Background: Breast biopsy, to determine the nature of a clinical or radiographic breast abnormality, was presumed to have increased in frequency with the widespread use of screening mammography. However, scant data exist regarding the utilization of breast biopsies in the community population.

Methods: Through the resources of the Rochester Epidemiology Project, the medical records of women 18 years and older who had a breast biopsy from January 1, 1988, through December 31, 1999, were reviewed for the type of biopsy, presentation at biopsy, and tissue pathological findings. The overall and age-specific utilization rates of breast biopsies were assessed, as were changes in the breast biopsy technique after the introduction of image-guided core-needle biopsy in 1992.

Results: The overall annual utilization rate of breast biopsies was 62.6 per 10,000 women per year and remained stable throughout the study. Excisional breast biopsies showed a decreasing trend and core-needle biopsies increased during the study duration. The age-adjusted incidence of benign results of breast biopsies for the study duration was 38.9 per 10,000 women. The benign-malignant ratio remained constant despite changes in the biopsy procedure.

Conclusions: This population-based study provides much-needed data regarding the frequency of breast biopsies and benign results of breast biopsies in a community population. The utilization rate of breast biopsies remained fairly constant throughout the study period despite the introduction of the image-guided, core-needle biopsy procedure in 1992. A multidisciplinary breast practice, along with established guidelines for breast biopsy, can ensure appropriate use of new technology and thereby improve patient care.

Arch Intern Med. 2005;165:1593-1598
graphically suspicious lesions, reducing the need for surgical intervention and reducing biopsy costs by more than 50%.7-10 However, the advent of such less invasive breast biopsy techniques may also have contributed to an increase in the utilization of biopsy. Hospital-based studies have shown an increase in the frequency of breast biopsies11,12; however, little is known concerning the frequency of breast biopsies in the general community.

Changes in guidelines for breast cancer screening, and the resultant increased risk of false-positive mammograms requiring further diagnostic testing, have led to understandable concern about an increase in the frequency of breast biopsies. We therefore conducted a population-based, retrospective, descriptive study to determine trends in the utilization of breast biopsy among Olmsted County, Minnesota, women during the period from January 1, 1988, through December 31, 1999, to estimate the age-specific utilization of breast biopsies, to assess the benign-malignant ratio of results of breast biopsies, and to determine changes with the introduction of newer diagnostic techniques.

STUDY DESIGN

This population-based descriptive study of breast biopsy procedures used the resources of the Rochester Epidemiology Project, a medical record linkage system that indexes all inpatient and outpatient medical care provided to residents of Olmsted County, Minnesota (2000 census urban population of 100 172 and rural population of 24 105), through an agreement between the Mayo Clinic, Rochester, Minn, and other local providers.13 Breast biopsy was defined as any surgical biopsy or image-guided core-needle biopsy (including stereotactic or ultrasound guided) performed on the breast for diagnostic purposes. After approval for the study from the Mayo Foundation and the Olmsted Medical Center (Rochester) institutional review boards, potential breast biopsy procedures performed at Mayo Clinic or its affiliated hospitals, on women 18 years and older, from January 1, 1988, to December 31, 1999, were identified by searching the Mayo Clinic Medical and Surgical Index, as well as the procedure database maintained by the Department of Radiology that captures all stereotactic and ultrasound-guided biopsies. All breast procedures performed at the Olmsted Medical Center and by other local providers were accessed by the Rochester Epidemiology Project resources. Medical records of all patients with “diagnostic procedures on the breast,” “local excision of breast tissue,” “resection of a quadrant of breast,” “subtotal mastectomy,” and “mastectomy” were reviewed to ensure complete case ascertainment. Olmsted County residency on the day of biopsy was confirmed by means of Rochester Epidemiology Project residency verification procedures. There were 211 patients identified through the indexing system as potential cases, but their eligibility could not be verified as they refused authorization to use their medical records for research.14

Women who had dermatologic procedures on the breast and ipsilateral biopsies after mastectomy were excluded from the study. Fine-needle aspirations on the breast were also excluded because of their inconsistent use as a diagnostic procedure and the poor reliability of test results. This procedure, mainly used to aspirate cysts, has been less frequently used as a diagnostic tool since the introduction of breast ultrasonography that can accurately differentiate a cyst from a solid breast lesion.

