Effect of Screening Result on Waiting Times to Assessment and **Breast Cancer Diagnosis**

Results from the Ontario Breast Screening Program

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ABSTRACT

Background: The effect of severity of screening result on delays to diagnosis has primarily been examined for mammographic abnormalities. This study will examine delays to assessment and diagnosis for women with an abnormal mammogram compared to women with an abnormal clinical breast examination (CBE) or abnormal CBE and mammogram.

Methods: Using data routinely collected by Ontario Breast Screening Program (OBSP), 12,675 women aged 50 to 69 with an abnormal screening result between January 1, 2000 and December 31, 2000 were followed prospectively to the completion of their assessment process. Median waiting times from abnormal screen to first assessment procedure and diagnosis were compared by modality of referral and among women with a breast cancer diagnosis by prognostic features.

Results: The median waiting time to first assessment and to diagnosis was significantly longer for women with only a clinical abnormality compared to women with a mammographic abnormality. In addition, women diagnosed with cancers of larger size had longer delays when the abnormality was detected only clinically. However, women referred by both modalities had significantly shorter waiting times to first assessment procedure and to diagnosis of poor prognosis cancers compared to women referred by mammography alone.

Interpretation: Women with an abnormal CBE and mammogram are assessed more promptly and have shorter diagnostic times. However, women with only a CBE abnormality had delays to diagnosis as a result of longer waiting times to first assessment procedure. Integration of the OBSP with assessment centres should improve times to diagnosis irrespective of modality of referral.

MeSH terms: Breast cancer; mass screening; mammography; physical examination; time factors; prognosis

La traduction du résumé se trouve à la fin de l'article.

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vidence of a reduction in breast cancer mortality rate through screening ∠comes from the results of several randomized controlled trials.¹⁻³ A national workshop in Canada recommended that women aged 50 to 69 be offered and encouraged to participate in an early detection program operated through dedicated screening centres with appropriate followup of abnormal findings through an effective referral system.⁴ Several studies have shown that a false positive mammogram result can cause anxiety, distress and intrusive thoughts, which may persist for several months and/or years after completion of assessment.⁵⁻⁷ In addition, a delay to diagnosis of greater than 6 months for women with screen-detected breast cancer is associated with increasing risk of lymph node metastases and larger tumour size.^{8,9}

Some studies have suggested that physicians may expedite assessment depending on the degree of suspicion of the cancer. This result has been reported by the shorter delays in diagnosis experienced among women who had a biopsy with a diagnosis of cancer and among women with 'high suspicion' mammograms classified primarily by radiologists.8-12 Only a few studies have examined the influence of delays in diagnosis resulting from an abnormal clinical breast examination (CBE) result for asymptomatic women. These studies have found that women with an abnormal CBE and normal mammogram had longer diagnostic intervals and were less likely to receive adequate diagnostic workup compared to women with an abnormal mammogram.^{10,13} The effect of these delays on prognostic factors is uncertain.

The Ontario Breast Screening Program (OBSP), under the auspices of Cancer Care Ontario, has operated since 1990 to deliver a population-based breast screening program. In Ontario, as in most of Canada, diagnostic assessment is usually co-ordinated by the family physician and women are assessed through community diagnostic facilities outside of the screening program.14 As the OBSP offers both CBE and mammography, it provides a unique opportunity to examine if the diagnostic process differs by modality of referral.

The purpose of this cohort study was to compare the waiting times to first assessment procedure and to diagnosis by modality of referral for women 50 to 69 years of age with an abnormal result who

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attended the OBSP. Among women with a breast cancer diagnosis, waiting times were compared further by prognostic features.

METHODS

Of the 115,835 women screened at OBSP between January 1, 2000 and December 31, 2000, 12,675 (10.9%) had an abnormal screening result and were eligible for the study. Women who did not undergo the assessment procedures studied (n=28), did not consent to have their assessment data sent to OBSP (n=11) or were lost to follow-up (n=292) were excluded.

A complete description of the operation of OBSP has been previously published.¹⁵ The OBSP offers eligible women 50 years or older biennial screening consisting of two-view mammography and CBE by a nurse. Women are not eligible if they have had a prior history of breast cancer or augmentation mammoplasty or if they currently have symptoms of breast disease. The data analyzed for this study were available from information routinely collected on all women screened within the OBSP. Abnormal screening results are recorded as "recommend clinical assessment by physician" by the nurse examiner and "needs additional evaluation by imaging and/or surgical consultation" by the radiologists. Both the woman in question and her physician are notified of the screening result by letter, however the nurse examiner informs the woman of the clinical abnormality at the time of the visit and recommends she visit her physician.

