are performing an increasing number of nipple-sparing mastectomy procedures as more breast oncology surgeons become comfortable with

the procedure and with expansion of our indications for nipple-sparing surgery."

The team noted that they are also increasingly using the inframammary incision due both to patient preference and to the lower complication rate. At that time they had shifted to a single-stage reconstruction procedure in more than two-thirds of their patients undergoing the nipple-sparing procedure. ■