

5 Feasibility of WF-OCT as an Adjunct to Intraoperative Specimen X-ray for Breast Conservation Surgical Specimens

Savitri Krishnamurthy,¹ Payal Salgia,² David Rempel,² Andrew Berkeley,² Beryl Augustine,² Chandandeep Nagi,³ Alastair Thompson³

¹The University of Texas MD Anderson Cancer Center, Houston, TX

²Perimeter Medical Imaging AI, Toronto, Ontario, Canada

³Baylor College of Medicine, Houston, TX

Background/Significance

Margin status after breast-conserving surgery (BCS) is a critical prognostic factor in breast cancer. Adjunct, intraoperative analysis of excised tumor margins reduces the risk of reexcision surgery by allowing the surgeon to take additional tissue if an involved margin is detected. While intraoperative specimen radiography (SXR) is commonly used as such an adjunct, wide-field optical coherence tomography (WF-OCT) imaging has also demonstrated performance for this purpose. WF-OCT uses near-infrared interferometry to produce high-resolution images of tissue microarchitecture at a depth up to 2 mm and may detect residual malignant tissue not apparent on SXR.

Materials and Methods

This retrospective case series compared SXR with WF-OCT images, collected, and analyzed prospectively. Adult women undergoing BCS for biopsy-proven invasive ductal carcinoma

(IDC) or ductal carcinoma in situ (DCIS) at 2 centers were included. Primary excised tumor specimens were imaged intraoperatively with SXR and WFOCT (Perimeter Medical Imaging AI). Additional shaves were taken based on SXR results. WF-OCT images were blinded and reviewed, and not used for clinical decision-making. After closing, all tissue was sent for permanent histopathology, which was designated as ground truth. Histopathology-positive margins in patients without additional cavity shaves were designated as SXR false negatives (SXR-FNs). The WF-OCT results and images from FN patients were compared with the corresponding SXR and final histopathology images.

Results

Eighty-nine consecutive patients undergoing BCS were imaged with SXR and WF-OCT prior to permanent histopathology. Average sensitivity and specificity of SXR were 76.5% and 69.6%, respectively. Six cases, comprising 4 DCIS, 1 IDC, and 1 DCIS with IDC, were designated SXR-FN (additional shaves not taken intraoperatively; positive margin present on final histopathology). In the 5 SXR-FN DCIS cases, suspicious tissue changes were present on WF-OCT; the 1 SXR-FN case not detected by WF-OCT was IDC. Side-by-side comparison of SXR-FN, WFOCT, and ground-truth histology shows the correlating lesion features.

Conclusions

This case series demonstrates that, consistent with ground-truth permanent histology, WF-OCT is able to detect margin positivity in excised tissue that was not apparent on SXR, particularly with respect to DCIS. Although a small case series, these results are encouraging. Additional studies should be tested in a randomized controlled trial.

20 Evaluating Number, Age, and Radiographic BIRADS of Patients Visiting Mammography Unit in Baghdad, Iraq, in 2019, 2020, and 2021: A Retrospective Study

Mustafa Majid¹, Mohammed Mutar, Sara Sh. Ahmad, Enam Al-Tameemi

¹Baghdad Medical College of Medicine, Baghdad City Complex; Tel: +964.7729414006; Email: mustafa.majid.1997@gmail.com

Background

Breast cancer is the most commonly registered cancer in Iraq, and 67.9% of patients present with stage III or IV disease, with 45% of patients presenting before the age of 50 years. Breast mammography represents the best screening tool in patients aged above 35 to 40 years of age. The objectives of this study are to find the number of patients having mammography and evaluate their age and radiography based on the Breast Imaging Reporting and Data System (BIRADS) 0 to 6 score to provide baseline data for future screening programs and to direct appropriate resources.

