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The PRoBe-SH: A Close-Coded Patient-Reported Survey tool to Assess Breast Surgery History

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ABSTRACT

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Background: Diagnosis and treatment of breast cancer often involves several surgical procedures. Women with breast cancer are asked repeatedly to report their breast surgery history, often elicited in an open-ended format and relying on patient recall. Electronic medical records (EMR) and other medical documentation are not always readily available. No comprehensive, validated patient-reported measure of breast surgery history exists. We developed a close-coded, digital survey tool to elicit patient-reported breast surgery history (PRoBe-SH).

Methods: We administered the PRoBe-SH survey tool to a convenience sample of patients with a history of breast cancer. We compared PRoBe-SH data to both surgical history documented in patients' EMR and open-ended surgical history ascertained from patient-completed clinic intake forms. Sensitivity/specificity analyses and McNemar's tests were performed.

Results: Data from fifty patients (median age 53.5 years, range 31-71, 70% non-Hispanic white) were analyzed. The sensitivity of the PRoBe-SH for accurately identifying surgical history was 100% for mastectomy, lumpectomy 96%, mastectomy sidedness 100% (right) and 100% (left), lumpectomy sidedness 36% (right) 55% (left), lymphadenectomy 64%, breast reconstruction 89%, and presence of a native nipple 100% (right) and 100% (left). Open-ended surgical history was more than 90% sensitive for identifying mastectomy and lumpectomy only. The PRoBe-SH was significantly more sensitive than open-ended surgical history for identifying mastectomy sidedness ($P < 0.01$), lymphadenectomy ($P < 0.01$), and breast reconstruction ($P < 0.01$).

Conclusion: Ascertaining accurate breast surgical history is important in the context of clinical care and for research purposes. The PRoBe-SH is a comprehensive, highly sensitive alternative to obtaining an open-ended breast surgical history when EMR data or other medical documentation are not available.

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INTRODUCTION

Women with breast cancer often undergo multiple surgical procedures over the course of their diagnosis and treatment including surgical removal of breast tissue (mastectomy or lumpectomy), axillary lymphadenectomy



and breast reconstruction. Increasingly, women choose to undergo breast-conserving therapy (BCT) with lumpectomy. Among women with early-stage breast cancer, rates of lumpectomy rose from 48% in 1998 to 58% in 2011.¹ Of more than 3.5 million breast cancer survivors in the U.S. today, an estimated one-third have undergone mastectomy.² Of these 1.2 million survivors, approximately 40% have had or are considering breast reconstruction procedures.^{3,4} Mastectomy and lumpectomy can be either nipple-sparing or include nipple removal. Lymphadenectomy may include sentinel or complete axillary lymphadenectomy. Breast reconstruction may be performed with either native or synthetic tissue and can include additional procedures such as nipple tattooing and revision surgeries.⁵

Medical history taking is an important component of the diagnosis and management of medical health problems.⁶ Commonly, medical and surgical history are ascertained in open-ended formats either via an interview during a clinical encounter or by completion of self-reported medical history intake forms. Prior studies show limitations in patient-reported history of medical problems using open-ended techniques.⁷⁻⁹

Women with breast cancer are often asked repeatedly during medical care and in the course of research to report their breast surgical history by recall. Women with breast cancer frequently obtain their breast surgical care in sub-specialty, academic and center of excellence locations separate from where they received their healthcare before a breast cancer diagnosis. In addition, women living in rural and suburban regions, younger women - like students - or those who move or travel frequently for military service or work, and women with frequent changes in insurance status often receive breast cancer surgical care at more than one site over time and records may not be fully integrated with EMR systems of their primary care, obstetrics and gynecology or even emergency care settings. Care across clinical sites and time can present a challenge to accurate record-keeping about breast surgeries and timely decision-making for clinical and research purposes. Previous patient-reported measures of medical history among patients with breast cancer indicate agreement between self-report and electronic medical record (EMR) data for general aspects of breast cancer care, including history of mastectomy and adjuvant therapy.^{10,11} Less is known about the accuracy of self-report for other aspects of breast surgery including breast reconstruction, sidedness, and presence of native nipple. Comprehensive cancer care relies on having accurate knowledge of patients' prior treatments, including surgical procedures.