The OBSP receives details about assessment procedures and their outcomes either through copies of reports provided to the screening centres or by requesting them from family physicians. Data collected from this report include all assessment procedures, procedure dates, and final result of each procedure. Information on women diagnosed with breast cancers is obtained either by the regional staff during the recall process or through record linkage with the Ontario Cancer Registry. A detailed coding manual and related data forms allow for standardization of data collection and entry across the province. Ethical approval to conduct the current study was received from the University of Toronto.

The number of weeks to complete three time intervals starting from an abnormal

TABLE I

Characteristics of Women Aged 50-69 with an Abnormal Screening Result by Modality of Referral, OBSP 2000

Characteristics	CBE* Alone	Mammography Alone	CBE and Mammography	Total
	N (%)	N (%)	N (%)	N (%)
Age of women assessed†				
50-59	2,165 (59.0)	4,948 (62.2)	662 (63.4)	7,775 (61.3)
60-69	1,507 (41.0)	3,011 (37.8)	382 (36.6)	4,900 (38.7)
Family history‡				
Yes	655 (17.8)	1,056 (13.3)	154 (14.8)	1,865 (14.7)
No	3,017 (82.2)	6,903 (86.7)	890 (85.2)	10,810 (85.3)
Breast density [§]				
<75%	3,065 (84.0)	7,105 (90.8)	860 (83.7)	11,030 (88.2)
<u>></u> 75%	585 (16.0)	720 (9.2)	167 (16.3)	1,472 (11.8)
First assessment procedure				
First physician visit	2,083 (57.2)	190 (2.4)	95 (9.3)	2,368 (18.8)
First imaging [¶]	925 (25.4)	7,641 (96.7)	892 (86.9)	9,458 (75.2)
First surgical consultation	633 (17.4)	72 (0.9)	40 (3.9)	745 (5.9)
Diagnosis				
Benign	3,635 (99.0)	7,504 (94.3)	870 (83.3)	12,009 (94.7)
Breast cancer	37 (1.0)	455 (5.7)	174 (16.7)	666 (5.3)
Type of breast cancer				
DCIS*	2 (5.4)	96 (21.1)	12 (6.9)	110 (16.5)
Invasive	35 (94.6)	359 (78.9)	162 (93.1)	556 (83.5)
Invasive tumour size**				
<10 mm	10 (29.4)	176 (49.2)	36 (22.2)	222 (40.1)
>10 mm	24 (70.6)	182 (50.8)	126 (77.8)	332 (59.9)
Lymph node status**				
[′] Negative	25 (73.5)	273 (83.2)	100 (66.2)	398 (77.6)
Positive	9 (26.5)	55 (16.8)	51 (33.8)	115 (22.4)
rosuve	9 (20.5)	55 (10.0)	51 (55.0)	113 (22.4)

* CBE = clinical breast examination; DCIS = ductal carcinoma in situ

† 292 women (2.3%) did not have complete follow-up information

‡ mother, sister or daughter with breast cancer

§ 173 women had missing breast density information

|| 104 women did not have a physician visit, imaging or surgical consultation before their first biopsy

¶ Includes diagnostic mammogram or breast ultrasound

** Invasive cancers only: tumours with unknown size excluded, tumours with unknown nodal status excluded

TABLE II

Duration of Times to First Assessment (in Weeks) for Women Aged 50-69 with an Abnormal Screening Result by Modality of Referral, OBSP 2000

Assessment Interval	Ν	Median	25th-75th percentile
Abnormal screen to first assessment* procedure Procedure type	12,571	2.0	1.1-3.4
First imaging	9,458	1.9	1.1-3.1
First physician visit	2,368	2.3§	1.4-4.0
First surgical consultation	745	3.3§	1.1-6.4
Modality			
Mammography alone	7,903	1.9	1.1-3.0
CBE† alone	3,641	2.6 [§]	1.3-4.7
CBE and mammography	1,027	1.3 [§]	0.9-2.6
First imaging			
Mammography alone	7,641	1.9	1.1-3.0
CBE alone	925	2.7§	1.1-4.7
CBE and mammography	892	1.3§	0.9-2.4
First physician visit			
Mammography alone	190	1.9	1.1-2.7
CBE alone	2,083	2.4§	1.4-4.3
CBE and mammography	95	1.1‡	0.9-2.6
First surgical consultation			
Mammography alone	72	5.0	3.0-7.9
CBE alone	633	3.1 [§]	1.1-6.3
CBE and mammography	40	2.8 [§]	1.1-4.3

For comparisons by type of procedure, imaging is the reference group.