Materials and Methods

This study was conducted retrospectively in an oncology teaching hospital from the period September 2019 to January 2022. The data were collected from the radiology unit. The records included data from patients who visited the unit for mammography. Patients were either on regular follow-up due to previous breast issues or had breast complaints for which a clinician referred them for mammography. The data were collected and administered using Excel and analyzed with Python programming language version 3.1. Data were analyzed using a 95% confidence interval and the study was approved by the ethical committee.

Results

The number of patients who had a diagnostic or follow-up mammography was 4838. The mean age was

50.93 ±9.5 years (range, 14-95), with 75% of patients being younger than 57 years. In total, 35.96% of patients had BIRADS 1 status and 16% had BIRADS 4 or 5 status. Of the 35.79% who were on regular follow-up mammography, 75% had BIRADS 1 or 2 and 10% had BIRADS 3. The most crowded days were Sunday and Wednesday, which accounted for 49.5% of the total patient appointments weekly.

Conclusion

During the 2 years and 3 months of the study, the center received 4838 patients for mammography, 75% of whom were younger than 57 years. This volume of participants creates a burden on the mammography unit and increases the need for human and financial resources, especially if a screening program is implemented.

28 Case Series: Imaging Appearance of Non-Breast Cancer Solid Masses in the Male Breast

Lindsay Miner,¹ Allison M. Aripoli,^{1,2} Onalisa Winblad,^{1,2} Jessica Peterson,¹ Marc Inciardi²

¹Division of Breast Imaging, The University of Kansas School of Medicine, Kansas City, KS

²Department of Radiology, The University of Kansas School of Medicine, Kansas City, KS

Background

Benign-appearing masses in male patients should be approached thoughtfully, given the overlapping morphologic features of benign and malignant tumors. In addition to gynecomastia, other benign male breast tumors include lipoma, pseudoangiomatous stromal hyperplasia, granular cell tumor, fibromatosis, myofibroblastoma, schwannoma, and hemangioma.¹ Diseases in the male breast can affect any component of the normal breast anatomy, including the skin, subcutaneous fat, stroma, glands, neurovascular structures, and lymphatic vessels. Typically, fat makes up most of the breast volume in men, with few residual ducts and stroma due to involution and atrophy from androgenic antagonistic effects.²

Learning Objectives

Present cases of male patients presenting with solid breast masses as well as the radiologic and clinical management.

Abstract Content

This is a case series of 12 solid breast masses identified in male patients who did not receive a breast cancer diagnosis. We will discuss the patient presentation, imaging findings, and histopathological appearance. Surgical or clinical management recommendations, when available, will also be presented.

Conclusion

Solid breast masses in male patients should be evaluated thoroughly to exclude malignancy, given the overlapping features of benign and malignant tumors. This could include clinical evaluation and thorough history, imaging and/or tissue sampling, and possible surgical consultation and/or excision.

References

1. Nguyen C, Kettler MD, Swirsky ME, et al. Male breast disease: pictorial review with radiologic-pathologic correlation. *Radiographics*. 2013;33(3):763-779. doi:10.1148/rg.333125137
2. Lattin GE Jr, Jesinger RA, Mattu R, Glassman LM. From the radiologic pathology archives: diseases of the male breast: radiologic-pathologic correlation. *Radiographics*. 2013;33(2):461-489. doi:10.1148/rg.332125208

38 Clinicopathological Risk Factors, Poorly Stratified Baseline Risk, and RT Benefit Compared to DCISionRT in Patients With Ductal Carcinoma in Situ

Pat W. Whitworth,¹ Rachel Rabinovitch,² Frank A. Vicini,³ Chirag Shah,⁴ Fredrik Wärnberg,⁵ G. Bruce Mann,⁶ Steven C. Shivers,⁷ Karuna Mittal,⁷ Troy Bremer,⁷

¹Nashville Breast Center, Nashville, TN

²University of Colorado, Colorado Springs, CO

³GenesisCare, Farmington Hills, MI

⁴Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH

⁵Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

⁶University of Melbourne, Melbourne, Australia

⁷PreludeDx, Laguna Hills, CA

Objective

Over- and undertreatment of ductal carcinoma in situ (DCIS) has been a persistent clinical problem with traditional clinicopathologic features unable to stratify patients appropriately. DCISionRT reports a decision score (DS) validated in multiple cohorts, including the randomized SweDCIS Trial, which is prognostic for 10-year ipsilateral breast recurrence (IBR) risk after breast-conserving surgery (BCS) and predictive for radiotherapy (RT) benefit. Here, stratification of IBR risk and RT benefit by clinicopathology was assessed with DCISionRT.