Ascertainment of accurate breast surgical history is also important to the integrity of research data in

this population, especially research aimed at investigating breast function, as surgical modification of the breast can result in deficits in physical, sexual, and psychosocial domains.¹² Relying on patients to remember all aspects of multiple, complicated surgeries may be burdensome and fraught with error. Timely ascertainment of EMR data or other medical documentation for research participants may be cumbersome or infeasible, as in the case of population-based cohorts and for the majority of women worldwide with breast cancer whose records are still primarily documented on paper, stored in EMR systems without optimized data abstraction capabilities, and may require expert translation.¹³

Despite the need for accurate data on breast surgical history, to our knowledge, no comprehensive, validated patient-reported measure of breast cancer surgical history exists. We sought to develop a highly sensitive tool to assess breast surgical history in women with breast cancer. This research aims to describe the development and validation of the novel Patient-Reported Breast Surgical History (PRoBe-SH) tool, a close-coded digital survey tool to ascertain breast surgical history.

METHODS

Participants

We recruited a convenience sample of 50 patients with a known history of breast cancer enrolled in the University of Chicago's Program of Integrative Sexual Medicine (PRISM) prospective patient registry between June and September 2019. Data were complete for all domains of the PRoBe-SH for all 50 participants.

Eligible participants included patients with a known history of breast cancer who had surgical records available in The University of Chicago Medicine's EMR. Research staff recruited participants using an introductory email, followed by phone follow-up. Interested participants were sent an online link to the digital survey tool administered via REDCap®. After completion of the survey, participants were provided a \$10 gift card for their participation. Chart abstraction was performed on site at The University of Chicago within 6 months of survey completion.

Measures

The PRoBe-SH was developed based on the review of extant literature on tools to assess surgical histories^{10,11,14}, best available evidence of breast cancer surgical trends³, expert review by gynecologic and breast surgeons, and accuracy of patient-reported medical history.⁷⁻⁹ The electronic survey tool queried the following five domains of breast surgery: (1) resection of breast tissue (mastectomy and/or lumpectomy), (2) surgical sidedness (left, right, both),



(3) lymphadenectomy, (4) reconstruction, (5) presence or absence of native nipple(s). Using branching logic, all domains were queried. Based on the participants' responses, additional questions regarding sidedness were asked within each domain.

We ascertained demographic and clinical data, including the patient's surgical history, from the patient's EMR using a combination of operative reports, pathology reports, and physician notes. The patients' self-reported, open-ended surgical histories were ascertained from PRISM clinic intake forms completed by the patients at their initial visit to the PRISM clinic. On these forms, the patients were asked to "Please indicate whether you have had surgery and, if so, the type, reason and approximate date of the operation."

Statistical Analysis

We used descriptive statistics to summarize demographic characteristics and breast surgical history. We calculated sensitivity, specificity and positive and negative predictive values, and corresponding 95% confidence intervals (CIs) for the domains of the PRoBe-SH tool and open-ended surgical history using EMR data as the gold standard. The precision of each estimate of sensitivity and specificity was dependent on the number of participants with the condition (sensitivity) or without the condition (specificity) based on the gold standard (EMR data). The number of participants with or without a given condition ranged from 11 to 50. Assuming an estimate of 50% (i.e., the maximum half-width of the 95% confidence interval), the precision would range from +/- 30% (11 participants) to +/- 14% (50 participants). We tested for significant differences in the sensitivity of the domains of the PRoBe-SH tool versus the open-ended surgical history using McNemar's test.

The study was approved by the University of Chicago Institutional Review Board (IRB) and was supported in part by funding from the National Cancer Institute and Janet D. Rowley Fund, University of Chicago Medicine. All participants provided documentation of the informed consent process.

RESULTS

Fifty-three women agreed to participate and completed the online survey tool. We excluded three participants with missing surgical EMR data. Participants (aged 31-71 years) were predominantly non-Hispanic white (70%), had a history of early-stage breast cancer (Stage I-38%, Stage II-48%), had undergone mastectomy (66%) and breast reconstruction (56%) (Table 1). All the patients had a documented history of lymphadenectomy. Most

participants had received adjuvant radiation (56%) and adjuvant chemotherapy (76%).