The study was started on January 1, 1988, because before this date, only the most extensive breast procedures were indexed for each patient registration. Beginning in 1988, all breast procedures performed were indexed. In 1992, less invasive alternatives to the open excisional biopsy, such as stereotactic breast biopsy and ultrasound-guided breast biopsy, were first introduced into clinical practice. Hence, we believed that at least 5 additional years of information would be needed to assess trends in breast biopsies after the introduction of new biopsy techniques. The study period ended on December 31, 1999, to enable assessment of this trend and ensure completeness of the data collection.

DATA COLLECTION

Data abstracted from the medical record included the date of birth, date of biopsy, presentation at the time of biopsy (dominant palpable mass, nipple abnormalities, or radiographic abnormality without a dominant mass), and histologic findings at biopsy (benign or malignant). The biopsy technique for each biopsy was also determined (“operative,” including excisional, incisional, and intraoperative needle biopsy; or “image-guided core-needle biopsy,” including stereotactic and ultrasound-guided biopsies). The data were collected by the principal investigator (K.G.), a board-certified internist with clinical experience in the management of breast disorders who is involved in clinical practice in the Breast Diagnostic Clinic at Mayo Clinic.

DATA ANALYSIS

Utilization rates were calculated assuming that all female residents of Olmsted County were at risk of having a breast biopsy. When utilization rates were determined, patients who had biopsies performed of both breasts at the same clinical evaluation were considered to have had 2 breast biopsies on that date. If a patient underwent multiple breast biopsies on the same breast at the same evaluation, the patient was considered to have undergone only one breast biopsy and the procedure “type” was the most extensive procedure. Multiple breast biopsies on the same breast at separate episodes, regardless of the time lag between biopsies, were considered to be unique procedures.

The number of women at risk per study year was estimated by linear interpolation between decile estimates from the US census data on Olmsted County.15 Age-adjusted rates were calculated by using the age structure of the 2000 US white women population as the standard. The 211 patients who had refused research authorization were treated as if they did not have a breast biopsy for determination of utilization rates. Hence, the overall unadjusted utilization rates may have been understated by about 4%.

Utilization rates were then plotted overall, by age at biopsy (18-39, 40-49, and ≥50 years), and by the type of biopsy, to visually assess trends. The Armitage test for trend16 was used to assess whether the age-adjusted utilization rates or the proportion of breast biopsies with malignant findings significantly increased throughout the study period.

RESULTS

PARTICIPANT CHARACTERISTICS

During the study period from January 1, 1988, through December 31, 1999, a total of 2940 breast biopsies were identified among 2580 Olmsted County women. Sixty-two procedures were excluded in 59 women who had bi-
opsies for dermatologic lesions or had a biopsy of a chest wall nodule after mastectomy. Thus, the study cohort consisted of 2878 biopsies on 2521 women known to be residing in Olmsted County when they underwent a diagnostic breast biopsy. Eighty-eight percent of these women had a single breast biopsy, while 12% had multiple biopsies. The average number of biopsies per woman in this period was 1.1. We found that 2215 women had 1 biopsy, 266 had 2 biopsies, 33 had 3 biopsies, 3 had 4 biopsies, and 4 had 5 biopsies.

OVERALL UTILIZATION RATE

The overall, age-adjusted, annual utilization rate of breast biopsies was 62.6 per 10,000 women (95% confidence interval [CI], 60.3-65.0) and remained fairly constant throughout the study period (Figure 1). Considering only the first breast biopsy during the study period, the age-adjusted rate was 54.7 per 10,000 (95% CI, 52.6-56.9). There was no significant change in the trends in breast biopsy utilization before or after the introduction of the core-needle breast biopsy procedure in 1992. Utilization rates for women aged 18 to 39 years, 40 to 49 years, and 50 years and older remained stable throughout the study period (Figure 2). The annual utilization rates for the 18- to 39-year, 40- to 49-year, and 50 years and older age groups ranged from 19 to 32, 68 to 97, and 83 to 100 per 10,000, respectively. The rate of utilization did not change in the 40- to 49-year age group despite the introduction of regular screening mammography guidelines in this group in 1997 (Figure 2).

