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The impact of standardized structured reporting of pathology reports for breast cancer care

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ABSTRACT

Purpose: With the increasing complexity of modern oncological patient management and the growing amount of information needed from the pathologist, traditional narrative pathology reports (NR) do not suffice. Standardized synoptic reporting (SR) increases both completeness and readability. In the Netherlands SR for breast cancer was introduced in 2009. We explore the impact of synoptic reporting on breast cancer care.

Methods: Using data from the Netherlands Cancer Registry and Dutch Nationwide Pathology Databank, a retrospective population-based cohort study was performed. Data of breast cancer resections from 2007 to 2014 were collected to compare NR and SR for all outcome measures. Kaplan-Meier analyses and log-rank testing were used to estimate overall survival.

Results: Over time there was an increase from 12% to 78.9% in the use of SR. SR resulted in higher completeness of pathology reports, particularly for hormone and HER2/neu receptor status. Although there was no difference in the administration of antihormonal therapy, anti-HER2 treatment was more frequently administered to eligible patients in the SR group. An effect on overall survival could not yet be confirmed on multivariate analysis.

Conclusions: We demonstrate that SR has led to more complete pathology reports, which meets the needs for precision of information in breast cancer care. This is expected to improve communication and discussions between specialists regarding parameters important for adjuvant breast cancer treatment decisions. SR thereby improves breast cancer care and leads to improved allocation of treatment based on pathologic parameters and more personalized treatment regimens.

1. Introduction

Globally breast cancer incidence is rising, with over 2.2 million new cases in 2019 worldwide [1]. Histological examination is a key element in the diagnostic and postoperative process and provides essential information for treatment planning and evaluation, including data on prognostic and predictive factors. Therefore, adequate breast cancer care depends on accurate pathology reporting.

With the increasing complexity of modern (multidisciplinary) oncological patient management and the growing amount of information needed from the pathologist, traditional narrative reports (NR) do not suffice. It has been demonstrated that NR have a high degree of variability and may miss essential information that is necessary for therapy decisions [2].

Pathology reporting is evolving from NR to standardized structured reports (SR). SR is a clinical documentation method in which a

Abbreviations: BR, Bloom and Richardson; ER, estrogen receptor; ICD-O, international classification of disease for oncology; NCR, Netherlands Cancer Registry; NR, narrative reporting; OS, overall survival; PR, progesterone receptor; SR, standardized synoptic reporting; WHO, World Health Organization.

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standardized structure of reporting helps to produce more complete, consistent and valuable medical reports [3]. The mandatory parameters, which are supporting decisions on adjuvant treatment regimens, are defined, thereby improving informational content. Both completeness and readability have been shown to increase with SR [2,4]. In the evaluation of the effects of SR for colorectal cancer patients, it was demonstrated that SR use improved colorectal cancer care and, as a consequence, improved patient outcome [5]. We hypothesize that the introduction of SR for breast cancer histopathology has had similar effects.

2. Materials and methods

2.1. Design, data sources and population

Patients for this nationwide population based study were retrospectively selected from the Netherlands Cancer Registry (NCR) and the Dutch Nationwide Pathology Databank (PALGA) [6]. Patients who underwent surgery for a single primary invasive breast cancer between 2007 and 2014 were selected.

Patients were selected from the NCR using the topographical ICD-O codes C50.0 until C50.9 for breast as anatomical site of origin. We excluded patients with only in situ carcinoma, neoadjuvant therapy, a history of cancer during the 5 years prior to the diagnosis of the breast tumor, and lymph node dissection only without resection of a primary tumor.

The data searches were registered under LZV2015-1191 (PALGA) and K15.164 (NCR). Linkage was performed as previously described [5]. Follow-up information on patients' vital status is obtained through linkage with the Municipal Personal Records Database.

2.2. Completeness, quality indicators and patient outcomes

To evaluate the quality of pathology reports all reports were classified into three groups: NR, SR and a reference group. NR and SR were compared from the introduction of SR in 2009 until 2014. Patients from 2007 to 2008 were used as a reference group for baseline measurement, to provide insight into developments that occurred independently of the introduction of SR.