Methods

DCISionRT and its integrated residual risk subtype (RRt) was evaluated in 493 patients from 3 cohorts at a Clinical Laboratory

Improvement Amendments (CLIA) lab (PreludeDx, Laguna Hills, CA) who were treated with BCS or BCS plus RT. Clinicopathology features were analyzed in a multivariable analysis with DCISionRT and its integrated RRt-classified risk groups for 10-year IBR.

Results

The biosignature classified patients into low ($DS \leq 2.8$, $n = 173$), elevated ($DS > 2.8$ without RRt, $n = 209$), and residual ($DS > 2.8$ with RRt, $n = 111$) risk groups. Patients had increased 10-year rates of IBR risk in the elevated (21.4%, $P < .001$) and residual (43.4%, $P < .001$) risk groups without RT, and benefited from RT (elevated: HR, 0.15, $P = .002$; residual: HR, 0.27, $P = .004$) versus the low-risk group (5.5%; HR, 1.28; $P = .7$). The residual versus elevated risk group had an increased 10-year IBR risk rate after RT (20.5% vs 3.2%, $P = .008$). Clinicopathologic features (age, grade, size, palpability, and necrosis) were not associated with the 10-year IBR risk rate in multivariable analysis including DCISionRT and treatment. The distribution of clinicopathologic features varied between biosignature risk groups; the residual risk group had a higher proportion of patients with nuclear grade 3 (71% vs 31%, $P < .001$), necrosis (89% vs 56%, $P < .001$), and size greater than 1 cm (54% vs 35%, $P < .001$) when compared with low- and elevated- risk groups, but no significant change was noted in the distribution between DCISionRT risk groups for age.

Conclusions

DCISionRT classified patients into 3 groups with distinct risk and RT benefit profiles, where the residual risk group had the highest 10-year IBR risk rate without RT and significantly elevated IBR risk after RT. The distribution of clinicopathologic features varied between biosignature risk groups but were not significantly associated with the 10-year IBR risk rate, accounting for DCISionRT risk groups and treatment.

39TiP The PREDICT Registry: A Prospective Registry Study to Evaluate the Effect of a Predictive Assay on Treatment Decisions in Patients with DCIS Following Breast Conserving Therapy

Steven C. Shivers,^{1,4} Pat W. Whitworth,² Rakesh Patel,³ Troy Bremer,¹ Charles E. Cox⁴

¹PreludeDx, Laguna Hills, CA

²Nashville Breast Center, Nashville, TN

³Good Samaritan Cancer Center, Los Gatos, CA

⁴University of South Florida, Tampa, FL

Background/Significance

The benefits of adjuvant radiation therapy (RT) in patients with ductal carcinoma in situ (DCIS) treated with breast-conserving surgery (BCS) remains controversial. Although there is level 1 evidence supporting the role of RT in reducing the risk of local recurrence, the absolute benefit is variable. Current guidelines generally recommend RT for all patients having BCS, but it is important to develop prognostic and predictive tools to better assess risk and understand the impact such a tool would have on treatment decisions. The DCISionRT Test (PreludeDx, Laguna Hills, CA) is a biologic signature that provides a validated score for assessing 10-year risk of recurrence and RT benefit using individual tumor biology as assessed by clinical and pathologic biomarkers.

