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Improving patient flow and timeliness in the diagnosis and management of breast abnormalities: the impact of a rapid diagnostic unit

J.M. Racz MD MBA,* C.M.B. Holloway MD PhD,†‡ W. Huang BSc MD, and N.J. Look Hong MD MSc†‡

ABSTRACT

Background Efforts to streamline the diagnosis and treatment of breast abnormalities are necessary to limit patient anxiety and expedite care. In the present study, we examined the effect of a rapid diagnostic unit (RDU) on wait times to clinical investigations and definitive treatment.

Methods A retrospective before–after series, each considering a 1-year period, examined consecutive patients with suspicious breast lesions before and after initiation of the RDU. Patient consultations, clinical investigations, and lesion characteristics were captured from time of patient referral to initiation of definitive treatment. Outcomes included time (days) to clinical investigations, to delivery of diagnosis, and to management. Groups were compared using the Fisher exact test or Student t-test.

Results The non-RDU group included 287 patients with 164 invasive breast carcinomas. The RDU group included 260 patients with 154 invasive carcinomas. The RDU patients had more single visits for biopsy (92% RDU vs. 78% non-RDU, $p < 0.0001$). The RDU group also had a significantly shorter wait time from initial consultation to delivery of diagnosis (mean: 2.1 days vs. 16.7 days, $p = 0.0001$) and a greater chance of receiving neoadjuvant chemotherapy (37% vs. 24%, $p = 0.0106$). Overall time from referral to management remained statistically unchanged (mean: 53 days with the RDU vs. 50 days without the RDU, $p = 0.3806$).

Conclusions Introduction of a RDU appears to reduce wait times to definitive diagnosis, but not to treatment initiation, suggesting that obstacles to care delivery can occur at several points along the diagnostic trajectory. Multipronged efforts to reduce system-related delays to definitive treatment are needed.

Key Words Breast cancer, diagnosis, wait times, efficiencies

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INTRODUCTION

Breast cancer is the 2nd most common cause of cancer death for women in Canada[1]. In the province of Ontario, in 2014, an estimated 24,400 women were diagnosed with breast cancer, and 5100 died of their disease[1]. The institution of breast cancer screening programs has increased the detection of early-stage cancers, albeit with a debatable effect on survival[2]. As a result, the number of individuals referred for assessment has surged, with a concurrent strain on health care resources. Clinicians, health care administrators, and policymakers aim collectively to triage patients in a timely way, but building capacity with stagnant or shrinking resources is an ongoing struggle. The resultant delay to completion of a diagnostic evaluation and treatment initiation, for those who require it, could have unintentional clinical and psychological impacts.

No benchmarks delineating acceptable wait times from diagnosis to treatment are currently established for cancer care in Ontario. For breast cancer, this phase begins with the first abnormal mammogram or symptom, which can occur several weeks or months before investigation is initiated and which is not documented administratively. After diagnosis of the index lesion, additional

Correspondence to: Nicole J. Look Hong, Sunnybrook Health Sciences Centre, 2075 Bayview Avenue, Room T2-102, Toronto, Ontario M4N 3M5.
E-mail: n.lookhong@utoronto.ca **DOI:** http://dx.doi.org/10.3747/co.23.3017

investigations such as mammography, ultrasonography, magnetic resonance imaging (MRI), further biopsies, assessment of medical comorbidities, and referral to other oncologic and non-oncologic specialists could be required to complete the diagnostic assessment or to plan treatment. Those events influence timely access to care, preceding or adding to the administratively recorded wait time at an individual institution. Evidence demonstrates that this period of diagnostic uncertainty is fraught with significant distress and anxiety for the patient, particularly as the diagnostic phase lengthens[3–5].

To expedite the diagnostic assessment of breast abnormalities and to improve the quality of patient-centred care, Sunnybrook Health Sciences Centre introduced a breast rapid diagnostic unit (RDU) in May 2011. Before the RDU, patients with a suspicious breast lesion were assessed by a multidisciplinary team, often requiring multiple visits on separate occasions.

The goal of the RDU is to provide rapid assessment and diagnosis for individuals with suspicious abnormalities (Breast Imaging Reporting and Data System 4 or 5) on mammography, breast ultrasonography, or clinical examination, thereby reducing not only the time that the patient waits for results, but also the number of outpatient appointments attended. Developed using the Lean methodology[6], the RDU is a carefully choreographed effort involving radiologists, pathologists, surgeons, nurses, and administrative personnel that streamlines the performance of common breast investigations (for example, mammography, ultrasonography), with the capacity for clinical judgment and individualization of patient care. An essential element of the RDU is the central involvement of a dedicated nurse navigator to guide each individual through the assessment process. Most patients referred to the breast RDU receive 2 appointments to achieve and deliver a diagnosis (Figure 1). The entire process—from referral, to evaluation, to delivery of results—typically occurs within 2–8 days.