The three groups were compared according to eight required parameters as recommended by the Dutch guideline for breast cancer at the time of diagnosis [7]: histological tumor type according to WHO, specific grading according to modified Bloom and Richardson (BR grade), maximum tumor diameter, the estrogen (ER), progesterone receptor (PR) status and HER2/neu status. Because of changes in the reporting guidelines during the study period, the status of the resection margin could only be analyzed for breast conserving surgery in the years 2009–2011. If a lymphadenectomy was performed, we looked at the number of metastases and the amount of evaluated nodes.

From 2012 on analyses for resection margin status could be performed for all surgical procedures. Although the resection margin is an essential and compulsory parameter in the latest guideline, this parameter was not included in the overall completeness analysis, to preserve comparability between the reports.

To study the effect of SR on patient management, we compared the proportion of patients with adjuvant hormonal therapy and anti-HER2/neu therapy, in relation to tumor characteristics. In addition, the impact of SR on overall survival (OS) was studied, which was defined as the time between date of diagnosis until date of death or date of last follow-up date (31 December 2014).

2.3. Statistics

Statistical analysis were performed with SPSS software, version 24.0 (SPSS Inc. IBM Corporation Software Group, Somers, NY, USA). Categorical data were presented as frequencies (%) and compared using Chi-squared tests. Continuous data were described as medians with an interquartile range (IQR) and analyzed with a Mann Whitney *U* test. Overall survival (OS) was calculated using a Kaplan-Meier method with log rank testing. Multivariate analysis of OS was performed using the Cox proportional hazard model, including sex, age, pT, pN, year of incidence, HER2/neu status, BR grade, hormone receptor status, chemotherapy, radiotherapy and targeted therapy as confounders. All tests were two-sided, and p values less than 0.05 were considered to be statistically significant.

3. Results

3.1. Patients and reporting

A total of 73,416 patients were eligible for inclusion in the analyses, with 30,351 (41.3%) NR, 25,518 (34.8%) SR and 17,547 (23.9%) in the reference group. Demographics and clinical characteristics are presented in Table 1. Median age was 61 years (IQR 51.0–70.0). Over time, the use of SR increased from 12.0% in 2009 to 78.9% in 2014 (Fig. 1a).

3.2. Quality of reporting

Overall completeness was high in all groups, in particular for standard histological parameters. Completeness of reporting was assessed for eight parameters (Fig. 1b). For SR completeness of reporting was significantly higher, compared with both NR and the reference group.

Table 1
Characteristics of the different patient groups.

Characteristics	Reference N = 17,547 (%)	NR N = 30,351 (%)	SR N = 25,518 (%)
Gender			
Female	17,421 (99.3)	30,128 (99.3)	25,334 (99.3)
Male	126 (0.7)	223 (0.7)	184 (0.7)
Age			
<50	3670 (20.9)	5856 (19.3)	4373 (17.1)
50-69	9376 (53.4)	16,860 (55.5)	14,418 (56.5)
≥70	4501 (25.7)	7635 (25.2)	6727 (26.4)
Histological type			
Ductal	14,860 (84.7)	25,865 (85.2)	21,530 (84.4)
Lobular	1867 (10.6)	3168 (10.4)	2757 (10.8)
Special	811 (4.6)	1316 (4.3)	1230 (4.8)
Missing	9 (0.1)	2 (0)	1 (0)
Tumor grade			
Well	4102 (23.4)	7410 (24.4)	6604 (25.9)
Moderately	7575 (43.2)	13,208 (43.5)	11,246 (44.1)
Poor	5295 (30.2)	8451 (27.8)	6881 (27.0)
Unknown	572 (3.3)	1282 (4.2)	787 (3.1)
ER status			
Negative	3118 (17.8)	4736 (15.6)	3718 (14.6)
Positive	14,227 (81.1)	25,304 (83.4)	21,669 (84.9)
Unknown	202 (1.2)	311 (1.0)	131 (0.5)
PR status			
Negative	5721 (32.6)	9414 (31.0)	7643 (30.0)
Positive	10,945 (62.4)	20,237 (66.7)	17,513 (68.6)
Unknown	881 (5.0)	700 (2.3)	362 (1.4)
HER2/neu status			
Negative	14,707 (83.4)	26,064 (85.9)	22,154 (85.7)
Positive	2087 (11.9)	3435 (11.3)	2819 (11.0)
Unknown	753 (4.3)	852 (2.8)	545 (2.1)
Tumor size			
T1	11,293 (64.4)	20,518 (67.6)	17,335 (67.9)
T2	5748 (32.8)	8895 (29.3)	7353 (28.8)
T3	403 (2.3)	781 (2.6)	649 (2.5)
T4	97 (0.6)	148 (0.5)	169 (0.7)
Unknown	6 (0)	9 (0)	12 (0)
Nodal status			
N0	11,386 (64.9)	20,421 (67.3)	17,549 (68.8)
N1	4295 (24.5)	6991 (23.0)	5928 (23.2)
N2	1026 (5.8)	1446 (4.8)	1010 (4.0)
N3	571 (3.3)	890 (2.9)	604 (2.4)
Unknown	269 (1.5)	603 (2.0)	427 (1.7)