Table 1. Characteristics of N=50 Survey Participants

Characteristic	No. (%)
Median age, years (range)	53.5 (31-71)
Race/ethnicity	
Non-Hispanic White	35 (70)
Non-Hispanic Black	12 (24)
Other or Unknown	3 (6)
Breast Cancer Stage	
Stage 0	2 (4)
Stage I	19 (38)
Stage II	24 (48)
Stage III	4 (8)
Stage IV	0 (0)
Unknown	1 (2)
Time Since Diagnosis	
< 6 years	26 (52)
≥ 6 years	24 (48)
Received Adjuvant Chemotherapy	38 (76)
Received Adjuvant Radiation	28 (56)
History of Mastectomy	33 (66)
History of Lumpectomy	23 (46)
History of Lymphadenectomy	50 (100)
History of Breast Reconstruction	28 (56)

The sensitivity of the PRoBe-SH was >90% for most domains of breast surgical history (Figure 1): mastectomy (100%, 95%CI 89%,100%), lumpectomy (96%, 95%CI 78%,100%), mastectomy sidedness (right 100%, 95%CI 87%,100%; left 100%,95%CI 86%,100%), and the presence of native nipple (right 100%, 95%CI 87%,100%; left 100%, 95%CI 88%,100%). Sensitivity for the history of breast reconstruction was 89% (95%CI 72%, 98%). Sensitivity of the PRoBe-SH was lower for lumpectomy sidedness (right 36%, 95%CI 13%, 65%; left 55%, 95%CI 23%, 83%) and lymphadenectomy (64%, 95%CI 49%, 77%). Neither age nor time since diagnosis was associated with the accuracy of the PRoBe-SH for lumpectomy sidedness or lymphadenectomy using Wilcoxon rank sum tests.

The sensitivity of open-ended patient-reported surgical history was >90% for mastectomy (94%, 95%CI 79%, 99%) and lumpectomy (91%, 95%CI 71%, 99%) only. No participant indicated lumpectomy sidedness or presence of native nipples on their open-ended history forms. Sensitivity for breast reconstruction was 41% (95%CI 22%, 61%) and sensitivity for lymphadenectomy was 16% (95%CI 7%, 30%).

The PRoBe-SH was significantly more sensitive than open-ended patient-reported surgical history in



capturing the history of mastectomy sidedness, left lumpectomy sidedness, lymphadenectomy, breast reconstruction, native nipple sidedness (Figure 1). The specificity of nearly all surgical domains for the PRoBe-SH and open-ended patient-reported surgical

history was >90% (Figure 1). Positive and negative predictive values are shown in Table 2. The PRoBe-SH yielded a few false positive results (mastectomy-1, mastectomy sidedness-1, lumpectomy-1, lumpectomy sidedness-9, native nipple sidedness-2).

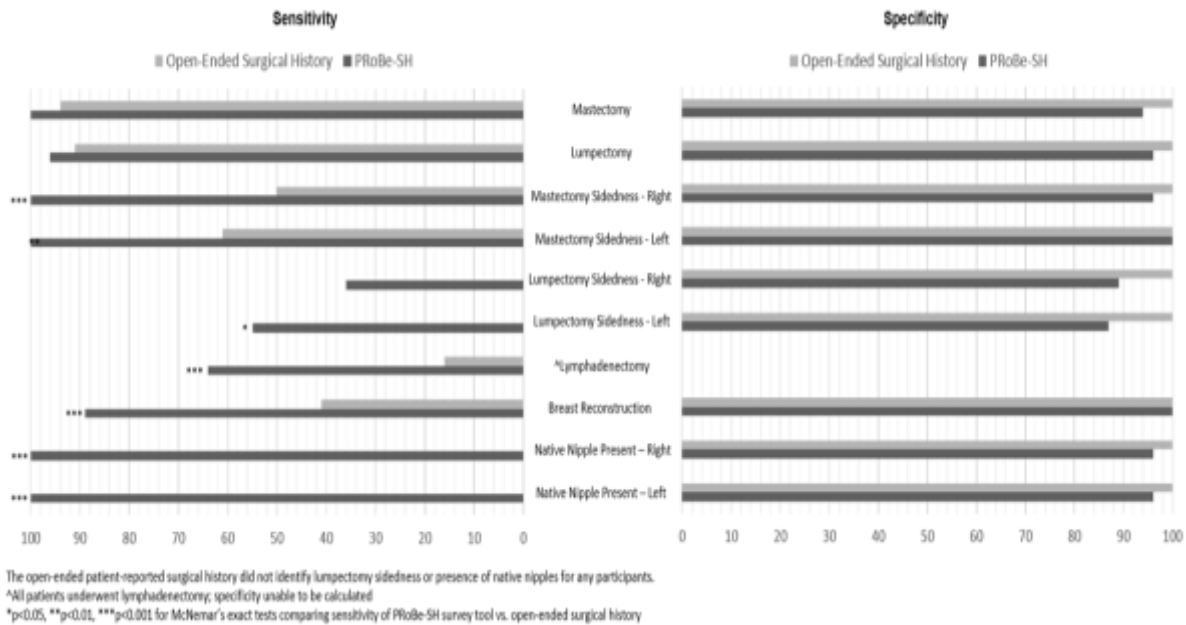


Figure 1. Sensitivity and Specificity of Close-Coded PRoBe-SH Survey Tool and Open-Ended Patient-Reported Surgical History