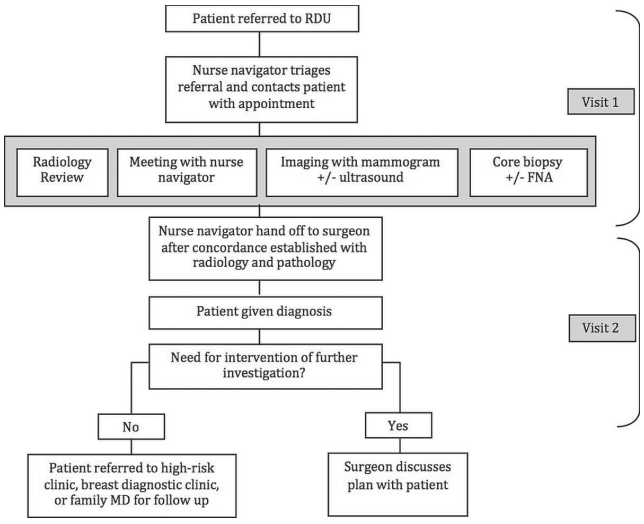

FIGURE 1 Clinic schema for the Rapid Diagnostic Unit (RDU). FNA = fine-needle aspiration; MD = physician.

The primary goal of the present study was to analyze the time from referral of the patient to the cancer centre to definitive management, documenting all events completed before treatment initiation. We sought to determine whether, compared with the previous evaluation system, the introduction of the RDU altered patient flow and time to definitive management.

METHODS

Patient Population

This descriptive retrospective before-and-after study considered all patients at the Odette Cancer Centre (OCC) who met the inclusion criteria. The OCC is Sunnybrook Health Sciences Centre's dedicated outpatient cancer facility; it is ranked the 2nd-largest comprehensive cancer centre in Canada and the 6th-largest in North America. The OCC supports more than 229,000 patient visits annually, including 2000 new patient consultations for breast-related concerns. Cancer patients are referred at varying times throughout their disease process, and although the OCC has a full spectrum of diagnosis and treatment services, many patients undergo surgery at neighboring institutions and come to the OCC strictly for multidisciplinary adjuvant care. The latter patients were not included in the present study.

The two patient populations that were included were non-RDU patients and RDU patients. Two 1-year periods were chosen for this comparison of the volume of patients assessed before and after initiation of the RDU. Subjects in the non-RDU group were identified in an archival database at the OCC that captures all patients referred to and evaluated by the breast program. That group included all patients evaluated between 1 January 2010 and 31 December 2010. A separate prospectively maintained database (Breast Biomatrix) contains all patients referred to the RDU since its inception in May 2011. The RDU group comprised all patients evaluated by the RDU between 1 January 2012 and 31 December 2012. The 7-month gap between RDU inception and the start of data analysis was used to ensure that the operational logistics of the RDU were optimized. Patients were excluded if they were less than 18 years of age, had a non-breast synchronous malignancy, or received all or part of their diagnostic evaluation outside the OCC.

Data Collection and Analysis

Research ethics board approval was obtained from Sunnybrook Health Sciences Centre. Cross-referencing was performed using the medical record number, and data were then de-identified for analysis. Clinical and pathologic patient and tumour data were collected (Table I) for the RDU and non-RDU groups. Table II defines wait times.

Patient and tumour characteristics, resource utilization, and wait times were compared for the non-RDU and RDU groups. The chi-square test was used to compare categorical variables, and the Student t-test was used to compare continuous variables. Mean wait times were calculated for each group and compared using the Student t-test, assuming parametric distributions. If parametric distribution was not observed, the Mann–Whitney U-test was used for comparisons. A 2-sided p value of 0.05 was considered significant.