For comparisons by modality, mammography alone is the reference group.

* 104 women did not have a physician visit, imaging or surgical consultation before their first

- biopsy
- CBE = clinical breast examination

‡ p≤0.01 § p≤0.0001

screen was examined. An abnormal screen was categorized by modality of referral: mammography alone (abnormal mammog-

raphy and normal CBE), CBE alone (abnormal CBE, normal mammography), and CBE and mammography (abnormal

TABLE III

Duration of Times to Final Diagnosis (in Weeks) for Women Aged 50-69 with an Abnormal Screening Result by Modality of Referral, OBSP 2000

Diagnostic Interval	Ν	Median	25th -75th percentile
Abnormal screen to diagnosis	12,675	3.0	1.6-7.0
Benign diagnosis			
No biopsy	10,386	2.7	1.3-5.7
Yes biopsy	1,623	7.1	3.9-11.0
Breast cancer diagnosis (biopsy)*	666	4.7	2.6-8.0
Modality			
Mammography alone	7,959	2.7	1.3-6.0
CBE† alone	3,672	4.3	2.1-9.0
CBE and mammography	1,044	3.1‡	1.3-7.4
Benign diagnosis (no biopsy)	6 160	0.1	1110
Mammography alone	6,468	2.1	1.1-4.3
CBE alone	3,237	4.0	2.0-8.4
CBE and mammography	681	2.4	1.1-6.6
Benign diagnosis (biopsy)	1.026	7.0	11100
Mammography alone	1,036	7.3	4.1-10.9
CBE alone	398	7.4	3.7-12.7
CBE and mammography	189	6.0 [§]	2.4-9.6
Breast cancer diagnosis (biopsy)	455	4.9	2.9-8.1
Mammography alone CBE alone	435	4.9 7.6 [§]	5.9-14.9
	174	3.9	1.9-5.9
CBE and mammography	1/4	3.9"	1.9-3.9

For comparisons by biopsy, no biopsy is the reference group.

For comparisons by modality, mammography alone is the reference group.

Compared to those with a benign diagnosis and who had a biopsy

CBE = clinical breast examination

p≤0.001

p<u><</u>0.0001

TABLE IV

Duration of Times to Breast Cancer Diagnosis (in Weeks) for Women Aged 50-69 by Modality of Referral, OBSP 2000

Diagnostic Interval	Ν	Median	25th -75th percentile
Type of breast cancer			
Invasive	556	4.6	2.5-7.3
DCIS*	110	6.0	3.0-11.1
Invasive tumour size†			
≤10 mm	222	4.9	2.3-7.7
>10 mm	332	4.3	2.6-7.1
Lymph node status†			
Ńegative	398	4.3	2.3-6.9
Positive	115	4.6	2.7-8.1
Modality			
Invasive breast cancer			
Mammography alone	359	4.6	2.6-7.4
CBE* alone	35	7.6	5.9-14.9
CBE and mammography	162	3.7§	1.9-5.9
<u>≤</u> 10 mm			
Mammography alone	176	4.7	2.4-7.4
CBE alone	10	7.3	5.9-8.6
CBE and mammography	36	4.3	1.9-8.2
>10 mm	102		2077
Mammography alone	182	4.4	2.9-7.7
CBE alone	24	8.4¶	5.5-16.6
CBE and mammography	126	3.6 [§]	1.9-5.1
Negative	272	4.2	2267
Mammography alone	273	4.3	2.3-6.7
CBE alone	25	7.0¶	5.9-9.3
CBE and mammography	100	3.9	2.0-6.4
Positive		F 1	2200
Mammography alone CBE alone	55	5.1	3.3-9.0
	9 51	16.0‡ 3.1	6.0-21.9 1.9-5.1
CBE and mammography	51	5.1"	1.9-5.1

For comparisons by type of breast cancer, invasive is the reference group.

For comparisons by invasive tumour size, ≤ 10 mm is the reference group.

For comparisons by lymph node status, lymph node negative is the reference group.