UTILIZATION RATE BY BIOPSY TYPE AND CLINICAL PRESENTATION

From 1988 to 1992, all breast biopsies were operative procedures composed of excisional biopsies, incisional biopsies, or intraoperative needle biopsies (Figure 3A). The utilization rate of operative breast biopsies declined from 58.8 per 10,000 (95% CI, 51.2-66.5) in 1988 to 26.0 per 10,000 (95% CI, 21.4-30.7) in 1999. After the introduction of image-guided (stereotactic and ultrasound-guided) core-needle breast biopsies in 1992, the utilization of image-guided breast biopsies increased from 0.2 per 10,000 (95% CI, 0.0-0.7) in 1992 to 27.7 (95% CI, 23.0-32.6) per 10,000 in 1999. At the end of the study period, 52% of biopsies were image-guided biopsies and 48% were operative biopsies.

Of the biopsies performed each year, 44% (range, 35%-51%) were done for palpable lesions with a dominant breast mass, 3% (range, 2%-4%) for nipple abnormal-
ties, and 53% (range, 46%-60%) for radiographic breast abnormalities without a dominant mass (Figure 3B).

HISTOLOGY OF BREAST BIOPSIES

The rate of benign results of breast biopsies remained stable throughout the study period (median, 39.1 per 10,000; range, 32.1-43.3). The benign-malignant ratio also remained stable (2.2:1) throughout the study period. The age-adjusted incidence of benign results of breast biopsies for the 12-year study was 38.9 per 10,000 (95% CI, 37.2-40.6). The rate of malignant results of breast biopsies ranged from a low of 14.6 per 10,000 (95% CI, 10.7-18.3) in 1989 to a high of 21.9 per 10,000 (95% CI, 17.5-26.4) in 1995. The benign-malignant ratio for both the biopsies performed for a clinical abnormality and those with predominantly radiographic presentation remained stable during the study (Figure 4).

COMMENT

Breast cancer is the most frequently diagnosed nonskin cancer among women. It is estimated that 211,240 new cases of both invasive and in situ breast cancer will occur in women in the United States in 2005.\textsuperscript{17} In a study of screening mammograms in the United States and the

Figure 3. Breast biopsy utilization rates, 1988 to 1999, among Olmsted County, Minnesota, women. A, By biopsy type. B, By presentation at biopsy.

Figure 4. Breast biopsy utilization rates, 1988 to 1999, among Olmsted County, Minnesota, women by presentation at biopsy (clinical or radiographic) and histologic finding (benign or malignant).
United Kingdom, it was found that 2.3% to 3.4% of first screening mammograms and 0.8% to 1.7% of subsequent screening mammograms resulted in a breast biopsy. Studies have suggested that 5% to 10% of all screening mammograms are reported as abnormal, and that the majority of women with abnormal mammograms do not have breast cancer. With the increasing utilization of screening measures for breast cancer, and the introduction of less invasive means for breast biopsy such as the core-needle biopsy technique, there was concern that the number of breast biopsies might be increasing. Population-based studies are needed to address this issue, and this report appears to be the first to assess the frequency of breast biopsies in a defined population, disclosing a fairly stable annual rate of 62.6 breast biopsies per 10,000 women during the study period from 1988 through 1999.

In 1997, the National Cancer Institute released guidelines recommending screening mammography every 1 to 2 years for women aged 40 to 49 years. In these younger women, screening mammography has lower sensitivity and positive predictive value than in those 50 years and older. Higher false-positive rates among women aged 40 to 49 years than in those 50 years and older are likely linked to higher breast density in younger women. In an attempt to determine whether younger women had breast biopsies more frequently than older women, we compared age-specific utilization of breast biopsies during the study. However, women aged 40 to 49 years had a rate of breast biopsy utilization similar to that of women 50 years and older. Women in the 18- to 39-year age group had a stable but low annual rate of breast biopsies.

Technological advances in imaging and image-guided breast biopsy techniques led to the introduction of the stereotactic breast biopsy and ultrasound-guided breast biopsy. The stereotactic breast biopsy procedure was initiated in Olmsted County (Mayo Clinic) in 1992, initially as an experimental study and then, after test accuracy was ensured, as established clinical practice. We found a decreasing trend for operative biopsies over time, along with an increasing trend in image-guided core-needle biopsies starting in 1992. At the end of the study period in 1999, only 48% of all biopsies were excisional, while 52% were core-needle biopsies. Several factors contributed to the increasing utilization of the core-needle biopsy technique. This procedure is more convenient for the patient; is less invasive, less expensive, and more easily performed than the excisional biopsy; and has been proven to provide comparable accuracy. In addition, in 1997, the sentinel lymph node biopsy procedure was introduced, wherein preoperative instillation of a radiocolloid and blue dye enabled the identification of the sentinel lymph node. Surgeons often prefer to have a tissue diagnosis before surgical excision of invasive breast cancer to enable the preoperative radiocolloid and blue dye placement, making the core-needle biopsy a favored diagnostic technique.