DISCUSSION

Accurate ascertainment of breast surgical history is important to the clinical care of and research involving patients with a history of breast cancer. Open-ended surgical history-taking is the prevailing standard in breast-related clinical care and research. Compared to the open-ended approach, we show that the structured, close-coded PRoBe-SH is a highly sensitive tool to accurately capture patients’ breast surgical history.

We find three prior studies that compared patient-reported breast surgery history with medical record data.^{10,11,15} Maunsell *et al.* (2004) reported high agreement (Kappa≥0.89) between patient surgical history elicited by structured telephone interviews and medical record data for history of breast surgery (yes/no), sidedness, type of mastectomy (total or partial), reconstruction, and axillary dissection among women with breast cancer (N=103, all<60 years old).¹¹ This study established the validity of self-reported breast cancer treatment history, including some aspects of breast surgery history. Similar to our findings, they reported high agreement for a wide range of aspects of breast surgical history. Unlike the PRoBe-SH, presence or absence of the native nipple was not ascertained.

Phillips *et al.* (2005) investigated the accuracy of self-reported medical history data in 895 women with

breast cancer using mailed, structured questionnaires which included history of mastectomy, lumpectomy, and removal of lymph nodes.¹⁵ They reported high agreement for history of mastectomy as compared to medical record data (Kappa=0.94), but lower agreement for lumpectomy (Kappa=0.58) and lymph node removal (Kappa=0.27). Their questionnaire included fewer aspects of breast surgical history than the PRoBe-SH, but was the first to establish that a self-administered, structured paper questionnaire was accurate for capturing broad aspects of breast cancer history.

Liu *et al.* (2010) assessed the level of agreement between self-report of breast cancer therapy and medical record data among 726 low income women in California with history of breast cancer using open-ended self-report questionnaires and structured telephone interviews.¹⁰ To our knowledge, this is the only similar study conducted in the United States and the first to evaluate self-report of breast cancer treatment in a population of low income women. Similar to the PRoBe-SH, this study found high agreement with history of mastectomy (Kappa=0.96) and lower agreement with lymphadenectomy (Kappa=0.51). In contrast to PRoBe-SH, they found lower agreement with lumpectomy (Kappa=0.72) and did not assess sidedness, reconstruction, or presence or absence of native nipples.



Building on this important prior work, we sought to develop a digital, self-administered, comprehensive survey tool that could accurately ascertain patients' breast cancer history without need for medical record review. Compared to prior work, our survey tool includes all aspects of surgical history previously investigated by the above authors, and is the first to include presence of native nipples as a domain of breast surgery history. While not previously investigated, we feel this is an important aspect of breast surgery with implications for quality of life after breast surgery¹⁶ as well as cosmesis and sexual function.¹⁷

To our knowledge, the PRoBe-SH is the first web-based survey tool to evaluate the accuracy of a close-coded, self-reported (rather than interviewer-administered) breast surgery history as compared to a gold standard. In contrast to structured telephone interviews or paper questionnaires, the PRoBe-SH tool is digitally self-administered and therefore more efficient and convenient for a wide range of patients with digital access. Our survey tool can be administered broadly, for example, in advance of a visit or while a patient is waiting to be seen, without reliance on research personnel to conduct telephone interviews or arrange document mailings.

Open-ended medical and surgical history-taking is commonplace in clinical care and research. To our knowledge, this study is the first to compare both a novel survey tool and open-ended breast surgical history with medical record data. We also compared the performance of the close-coded PRoBe-SH and open-ended surgical history and found the PRoBe-SH is significantly more sensitive than open-ended history for most domains of breast surgery history. Unlike open-ended questions, the structured, close-coded nature of the PRoBe-SH captures more aspects of breast surgical history and is highly sensitive when compared to the EMR. As expected, the specificity of the PRoBe-SH (the ability of the tool to correctly identify patients who did not have a given procedure) was 90-100% for most domains of breast surgical history. For domains with specificity < 100%, the PRoBe-SH yielded few false positive results, meaning a patient indicated via the PRoBe-SH that she underwent a procedure, but the EMR indicated otherwise. False positives most commonly resulted from a woman misremembering the side of a lumpectomy procedure. This finding is perhaps not surprising given that lumpectomy procedure is typically less invasive and yields lower morbidity relative to the other procedures queried.¹⁸ In contrast, the open-ended surgical history approach yielded no false positive reports.

