Original article

Quality of pathology reporting is crucial for cancer care and registration: A baseline assessment for breast cancers diagnosed in Belgium in 2008

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ABSTRACT

Objectives: Given the crucial role of pathology reporting in the management of breast cancers, we aimed to investigate the quality and variability of breast cancer pathology reporting in Belgium.
Materials and methods: Detailed information on non-molecular and molecular parameters was retrieved from the pathology protocols available at the Belgian Cancer Registry for 10,007 breast cancers diagnosed in Belgium in 2008.
Results: Substantial underreporting was shown for several clinically relevant non-molecular parameters, such as lymphovascular invasion. High-volume laboratories performed only slightly better than others, and analyses at the individual laboratory level showed clear inter-laboratory variability in reporting for all volume categories. Information on ER/PR and HER2 IHC was mentioned in respectively 91.7% and 90.8% of evaluative cases. HER2 ISH data were available for 78.5% of the cases judged to be 2+ for HER2 IHC. For cases with different specimens analysed, discordance between these specimens was highest for HER2, followed by PR. For HER2, results obtained from different laboratories were even less concordant. In addition, inter-laboratory differences were noted in the used ER/PR scoring systems, the proportion of ER−/PR+ cases, and the relation between histological grade and ER/PR positivity. Data on Ki67 were only available for 43.8% of the investigated cases, and showed inconsistent use of cut-off values.
Conclusion: Breast pathology reporting in Belgium in 2008 was suboptimal and showed considerable inter-laboratory variability. Synoptic reporting has been proposed as a facilitator towards increased reporting quality and harmonization, but the lack of aligned informatics remains a major hurdle in its concrete implementation.

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Introduction

Each year, approximately 10,000 new breast cancers are diagnosed in Belgium, rendering it the most frequently occurring cancer in females [1]. The Belgian Cancer Registry (BCR) is population-based and includes data on all newly diagnosed malignant cases since 2004. It is estimated to be more than 95% complete. Part of the dataflow to the BCR consists of a network with the pathologists, including the delivery of structured files containing the pathology reports. Besides cancer epidemiology descriptives, the BCR is

increasingly involved in the evaluation of quality of care for cancer patients at the population level. Several collaborations with its scientific partners have resulted in publications confirming that the quality of pathology reporting must be considered as an integral part of quality of cancer care [2–8]. In the current evolution towards individualized cancer treatments, a thorough description of both non-molecular and molecular parameters by the pathologist will guide the clinician in choosing the most adequate treatment for each individual patient.

International guidelines on breast cancer pathology have been made available at the American (College of American Pathologists (CAP)) level in 2000 and at the European level in 2005 [9,10]. Concerning non-molecular tumour characteristics, these guidelines mentioned which elements should be reported by the breast cancer pathologists. Concerning hormone receptors, they referred to the necessity of testing if clinically relevant, but did not explicitly state which cut-offs should be used. Recommendations on immunohistochemical (IHC) and in situ hybridization (ISH) testing for human epidermal growth factor receptor 2 (HER2) were included in the European guidelines of 2005 [10] and published by the American Society of Clinical Oncology (ASCO)/CAP in 2007 [11], with an update in 2013 [12]. Guidelines for immunohistochemical testing of oestrogen and progesterone receptor (ER/PR), including the recommendation of considering ≥1% staining as positive, were published by ASCO/CAP in 2010 [13]. Specific Belgian guidelines for HER2 testing have been developed in 2007 [14] and a proposal for standardization of the breast pathology report has been made in 2010 [15].

Although both national and international guidelines are assumed to be known to Belgian pathologists, it remains unclear whether these have been implemented in daily practice. An estimation of the actual quality of breast pathology reports regarding non-molecular and molecular predictive and prognostic characteristics at the Belgian population level has previously not been reported.

This study first evaluated the availability of pathology reports at the BCR for the incidence year 2008. For non-molecular parameters, the quality of the breast pathology reports delivered to the BCR was assessed for all studied parameters at the population level and by volume of the laboratory, completed with analyses on interlaboratory variability in reporting for a selection of parameters. Reporting on molecular parameters was studied at the population level in terms of availability of information on ER, PR, HER2 (IHC and ISH) and Ki67, used scoring systems for ER and PR, cut-off values for Ki67 and concordance between specimens for ER, PR and HER2. Some surrogate quality indicators for molecular testing such as the proportion of ER negative/PR positive cases were calculated both at the overall and at the inter-laboratory level.