TABLE I Patient characteristics, clinicopathologic variables, and resource utilization for patients with invasive breast carcinoma before and after initiation of the Rapid Diagnostic Unit (RDU)

Variable	Patients seen ...		*p* Value
	Before RDU	After RDU	
Patients (*n*)	164	154	
Age at diagnosis (years)			
Mean	59	63	0.0135
Range	27–90	24–93	
Size of lesion [*n* (%)]			
<2 cm	68 (41.5)	62 (40.3)	0.909
2–5 cm	71 (43.3)	74 (48.1)	0.431
>5 cm	25 (15.2)	17 (11.0)	0.321
Laterality [*n* (%)]			
Unilateral	158 (96.3)	150 (97.4)	0.751
Bilateral	6 (4.7)	4 (2.6)	
Lymph node involvement [*n* (%)]			
None	113 (68.9)	97 (63.0)	0.288
Clinically palpable[a]	30 (18.3)	29 (18.8)	0.999
Radiologically detected[a]	21 (12.8)	28 (18.2)	0.215
Distant metastatic spread [*n* (%)]			
Unknown	0	4 (2.4)	0.054
No	157 (95.7)	134 (87.0)	0.008
Yes	7 (4.3)	16 (10.4)	0.050
Tumour morphology [*n* (%)]			
Invasive ductal	140 (85.4)	138 (89.6)	0.311
Invasive lobular	24 (14.6)	16 (10.4)	
Method of diagnosis [*n* (%)]			
Fine-needle aspiration	3 (1.8)	1 (<1.0)	0.623
Core biopsy	85 (51.8)	84 (54.5)	0.654
Fine-needle aspiration and core biopsy (same visit)	35 (21.3)	54 (35.1)	0.009
Multiple visits	41 (25.0)	15 (9.7)	0.0004
Total biopsies [*n* (%)]			
1	124 (75.6)	139 (90.3)	0.601
2	34 (20.7)	13 (8.4)	0.003
3	6 (3.7)	2 (1.3)	0.285
Resource utilization [*n* (%)]			
CT imaging	46 (28.0)	56 (36.4)	0.120
Bone scan	45 (27.4)	43 (27.9)	0.999
Magnetic resonance imaging	32 (19.5)	60 (39.0)	0.0002
MUGA imaging	20 (12.2)	39 (25.3)	0.004
Repeat biopsy	45 (27.4)	4 (2.6)	0.0001
Consultations [*n* (%)]			
Medical oncology	48 (29.3)	77 (50.0)	0.0002
Radiation oncology	16 (9.8)	52 (33.8)	0.0001
Anesthesia	47 (28.7)	34 (22.1)	0.1988
Plastic surgery	4 (2.4)	9 (5.8)	0.1599
Social work	2 (1.2)	7 (4.5)	0.0953
Psychiatry	2 (1.2)	3 (1.9)	0.6761
Initial management [*n* (%)]			
Surgery	121 (73.8)	80 (51.9)	0.0001
Chemotherapy	39 (23.8)	57 (37.0)	0.011
Radiation	1 (<1.0)	1 (<1.0)	0.999
Palliative chemotherapy	2 (1.2)	9 (5.8)	0.031
Palliation[b]	0	1 (<1.0)	0.484
No active treatment	0	0	0
Unknown	1 (<1.0)	6 (3.9)	0.012

[a] Confirmed in fine-needle aspirate.
[b] Care that aims to optimize the comfort, function, and social support of a patient and family when illness is incurable (definition adapted from the European Society for Medical Oncology).
CT = computed tomography; MUGA = multigated acquisition scan.

TABLE II Waits for pre-defined intervals for patients with invasive breast carcinoma before and after initiation of the Rapid Diagnostic Unit (RDU)

Wait ID	Interval	Wait time (days)		*p* Value
		Mean	SD	
1	Referral to consultation[a]			
	Before RDU	8.2	7.5	0.051
	After RDU	9.9	8.0	
2	Consultation to diagnosis			
	Before RDU	16.7	17.8	0.0001
	After RDU	2.1	1.84	
3	Diagnosis to IHC[b]			
	Before RDU	34.2	27.3	0.001
	After RDU	7.9	17.5	
4	IHC to management			
	Before RDU	32.8	34.5	0.3562
	After RDU	36.8	29.0	
5	Overall referral to management			
	Before RDU	50.1	33.4	0.3806
	After RDU	53.1	29.5	

[a] "Consultation" refers to patient visit 1 within the RDU schema (after RDU) *or* the first physician consultation (before RDU).
[b] Calculated only for patients with IHC available before management start.
SD = standard deviation; IHC = immunohistochemistry.