In contrast to an open-ended approach (for example, "Please list all of the breast surgeries you

have had"), the PRoBe-SH tool presents patients with a comprehensive list of breast procedures and asks them to endorse all that apply. This approach could generate false positives by error if a patient accidentally checks a box she did not intend to select, for example. It is also possible that presentation of a procedure list may be more likely than an open-ended approach to capture a woman's misunderstanding or lack of understanding or knowledge about procedures involving her breasts. The PRoBe-SH is unable to account for inaccuracy due to patient knowledge or understanding gaps. Physical examination and conversation with the patient could be used in the clinical setting to corroborate PRoBe-SH findings.

While the PRoBe-SH was significantly more sensitive than open-ended history for identifying the history of lymphadenectomy, the sensitivity for lymphadenectomy was lower than that of many other domains of breast surgical history. The study by Liu *et al.*, referenced above, also found lower agreement of patient-reported lymphadenectomy or axillary dissection and medical record data (Kappa statistic=0.51) compared to other breast surgical domains. The authors reported those with at least one co-morbidity and those who reported receiving more information from their physicians were more likely to accurately report lymphadenectomy, while Asian/Pacific Islander and Latina women were less likely, compared to white women, to report this history.¹⁰ Our finding may be due to lack of patient understanding of lymphadenectomy as a separate component of breast surgical history. This explanation is supported by the findings of Lui *et al.* in which patients reporting they received more information from their physicians were significantly more likely to accurately report they underwent lymphadenectomy. Explaining lymphadenectomy and use of patient-friendly terminology in medical record documentation may be an area of targeted improvement for counseling of patients undergoing breast surgical procedures. Cancer organizations, such as the American Cancer Society, provide resources explaining aspects of breast surgery, including lymphadenectomy, that may be helpful for patient counseling.¹⁹

Our findings should be interpreted in the context of certain limitations. The study sample was drawn from a prospective registry of English-speaking patients at one institution. Our sample may differ from other patient populations in terms of key sociodemographic or health characteristics. Further validation is needed for non-primary English speakers. Prior research suggests that additional testing of the tool with a broader diversity of racial and ethnic groups may be important for reliability.²⁰ Though low overall, the possibility of false positive



results (especially for lumpectomy sidedness) is important to consider when using the PRoBe-SH. Although we developed the survey with attention to literacy level, we neither assessed nor had access to patient literacy or education level. Additionally, our sample size did not permit investigation of factors that might impact accuracy of our survey instrument.

Open-ended patient-reported history-taking is commonly used to ascertain patients' past medical and surgical histories. The complexity of breast surgical history – including the variety and temporality of procedures over a woman's life course - may hinder women from accurately reporting their surgical history without a structured approach. While EMR data are the gold standard, complete review of all patients enrolled in research studies or in some contexts of clinical care may not be feasible. Although EMR systems have been widely adopted in the U.S., the majority of women globally who have undergone breast surgeries are cared for in contexts that still rely on paper documentation or lack integration, especially of historical documents, across EMR systems.¹³

CONCLUSION

The PRoBe-SH is a comprehensive, highly sensitive alternative to obtaining an open-ended breast surgical history when comprehensive, historical EMR data are not available.

ABBREVIATIONS

PRoBe-SH: patient-reported breast surgery history

EMR: Electronic medical record

BCT: Breast-conserving therapy

PRISM: Program of Integrative Sexual Medicine

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CI: Confidence Interval

IRB: Institutional Review Board

ETHICAL CONSIDERATIONS

The study was approved by the University of Chicago Institutional Review Board (IRB). Informed consent was obtained from all individual participants included in the study.

CONFLICTS OF INTEREST

Dr. Lindau has financial interests unrelated to the subject matter of this study. She discloses that she and her spouse own healthcare-related stock and mutual funds managed by third parties and holds equity in a healthcare company unrelated to the subject of this study. She is a contributor to UpToDate, Inc. which provides royalty payments to the University of Chicago. Janelle Sobecki, Emily Abramssohn, Alexes Hazen, Jennifer Makelarski, Chenab Navalkha, and Kristen Wroblewski declare they have no conflict of interest.

DATA AVAILABILITY

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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