The study was set up as a collaboration between the BCR and the Belgian Working Group for Breast Pathology (BWGBP).

Materials and methods

All newly diagnosed invasive breast cancers in females (Belgium, 2008) were selected from the database of the BCR. Following exclusion of atypical morphologies such as phyllodes tumours, 10,007 breast cancers corresponding to 9764 different patients were considered for further analysis. To retrieve detailed information from all available pathology reports, an extended dataset with a total of 151 variables was developed. The following variables were included: (a) non-molecular information on the primary invasive tumour (i.e. largest tumour in case of

Table 1
Overall reporting of non-molecular parameters.

Non-molecular parameter	% Available information			
	All cases	High volume[a]	Middle volume[a]	Low volume[a]
All cases	*n = 10,007*	*n = 2793*	*n = 3342*	*n = 2454*
Histological grade	95.3%	97.0%	95.2%	93.9%
Primary invasive tumour[b]	*n = 7827*	*n = 2187*	*n = 2548*	*n = 1971*
Tumour extent (uni/multifocal)	98.4%	98.3%	98.7%	98.7%
Number of invasive foci	77.7%	85.7%	70.1%	77.3%
Maximal diameter of invasive tumour[c]	95.5%	95.4%	96.3%	96.0%
Presence/absence of lymphovascular invasion[c]	61.7%	66.9%	63.9%	54.2%
Resection margins first resection	88.9%	92.7%	86.1%	89.7%
Resection margins additional resection[d]	87.0%	86.8%	88.2%	85.7%
Presence of in situ component	75.4%	79.5%	75.4%	70.5%
Associated DCIS[b]	*n = 4375*	*n = 1324*	*n = 1393*	*n = 994*
Nuclear grade of DCIS	76.9%	80.5%	79.6%	67.6%
Total diameter invasive carcinoma + DCIS	32.6%	41.4%	32.4%	22.9%
Resection margin DCIS	51.1%	60.7%	48.7%	43.3%
Sentinel node procedure	*n = 3332*	*n = 1080*	*n = 1386*	*n = 866*
Number of sentinel nodes examined	98.4%	99.4%	97.4%	98.7%
Presence of isolated tumour cells[c]	51.8%	50.5%	57.1%	43.3%
Number of positive sentinel nodes[c]	99.2%	99.5%	98.9%	99.3%
Positive sentinel nodes	*n = 923*	*n = 266*	*n = 338*	*n = 191*
Maximal diameter of largest metastasis in sentinel node[c]	47.1%	44.0%	52.1%	47.1%
Extracapsular spread of sentinel node metastasis[c]	59.8%	63.0%	62.0%	56.5%
Axillary lymph node dissection	*n = 5539*	*n = 1402*	*n = 1927*	*n = 1361*
Number of lymph nodes examined	98.7%	99.1%	98.6%	98.7%
Number of positive axillary lymph nodes[c]	99.3%	99.2%	99.3%	99.5%
Positive axillary lymph nodes	*n = 2266*	*n = 571*	*n = 801*	*n = 567*
Maximal diameter of largest metastasis in axillary clearance[c]	29.7%	41.5%	28.2%	24.5%
Extracapsular spread − axillary clearance[c]	74.7%	76.7%	77.1%	76.5%

The italics in the first column indicate the different categories of non-molecular parameters for which reporting was assessed. The numbers in italics in 2nd to 5th column refer to the number of reports available for assessment of pathology reporting for parameters of the concerned category, by laboratory volume (all cases, high volume, middle volume, low volume).
[a] For the volume analyses, only the cases that could be assigned to one laboratory were taken into account (see methodology section).
[b] Limited to cases for which at least one complete report of a resection specimen was available.
[c] Parameters additionally explored at the individual laboratory level.
[d] Only cases with an additional resection were taken into account (*n* = 2440 for all cases, 744 for high volume, 730 for middle volume and 565 for low volume laboratories).