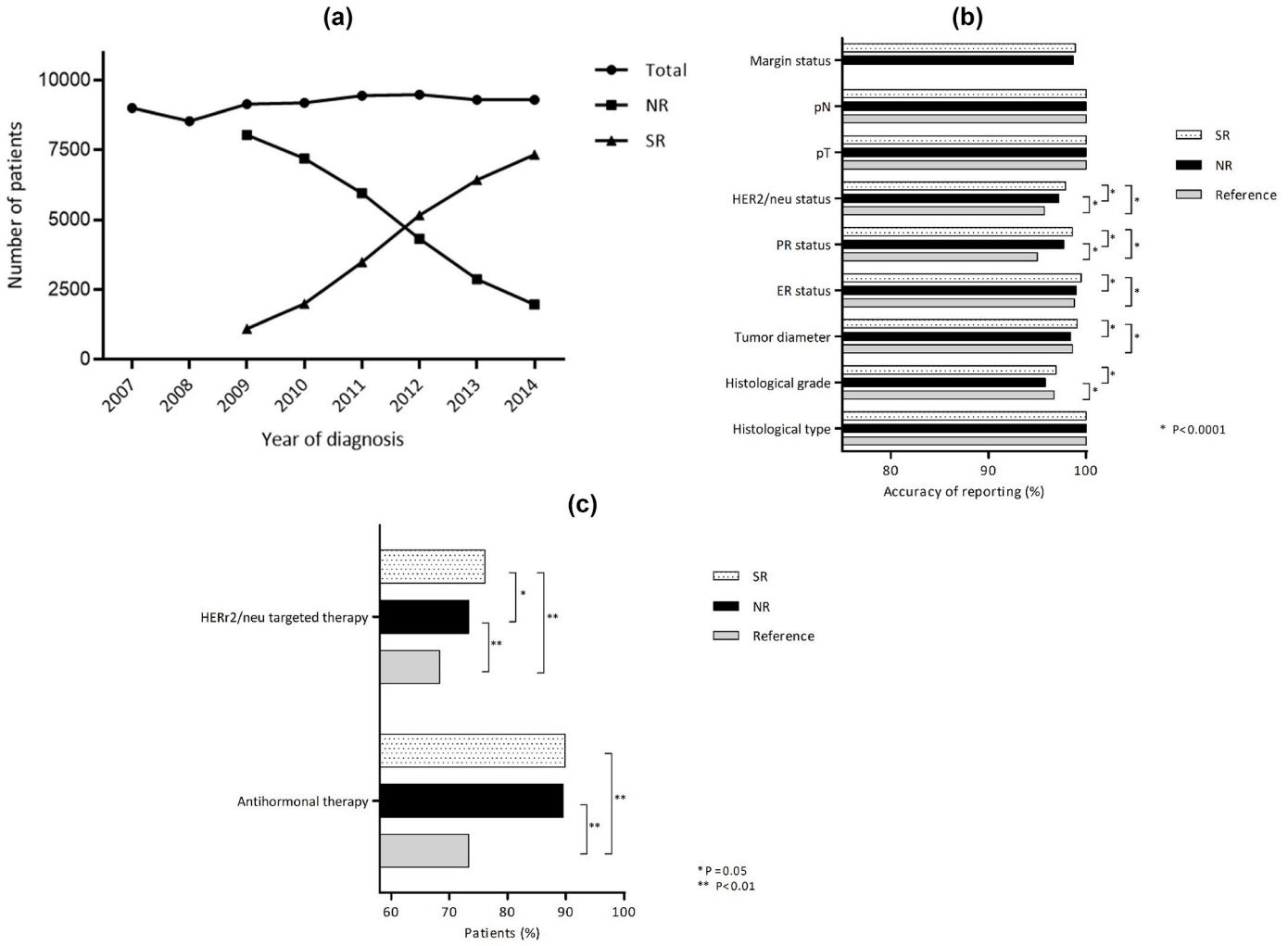

Fig. 1. a. Introduction of SR compared to the use of narrative reports (NR), as absolute number of cases, Fig. 1b. Completeness of reporting per histopathological parameter, according to reporting type. Margin status was only assessed for the interval 2012–2014., Fig. 1c. Administration of antihormonal therapy and HER2/neu targeted therapy in eligible patients according to type of reporting.

Overall, PR status (5.0%, 2.3% and 1.4%) and HER2/neu status (4.3%, 2.8%, 2.1%) were most frequently missing in the reference, NR and SR groups respectively ($P < 0.0001$).

3.3. Quality of care

According to the Dutch guideline, patients with a BR grade 2/3 ER-positive breast cancer over 1 cm in size and patients with a BR grade 1 ER-positive tumor over 2 cm in size and all patients with node positive disease are eligible for antihormonal therapy. There was no difference in the administration of adjuvant antihormonal therapy between the NR and SR group (89.5% versus 89.9%, Fig. 1c). Targeted therapy for HER2/neu positive tumors is advised for patients with a tumor bigger than 2 cm or in case of positive lymph nodes. In the SR group eligible patients were more frequently treated with adjuvant HER2/neu targeted therapy (76.1% versus 73.3%, $P = 0.05$).

3.4. Impact on outcome

