ORIGINAL ARTICLE

Impact of the New Jersey Breast Density Law on Imaging and Intervention Volumes and Breast Cancer Diagnosis

Linda M. Sanders, MD[a,b], *Alexander B. King, MD*[a], *Koren S. Goodman, PhD, CHES, MSEd*[c]

Abstract

Purpose: Increased breast density is acknowledged as an independent risk factor for breast cancer and may obscure malignancy on mammography. Approximately half of all mammograms depict dense breasts. Legislation related to mandatory breast density notification was first enacted in Connecticut in 2009. On May 1, 2014, New Jersey joined other states with similar legislation. The New Jersey breast density law (NJBDL) mandates that mammography reports acknowledge the relevance and masking effect of mammographic breast density. The aim of this study was to assess the impact of the NJBDL at one of the state's largest ACR-accredited breast centers.

Methods: A retrospective chart review was performed to determine changes in imaging and intervention utilization and modality of cancer diagnosis after enactment of the legislation. Data for the present study were extracted from a review of all patients with core biopsy—proven malignancy at a large outpatient breast center between November 1, 2012, and October 31, 2015. Data were divided into the 18-month period before the implementation of the NJBDL (November 1, 2012 to April 30, 2014) and the 18-month period after passage of the law (May 1, 2014 to October 31, 2015).

Results: Screening ultrasound increased significantly after the implementation of the NJBDL, by 651% (1,530 vs 11,486). MRI utilization increased by 59.3% (2,595 vs 4,134). A total of 1,213 cancers were included in the final analysis, 592 in the first time period and 621 after law implementation. Breast cancer was most commonly detected on screening mammography, followed by diagnostic mammography with ultrasound for palpable concern, in both time periods. Of the 621 cancers analyzed, 26.1% (n = 162) were found in patients 50 years of age or younger. Results demonstrated that with respect to how malignancies were detected, age and average mammographic density were both statistically significant ($P = .002$).

Conclusions: The NJBDL succeeded in publicizing the masking effect of dense breasts. The number of supplemental screening ultrasound and MRI examinations increased after the implementation of this legislation. An efficacy analysis affirmed the high sensitivity of screening MRI compared with other modalities. The use of MRI increased core biopsy efficiency and reduced the number of biopsies needed per cancer diagnosed.

Key Words: Breast, screening, imaging, density, risk, breast cancer, MRI

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INTRODUCTION

More than 220,000 new cases of breast cancer are diagnosed annually in the United States, with approximately 40,000 deaths [1]. Increased breast density is acknowledged as an independent risk factor for breast cancer. In a case-control study, Boyd et al [2] demonstrated that women with breast density higher than 75% (extremely dense) have an elevated risk for breast cancer (odds ratio, 4.7) compared with women with density less than 10% (fatty breasts). Dense tissue is a common finding, present in more than one-half of women younger than 50 years of age and in nearly one-third of women older than 50 years of age; therefore, this elevated risk affects millions of women [3,4].

Legislation related to mandatory breast density notification was first enacted in Connecticut in 2009. On May 1, 2014, New Jersey joined Connecticut and other states with similar legislation [5]. Currently there are 24 states with such legislation. The aim of these laws is to inform

[a]Breast Center, Barnabas Health Ambulatory Care Center, Livingston, New Jersey.

[b]Rutgers New Jersey Medical School, Newark, New Jersey.

[c]Department of Surgery, Saint Barnabas Medical Center, Livingston, New Jersey.

Corresponding author and reprints: Linda M. Sanders, MD, Barnabas Health Ambulatory Care Center, Breast Center, 200 South Orange Avenue, Livingston, NJ 07039; e-mail: lsanders@barnabashealth.org.

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women of the issue of breast density and to encourage supplemental imaging for improved early detection in women with dense breasts. The New Jersey breast density law (NJBDL) mandates that mammography reports acknowledge the masking effect of breast density; however, it does not require that patients be specifically informed of their mammographic density. Provisions regarding insurance coverage for supplemental screening vary by state; the NJBDL requires insurers to cover supplemental imaging.