For comparisons by modality, mammography alone is the reference group.
* DCIS = ductal carcinoma in situ; CBE = clinical breast examination

Invasive cancers only: tumours with unknown size excluded, tumours with unknown nodal status excluded

- p≤0.05
- p<0.01

 $p \le 0.001$

p<0.0001

CBE, abnormal mammography). The end points for the time intervals were defined as follows: first assessment procedure end point was first date of the physician visit, diagnostic mammogram, breast ultrasound, or surgical consultation; benign diagnosis end point was last assessment procedure before a recommendation to return to screening or to return to early recall; and breast cancer diagnosis end point was first pathology report. Pathological diagnosis of primary invasive breast cancer of any histological type or ductal carcinoma in situ was considered a breast cancer diagnosis. Time to invasive cancer diagnosis was stratified further by tumour size (greater than or less than or equal to 10 mm) and presence of axillary lymph node metastases categorized as either positive (one or more lymph nodes involved) or negative (no lymph node involvement).

Length of time between the abnormal screening result and assessment procedures or final diagnosis was calculated in weeks for all study subjects with valid dates reported. Measure of central tendency was estimated using sample medians to examine the effect of anticipated skewness in the data and the variability observed was described using the 25th and 75th percentiles. All significance tests were twosided and used the Wilcoxon rank-sum test for 2-way comparisons and Kruskal-Wallis test for 3-way comparisons.¹⁶ Statistical analyses were performed using SAS System version 6.12.17

RESULTS

Of the 12,967 women eligible for the study, 12,675 (97.7%) were followed prospectively to the completion of their assessment (Table I). A higher percentage of women referred by CBE alone or by both modalities had a breast density greater than 75%. More women referred by CBE alone also had a family history of breast cancer, had a physician visit as their first assessment procedure or had a benign diagnosis. Women referred by both mammography and CBE were more likely to have an invasive breast cancer diagnosis of greater size and with lymph node metastases

Women having a surgical consultation or physician visit as their first assessment

p≤0.05

procedure waited significantly longer than women having an imaging procedure (Table II). Compared to women referred by mammography alone, women referred by CBE alone had a significantly longer median waiting time to first assessment and women referred by CBE and mammography had a significantly shorter median waiting time. This pattern was similar for women having imaging or a physician visit as their first assessment procedure.

Women with a benign diagnosis without a biopsy had the shortest median waiting times to diagnosis (Table III). Women referred by CBE alone had significantly longer waiting times to diagnosis compared to women referred by mammography alone if they had a benign diagnosis without a biopsy or a breast cancer diagnosis. By comparison, women referred by both CBE and mammography who had a biopsy had a significantly shorter waiting time to both benign and breast cancer diagnoses.

Among women with a cancer diagnosis, the median waiting time was significantly shorter for women with a diagnosis of invasive breast cancer compared to women with a diagnosis of ductal carcinoma in situ (Table IV). For women with a diagnosis of invasive breast cancer, the median waiting time did not differ significantly by tumour size or nodal status. However, some differences were observed by modality of referral. Women referred by both modalities had significantly shorter waiting times to diagnosis of invasive tumours greater than 10 mm or with lymph node involvement while women referred by CBE alone had significantly longer median waiting times to diagnosis of larger size tumours compared to women referred by mammography alone.

DISCUSSION

Our study along with one other found that women referred by CBE alone had significantly longer waiting times to diagnosis.¹⁰ Our study also found that these women waited on average longer for their first assessment procedure. As the recommendation in OBSP for an abnormal CBE is clinical assessment by a physician, most of the women with a CBE referral had a physician visit or surgical consultation as their first assessment procedure. This may explain the delays in assessment as these procedures had significantly longer waiting times as compared to imaging procedures. Therefore, referral of women with an abnormal CBE back to their family physician may increase their time to diagnosis. In addition, normal mammograms of palpable breast masses may provide a false sense of security for the physician and woman and possibly delay further assessment and diagnosis.

The shorter waiting times to first assessment for women with an abnormal mammogram may have occurred as many of the women screened at OBSP have further diagnostic imaging arranged directly from the screening centre with permission from the family physician. Shorter diagnostic intervals have also been reported by other Canadian breast screening programs for women with an abnormal mammogram who had facilitated referral directly from the screening centre to a diagnostic facility.¹⁸⁻²⁰ In the Manitoba Breast Screening Program (MBSP) that offers both CBE and mammography, women with an abnormal CBE regardless of mammogram result were referred directly to a comprehensive breast health centre.²⁰ The MBSP found that their direct referral process significantly reduced the time to diagnosis independent of modality of referral.