Survival improved over time with a better OS for SR and NR compared with the reference period (5 year OS 89.5% and 88.9% versus 87.5%, $P < 0.0001$, Fig. 2a). For patients who were eligible for adjuvant antihormonal therapy, on univariate analysis OS was better in the SR group than in the NR group (Fig. 2b). This was also the case for HER2/neu positive patients who were eligible to receive targeted therapy (Fig. 2c). The prognostic impact of the type of report was not confirmed in a multivariate analysis.

4. Discussion

In this large scale evaluation of the impact of SR in a national cohort of 75,316 patients, we showed an increase in completeness of reporting. The high rate of completeness of reporting in all three reporting groups is indicative for the excellent reporting of well-established pathological parameters. Reporting rates over 95% leaves little margin for improvement. Nevertheless, SR also improves readability of the pathological report. Although it cannot be measured, a higher rate of completeness of reported histological parameters, presented in a standardized manner is expected to improve inter-specialty communication. This may have led to improvements in breast cancer patient care as the introduction of SR resulted in more adequate treatment for patients with HER2/neu amplifications, by an increased rate of administration of targeted therapy in this patient group. These results are in line with our observations in colorectal cancer patients [5], in whom a multivariable OS benefit was demonstrated. Survival benefits in breast cancer patients are smaller, and were not significant in the multivariate analysis, which included several factors to overcome the bias and heterogeneity introduced by the nature of the study. Notably, a multivariate analysis