RESULTS

In 2010, 287 patients underwent a full work-up and initiated treatment at the OCC; they constituted the non-RDU group, 164 of whom were diagnosed with invasive breast carcinoma. In 2012, in the RDU group, 260 patients were investigated, resulting in 154 diagnoses of invasive carcinoma. Mean age at diagnosis was 59 years in the non-RDU group and 63 years in the RDU group ($p = 0.0135$). Most patients in both groups presented with tumours that were unilateral and 2–5 cm in size, with no evidence of lymph node involvement or distant metastatic disease.

Although the most common method of diagnosis in both groups was core-needle biopsy, an axillary lymph

node fine-needle aspirate in addition to a breast core-needle biopsy was more common in the RDU group (13.6% non-RDU vs. 23.5% RDU, $p = 0.004$). The RDU patients had statistically fewer additional visits for breast biopsies (92% in the RDU group with single visit for biopsy vs. 78% in non-RDU group, $p < 0.0001$). A greater proportion of patients underwent MRI in the RDU group than in the non-RDU group ($p = 0.0002$).

The form of initial management differed significantly between the groups (Table I). For patients with invasive breast cancer, surgery was the definitive treatment modality in 73.8% of non-RDU patients and 51.9% of RDU patients ($p = 0.0001$). Neoadjuvant chemotherapy was administered in 23.8% of non-RDU patients and 37.0% of RDU patients ($p = 0.0106$). In the non-RDU group, immunohistochemical biomarkers (that is, estrogen and progesterone receptor status, HER2 amplification status) were available only after definitive surgical excision in 50% of patients; in the RDU group, immunohistochemical markers were available for 95% of patients before treatment initiation.

Patients with invasive disease in the RDU group had a significantly shorter wait time from initial consultation to delivery of diagnosis (mean: 2.1 days vs. 16.7 days; $p = 0.0001$). Overall time from referral to management remained statistically unchanged (mean: 53 days for RDU patients vs. 50 days for non-RDU patients, $p = 0.3806$; Table II). For patients in the RDU group, wait time from referral to initiation of surgery was significantly longer than from referral to initiation of neoadjuvant chemotherapy (mean: 63.3 days vs. 42.2 days; $p = 0.0001$). A similar trend was not seen in the non-RDU patients (mean: 52.3 days vs. 44.5 days; $p = 0.2060$).

DISCUSSION

The goal of the RDU is to reduce overall time in the diagnostic pathway, while streamlining care for individuals suspected to have cancer. Establishment of a RDU at the OCC dramatically shortened the time to diagnosis, but did not significantly alter the time to definitive treatment initiation. Thus, it appears that implementation of the RDU has led to the transposition of wait times to other parts of the diagnostic trajectory, without changing the overall wait time. It is evident that important opportunities remain for process modification that will improve treatment delivery and, ultimately, the patient experience.

In an era of limited health care resources, issues with wait times have populated the literature, particularly with respect to surgical procedures for cancer treatment[7–11]. In Canada, health care is delivered though a universal system in which administration and funding are handled jointly at the federal and provincial levels. Centrally derived and administered strategies to mitigate wait times are therefore meant to equitably improve health care delivery across the province. Although the province maintains suggested guidelines for wait times from the date of decision-to-treat to the date of surgery, defining the exact point at which patients and providers perceive "readiness" for treatment is often difficult to define and to accurately record administratively. Furthermore, details about the period of investigation before the decision-to-treat date are unavailable. The present study is one of few to accurately document patient wait times for the entire diagnostic trajectory from referral to initiation of treatment.

The transposition of wait times observed here could in part be related to the changes in management strategies documented in the study. The increased availability and knowledge of immunohistochemical receptor status could have resulted in the more prominent use of neoadjuvant chemotherapy in the RDU group. We also observed a significant increase in the use of preoperative MRI in the RDU group, which has been shown in the literature to contribute to overall wait time. Bleicher *et al.*[12] demonstrated a 22.4-day delay in pre-treatment evaluation when MRI was used. Similarly, Nessim *et al.*[13] showed that median time from surgical consultation to surgery was significantly longer in women who underwent MRI. In the COMICE trial, use of breast MRI led to additional imaging and a longer wait until surgery, without associated changes in clinical outcomes[14]. In the present study, it is difficult to tease out with certainty the reasons for the varying use of neoadjuvant chemotherapy and MRI between the RDU and non-RDU groups. Although use of those resources could be construed as coping strategies to mitigate wait times, it is possible that an increasing availability of MRI, changes in the temporal indications for the use of neoadjuvant therapy and MRI, and fluctuating availability of clinical trials could all have uniquely contributed to the trends observed in our study. In addition, given that the RDU is meant to assess and expediently diagnose patients with more suspicious lesions, the RDU group might have had slightly more complex or advanced disease, thus requiring further investigation with MRI or initiation of chemotherapy—albeit with comparative differences too small to be detected with the statistics calculated in our study.