There are four categories of breast density as per the ACR's BI-RADS®: fatty, scattered fibroglandular, heterogeneously dense, or extremely dense [6]. In addition to being an independent risk factor for cancer, dense breast tissue can obscure cancer on mammography [7]. MRI, which has been increasingly used in screening, has higher sensitivity compared with mammography in detecting in situ and invasive breast cancer [8,9].

Literature regarding breast density legislation and its impact remains sparse. Currently, there have been few longitudinal studies examining the time periods before and after legislative action. In this study, we assessed the impact of the NJBDL at one of the state's largest ACR-accredited breast centers in two time periods: 18 months before and 18 months after NJBDL implementation. Utilization changes in supplemental screening breast ultrasound and MRI were examined, as well as the impact these modalities had on breast core biopsy rates. Cancers detected in the two time periods were analyzed to determine how the legislation affected the modalities by which they were found.

METHODS

All patients undergoing mammography, ultrasound, MRI, and core biopsy at an outpatient breast center affiliated with a large, nonprofit teaching hospital were examined over a three-year period: November 1, 2012, through October 31, 2015. The data were divided into two time periods: the 18 months before the implementation of the NJBDL (November 1, 2012, to April 30, 2014) and the 18 months after its implementation (May 1, 2014, to October 31, 2015). Core biopsies were categorized by modality used.

All core biopsy–confirmed cancers, invasive or in situ, during the two time periods were tallied, and the following data were extracted from a retrospective chart review: age of patient, modality of detection, mammographic breast density, and lifetime risk for breast cancer.

Modality of detection was defined as the imaging study that first identified the lesion and was subclassified into screening or diagnostic. Diagnostic mammography was further subcategorized by indication. Cancers detected by MRI with indication of family history, high risk, remote personal history, dense breasts, or fibrocystic disease were classified as found by screening. Cancers found by MRI performed for all other indications were considered diagnostic. MRI examinations performed in patients with known cancer for extent of disease evaluation or response to neoadjuvant chemotherapy were counted. Contralateral cancers diagnosed on MRI were also recorded. Patients who were referred for biopsy on the basis of outside imaging were grouped separately because modality of diagnosis could not be determined.

Breast density was categorized from 1 to 4 (1 = fatty, 2 = scattered fibroglandular, 3 = heterogeneously dense, and 4 = extremely dense) according to ACR BI-RADS [6]. Lifetime risk was obtained from PenRad (PenRad Technologies, Inc., Buffalo, Minnesota), our breast reporting system, which uses the National Cancer Institute's algorithm. Patients with histories of breast cancer are not assigned a risk by this algorithm; therefore, the value before diagnosis was used.

Patients with normal results on imaging studies who may have gone directly to surgery, bypassing core biopsy, were excluded from this study. Patients with abnormal results on imaging studies who did not undergo core biopsies at this center were also excluded from this study.

Equipment

All mammographic examinations were digital, performed on Hologic Selenia units (Hologic, Bedford, Massachusetts). Ultrasound studies were performed on Acuson Sequoia, Siemens Antares (both Siemens Healthcare, Erlangen, Germany), GE Logiq 7, and GE Logiq S8 (both GE Healthcare, Little Chalfont, United Kingdom) units. All MRI examinations were performed using Philips 1.5-T systems, either Achieva or Ingenia (Philips Medical Systems, Andover, Massachusetts), and included T1, T2, and dynamic fat-suppressed sequences with 1-mm in-plane resolution. Screening ultrasound studies were performed by certified ultrasound technologists. All mammograms and ultrasound studies were read by a group of nine Mammography Quality Standards Act credentialed radiologists. All MRI examinations were interpreted by four board-certified radiologists with expertise in breast imaging and intervention.

Statistical Analysis

Data extracted on biopsy-proven breast cancers included imaging modality of diagnosis in the two time periods. Percentage change and *P* values were calculated. Means for