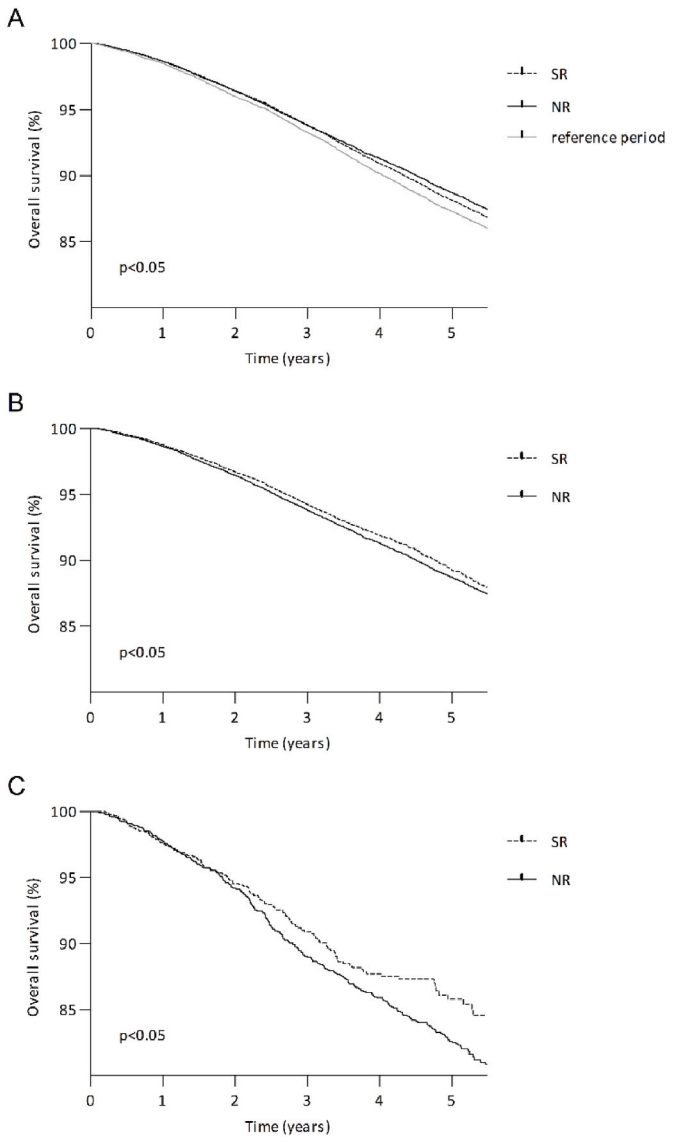

Fig. 2. Survival according to type of reporting for (A) all patient, (B) patients eligible for adjuvant antihormonal therapy and (C) patients eligible for Her2/neu targeted therapy.

remains merely a model which cannot correct for all factors involved in patient care, such as variations in adherence to therapeutic protocols, evolution of recommendations and patient preferences. The difference in impact on survival between breast cancer patients and colon cancer patients may also be related to the higher 5-year survival rates in breast cancer patients compared with colorectal cancer patients. Another explanation might be the relative limited follow-up for SR, compared to NR. It is, however, not inconceivable that the benefit of improved reporting not necessarily translates into improved survival, but may have led to improved local control.

Internationally, the benefit of SR has been recognized and the International Collaboration on Cancer Reporting [8] is the established institute for the development of datasets that form the basis of SR. Recently, the breast cancer datasets have become available [9]. The use of these datasets facilitates interdisciplinary communication [10]. In addition to direct benefits for the individual patient, the collected data can also be used for continuous quality improvement schemes as well as for research purposes [11].

The exclusion of cases with neoadjuvant therapy in this study may have led to inclusion bias. As both triple negative and HER2-positive patients are generally treated with neoadjuvant therapy, this group may have been underrepresented in more recent years. The current study analyzed the impact of reporting on the administration of adjuvant therapy. It is, however, important to realize that treatment decisions are not solely based on histopathological parameters and patient factors may have influences therapy allocation as well. This bias applies to patients in all groups, and is therefore considered neglectable.

In conclusion, the nationwide implementation of SR led to increased completeness of pathology reporting and better treatment allocation for breast cancer patients. These findings support the use of SR in oncology.

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Author contributions

Conception and design: IDN, HJvS, Collection and assembly of data: AFS, EvdB, IDN. Data analysis and interpretation: AFS, EvdB, IDN, NH, HJvS. Manuscript writing: all authors.

Ethical approval and consent to participate

This study was exempt from ethical approval due to the use of anonymous data.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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