Understanding overall wait times from referral to treatment is a multifactorial exercise, resulting from a complex interplay of factors such as patient volume, budgetary constraints, and resource availability. To improve wait times, and thus to reduce patient anxiety and possibly mitigate changes in patient survival, all components of the process have to be examined[15,16]. When faced with a complex system that aims to maximize throughput, it is important to consider not only the factors that affect volumes, but also those that affect efficiency.

One patient-centered process improvement aimed at increasing efficiency in the diagnostic pathway of women undergoing breast evaluation includes a formalized navigational approach. That approach provides patients with anticipatory guidance from diagnosis to the end of treatment and has been shown to reduce the time required for, and the anxiety associated with, breast evaluation[17–19]. Increasing the volume of patients processed through the system could be concurrently achieved by addressing various aspects of the diagnostic trajectory. Enhanced risk stratification schema (for example, triaging patients within a network of hospitals with varying resources) and implementation of nonoperative strategies for breast cancer treatment (for example, ablative techniques) might ultimately lower the demand on the system. Similarly, an improvement in operating room capacity (that is, reduced time for operating room turnover, increased operating

room hours) could aid in improving throughput. Finally, consideration could be given to uncoupling the diagnostic and treatment phases of the breast cancer journey and creating regional centres in which individual components are efficiently performed. The challenge, however, is to establish reasonable target wait times that carefully balance the quality of the services delivered with the cost-constrained availability of resources.

The National Health Service in the United Kingdom instituted a 2-week wait time target from referral by a family doctor to consultation by a hospital consultant, with an accompanying increase in resources to assist in meeting the target. Although modest improvement in wait times from referral to first appointment were achieved, overall wait times to treatment changed little after implementation of the policy[20,21], thus mirroring the experience described in the present study.

The National Health Service experience highlights not only the challenges in translating increased resources into improved outcomes, but also the difficulties in finding metrics to define thresholds of "acceptable" care on an aggregate level. From the government's perspective, knowing that fluctuations in patient volumes will prevent a consistent granular relationship between the demand for (represented by patients suspected to have breast cancer) and the supply of diagnostic services, a reasonable threshold wait time target must be set based on patient volume forecasts and available resources. Currently, the arbitrary thresholds in Canada and in the United Kingdom are used as metrics to compare the efficiency of centres performing breast cancer care. However, case complexity and quality of care are difficult to ascertain and are not directly reported in conjunction with wait times. As a result, resource-related or remunerative institutional consequences are lacking, and the recommended targets are inconsistently met.

To understand and change overall wait times, policymakers have the difficult job of creating reportable metrics representative of case mix and targets that are realistic and sustainable given the prevalence of the particular disease. On the institutional side, administrators and health care professionals are responsible for justified and efficient use of resources provided without compromise to patient outcomes. Integrating those tasks is an ongoing challenge.

The limitation of a single-institution study lies in its generalizability; however, we believe that the essential themes and measured elements in the present study are applicable to other centres and that the results are consistent with the literature. Further study should be undertaken to assess the psychological impact of the RDU on patient well-being, and the financial impact of the RDU program in terms of initiation and ongoing maintenance, both of which are ongoing.

CONCLUSIONS

The RDU is an efficient, coordinated, multidisciplinary effort with demonstrated ability to expedite the diagnosis of patients with suspicious breast lesions. However, initiation of a RDU in isolation fails to mitigate the overall wait to treatment delivery. Our evidence shows that a transposition of wait times to other parts of the diagnostic trajectory might encourage the use of alternate coping strategies—for example, the increased use of neoadjuvant chemotherapy. Broader multi-pronged initiatives aimed at increasing overall system capacity, efficiency, and coordinated service delivery are needed.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare the following interests: CMBH is employed by Cancer Care Ontario as a consultant. The other authors have no conflicts of interest to declare.

AUTHOR AFFILIATIONS

*University of Toronto, Department of Surgical Oncology, Toronto, ON; †Division of Surgical Oncology, Odette Cancer Centre and Sunnybrook Health Sciences Centre, Toronto, ON; ‡Department of Surgery, University of Toronto, Toronto, ON.

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