A few studies have found that among women with breast cancer, those with mammogram results suggestive of malignancy had much shorter diagnostic intervals.⁸⁻¹⁰ These results suggest that physicians may expedite assessment depending on the degree of suspicion. This may also explain our finding among women with breast cancer of a significantly shorter time to diagnosis for those diagnosed with invasive breast cancer as compared to ductal carcinoma in situ. Our study also found that women with abnormalities on both their mammogram and CBE considered to be high suspicion screens had significantly shorter diagnostic times. In addition, these women with high suspicion screens had shorter waiting times for diagnoses of breast cancers with a poor prognosis. Interestingly, women diagnosed with cancers of larger size had longer delays when the abnormality was detected only clinically.

Canadian screening programs may be at a disadvantage compared with national screening programs in other countries where the diagnostic process is undertaken at specialized assessment centres affiliated with the screening program.²¹ Concerns regarding identified delays during the assessment process and poor integration of screening and diagnosis prompted the setting of national timeliness targets to be reached for 90% of the women with abnormal screens.²² During the time period of this study, OBSP did not meet these targets with 75.7% of the women given a diagnosis within 5 weeks without a surgical biopsy and 53.9% receiving a diagnosis within 7 weeks with a surgical biopsy.²³ Recent efforts have been made to improve the assessment process through integration with comprehensive breast assessment affiliates to which OBSP women can be referred directly. Further analysis will examine if these efforts have improved waiting times.

One of the limitations of this study is that patient and/or physician reasons for delays in waiting times could not be assessed. Another limitation is that complete follow-up information was unavailable for 2.3% of the women in this study and that women referred by CBE alone were significantly more likely to have incomplete follow-up information. Although this may have led to slightly underestimated median waiting times for them, the patterns of distributions of median waiting times observed would likely not have been appreciably altered.

In summary, women with an abnormal CBE and mammogram are assessed more promptly and have shorter waiting times to diagnosis than those with clinical findings alone. However, women with only a CBE abnormality had delays to diagnosis as a result of longer waiting times to first assessment procedure. These delays could in part be explained by the practice of referring these women back to their family physicians. These women were also found to have delays to diagnoses of poor prognosis cancers. As the OBSP increases its efforts for co-ordinating follow-up of abnormal screens, waiting times should begin to show improvements independent of modality of referral.

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RÉSUMÉ

Contexte : Le rapport entre la gravité du résultat d'un test de dépistage et le délai d'obtention d'un diagnostic a surtout été étudié pour les mammographies anormales. Nous avons étudié les délais d'évaluation et de diagnostic des femmes ayant eu des résultats anormaux à une mammographie, et nous les avons comparés aux délais des femmes ayant eu des résultats anormaux à un examen clinique des seins (ECS), ou à un ECS combiné à une mammographie.

Méthode : À l'aide des données recueillies systématiquement par le Programme ontarien de dépistage du cancer du sein, nous avons suivi rétrospectivement 12 675 femmes âgées de 50 à 69 ans ayant obtenu des résultats anormaux entre le 1^{er} janvier et le 31 décembre 2000 jusqu'à l'aboutissement de leur processus d'évaluation. Nous avons comparé les délais d'attente médians entre le test de dépistage et la première évaluation et le diagnostic, d'abord selon le mode d'acheminement des patientes, puis, pour les femmes ayant reçu un diagnostic de cancer du sein, selon leur pronostic.

Résultats : Le délai d'attente médian avant la première évaluation et le diagnostic était sensiblement plus long pour les femmes ayant eu un ECS anormal que pour celles ayant eu une mammographie anormale. De plus, les femmes chez qui on avait diagnostiqué des cancers avancés attendaient plus longtemps lorsque l'anomalie avait été décelée par ECS seulement. Toutefois, les femmes dirigées après un ECS combiné à une mammographie attendaient sensiblement moins longtemps avant la première évaluation, et donc avant le diagnostic de cancer avancé, que les femmes dirigées après une mammographie seulement.

Interprétation : Les femmes dont l'ECS et la mammographie sont tous les deux anormaux sont évaluées plus rapidement, et elles attendent moins longtemps leur diagnostic. Pour les femmes n'ayant qu'un ECS anormal, le délai de diagnostic est plus long, du fait qu'elles attendent plus longtemps avant leur première évaluation. En intégrant le Programme ontarien de dépistage du cancer du sein dans les centres d'évaluation, on devrait pouvoir améliorer les délais de diagnostic, quel que soit le mode d'acheminement des patientes.