Design and Methods

This is a prospective cohort study for patients diagnosed with DCIS of the breast. Treating physicians complete a treatment recommendation survey before and after receiving DCISionRT test results. Test results, treatment recommendations, patient preferences, and clinicopathologic features are stored in a deidentified registry for participating institutions from a variety of geographic regions across the United States. The study will also collect 5- and 10-year recurrence and survival data. The study includes women over 25 years of age who are candidates for BCS and eligible for RT and/or systemic treatment with sufficient tissue to generate test results. Subjects must not have been previously treated for DCIS or have previous or current invasive or microinvasive breast cancer. The primary end points are changes in treatment recommendations for surgical, radiation, and

hormonal therapy. Secondary end points are identification of key drivers for treatment recommendations, including age, size, grade, necrosis, hormone receptor status, and other clinicopathologic factors. Changes in treatment recommendations will be assessed using McNemar's test with an α level of 0.05. Differences in recurrence-free and overall survival will be evaluated by Kaplan-Meier survival analysis using the log-rank test and/or the Cox proportional hazards model.

Status

On January 4, 2022, the study met its phase 1 accrual goal of 2500 patients from 67 institutions. Additional research objectives are being planned, and accrual is scheduled to reopen around midyear 2022.

44 Implementation of a Novel Radiopaque Filament Marker at a Single Breast Cancer Surgery Center

Helene M. Sterbling,¹ Ashish Chawla,² Lolita Ramsey,¹ Stephanie Akbari,³ David Weintritt,⁴ Shawna C. Willey⁵

¹Inova Health Systems, Department of Surgery, Fairfax, VA

²Inova Health Systems, Department of Radiation Oncology, Fairfax, VA

³Virginia Cancer Specialists, Fairfax, VA

⁴National Breast Center, Alexandria, VA

⁵Inova Schar Cancer Institute, Fairfax, VA

Corresponding author: Helene M. Sterbling, MD, MA; Inova Health Systems, Department of Surgery; Tel: 540-556-0186; Helene.Sterbling@inova.org

Background

Marking of lumpectomy sites for adjuvant radiation therapy (XRT) in breast-conserving surgery historically uses metal clips, with reports of suboptimal tumor bed delineation. A novel radiopaque filament marker (FM) has been adopted at our breast center to map tumor beds. The aim of our project is to understand the clinical characteristics of the population in which the FM is placed and optimize device utilization through collaboration with radiation oncologists.

Methods

Patients undergoing breast surgery receiving the radiopaque FM at our breast cancer center from 2019 to 2021 were retrospectively queried. Patient demographics, tumor characteristics, and surgical and radiation treatment data were recorded. An anonymous REDCap survey was sent to

local breast radiation oncologists evaluating their impressions on the use of the FM. Continuous and categorical variables were analyzed by independent t-test and chi-square test, respectively. Survey responses were compiled.

Results

The radiopaque FM was placed in 104 patients, with 50 patients having complete follow-up data. The average age of this all-female cohort was 62 years (standard deviation, ± 11.2). Invasive ductal carcinoma was the most common pathology (39.2%), followed by ductal carcinoma in situ (31.4%). Over half were stage IA on clinical (50%) and pathologic (52.9%) staging. The surgical treatment was lumpectomy (98.1%), with 58.8% having a sentinel lymph node biopsy and all patients undergoing some level of oncoplastic reconstruction. XRT was given in 82.4% of cases. The survey was completed by 5 local breast radiation oncologists, with 100% agreeing that the use of the FM simplified radiation planning and 80% agreeing that its use enhanced target coverage and reduced normal tissue exposure. Free text suggestions included the strategic use of FM in deeper lumpectomy beds to distinguish between surgery tract and cavity as well as the containment of filament tails within the lumpectomy defect.

Conclusion

Our study found that radiopaque FM is mainly used in patients undergoing breast-conserving surgery with anticipated adjuvant XRT and that it can be used with oncoplastic reconstruction. In addition, our survey proposes actionable technical changes and raises salient questions regarding the permanent nature of the device and how it may affect patients' longitudinal care. Ultimately, multidisciplinary investigations are needed to determine how to best integrate new FM technologies into surgical and radiation oncology practices.