Another question of interest is the presentation at the time of breast biopsy. The available medical literature has looked at breast biopsies being done for women presenting with clinical abnormalities or with reference to mammography practice, but has not addressed the presentation at the time of breast biopsy in a community population. We assessed the proportion of women who had a clinical abnormality, ie, palpable mass or nipple abnormality, vs those with a radiographic breast abnormality at the time of biopsy and found that, despite changes in the breast biopsy technique (with increased use of image-guided technology), this ratio remained stable throughout the study.

The new availability of a surgical or diagnostic procedure, in itself, can result in an increase in the utilization of that procedure, thereby potentially resulting in an apparent increase in the incidence of the underlying disease. In a study looking at the performance of screening mammography, Kerlikowske and Barclay described findings from 34,000 examinations in a community-based breast cancer screening program. After the first screening mammography, women aged 40 to 49 years had 15 (95% CI, 13-17), women aged 50 to 59 years had 19 (95% CI, 17-23), and women 60 years and older had 28 (95% CI, 24-34) biopsies per 1000 examinations. Among women aged 40 to 49 years, 20% of the biopsy findings showed breast cancer (invasive and ductal carcinoma in situ), and 32% for women 50 to 59 years old and 42% for women 60 years and older. In our study, the overall malignancy rate did not change during the study, and the benign-malignant ratio (2.2:1) did not change with time, suggesting that the introduction of a new diagnostic breast biopsy technique, in this instance, was not associated with an increase in unnecessary biopsies. Factors that may have contributed to the steady rate of biopsies, and the stable benign-malignant ratio, is that most of these patients were examined at the Mayo Clinic, where there is an established mammography practice and a multidisciplinary team approach with agreed-on criteria for breast biopsies.

The strength of this study lies in the use of the Rochester Epidemiology Project, a unique community data resource that has been used multiple times to estimate utilization rates and potential national needs for various procedures. A related liability of this study is its potential generalizability. However, the demographics of the Olmsted County population are similar to those of the US white population with the exception that a greater proportion of the working population are employed in health care. If anything, because of the easy access to medical care, both primary and specialty care, the utilization of breast biopsies in Olmsted County is likely to be somewhat greater than that in the general population. In the absence of any prior data, the information obtained by this study should provide valuable insight into the trends in utilization of breast biopsies and their potential implications relating to health care utilization and costs. The advent of newer diagnostic technology for breast cancer, such as breast magnetic resonance imaging and magnetic resonance imaging–guided breast biopsies for suspicious lesions, could potentially result in changes in breast biopsy utilization in the future.

In conclusion, this population-based study is an assessment of clinical breast practice across a 12-year period during which there was increasing use of mammography and the introduction of new, less invasive biopsy techniques, presumably increasing breast biopsy utilization. To our knowledge, there is no comparable study...
in the medical literature that has looked at the utilization of breast biopsies or benign results of breast biopsies in a defined population. Breast biopsy utilization rates remained stable throughout the study, although the biopsy technique itself changed with increasing utilization of image-guided core-needle biopsies. The benign-malignant ratio also remained stable despite the change in biopsy techniques. A multidisciplinary breast practice, along with established guidelines for breast biopsy, can ensure the appropriate use of new technology and thereby improve patient care.

Accepted for Publication: March 21, 2005.
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Funding/Support: This study was supported by grant DAMD 17–02–1–0473 (principal investigator, Dr Hartmann) from the Department of Defense Breast Cancer Center of Excellence located at Mayo Clinic, Rochester, Minn.

Previous Presentation: Some of the initial results of this study were presented as a poster at the San Antonio Breast Cancer Symposium; December 6, 2003; San Antonio, Tex. The abstract was published previously (Breast Cancer Res Treat. 2003;82[suppl 1]:148).

Acknowledgment: We are extremely grateful to Kathleen Tenner, BS, and Ming Wen An, BA, for performing the data analysis. We thank Marie Nepper and Mitch Baias for their help with pulling the medical records expeditiously for review. We also thank Gloria Bahr for secretarial assistance and Hannah Koble for help with the manuscript preparation.

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