

Improvement of Care in Patients With Colorectal Cancer: Influence of the Introduction of Standardized Structured Reporting for Pathology

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PURPOSE The use of standardized structured reporting (SSR) can improve communication between cancer specialists, which might improve clinical care; however, there are no reliable data on whether the introduction of SSR is associated with improvements in clinical outcome.

PATIENTS AND METHODS We performed a retrospective cohort study in the Netherlands, including all patients with colorectal cancer (CRC) from 2009 to 2014. As a reference, cohorts of 2007 and 2008 were included. Data from the Netherlands Cancer Registry were used and combined with data from the Dutch Pathology Registry (PALGA) and the Dutch ColoRectal Audit. We tested the preformulated hypothesis that use of SSR improves the care of patients with CRC by improving the completeness of the pathology reports, the quality of the pathology evaluation, and patient outcomes with respect to treatment and survival.

RESULTS We included 72,859 patients with CRC (23.8% reference, 32.9% SSR, and 43.3% narrative reports). Use of SSR increased over time, which resulted in more complete pathology reports (95.8% v 89.8%; $P < .001$). Risk assessment in stage II colon cancer was more adequate and resulted in an increased delivery of adjuvant therapy in patients with SSR (19.6% v 15.1%; $P = .001$). Risk of death for patients in the SSR group was significantly lowered (corrected hazard ratio, 0.94; 95% CI 0.90 to 0.97).

CONCLUSION We demonstrate that use of SSR improved patient care in those with CRC by providing more complete reports of higher quality, which had significant effects on the delivery of adjuvant therapy and patient outcomes.

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INTRODUCTION

With the increasing complexity of modern multidisciplinary cancer treatment, adequate exchange of diagnostic information is increasingly important. Postoperative pathology reports describe the definitive staging and typing of tumors and are the basis of additional treatment plans. For colorectal cancer (CRC), the decision of whether to administer adjuvant chemotherapy is dependent on tumor stage and high-risk features. It has been demonstrated that adjuvant chemotherapy results in a survival benefit for all stage III patients and those with high-risk stage II disease.¹ High-risk features of stage II CRC—poor differentiation, extramural vascular invasion (EMVI), tumor perforation, T4, fewer than 10 examined lymph nodes, and obstruction/ileus—are mainly determined by the pathologist. Therefore, the accuracy and completeness of pathology reports are important for adequate adjuvant chemotherapy delivery and patient outcome.²

Traditional narrative reports (NRs) are no longer considered adequate as it can be difficult to distill the

necessary information from long-winded sentences that describe morphologic features rather than clinically relevant information. In standardized structured reporting (SSR) systems, mandatory parameters are defined and presented in a standardized structure, thereby improving informational content³. Use of these systems has been shown to improve both the readability and completeness of postoperative pathology reports.⁴ Several smaller studies have proven that use of SSR resulted in increased completeness for a variety of prognostic factors, such as involvement of the circumferential resection margin (CRM),⁵⁻¹¹ EMVI,^{5,9,11,12} and TNM stage.^{7,10,11,13} However, whether this also leads to increased quality of the diagnostic process and subsequent treatment decisions has not yet been explored.

In the Netherlands, we introduced SSR nationwide for CRC resections in 2009. All mandatory parameters were defined in the Dutch guidelines for the diagnosis and treatment of CRC.¹⁴ To explore the impact of SSR on the diagnosis and treatment of patients with CRC and to test the hypothesis that the introduction of SSR

ASSOCIATED CONTENT

Appendix

Author affiliations and support information (if applicable) appear at the end of this article.

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CONTEXT

Key Objective

To investigate the impact of standardized synoptic pathology reporting on the diagnosis and treatment of patients with colorectal cancer in a nationwide cohort study.

Knowledge Generated

Implementation of standardized structured reporting of pathology findings for patients with colorectal cancer resulted in increased completeness of pathology reports and higher-quality pathology evaluation, and was associated with better outcome for patients.

Relevance

These findings support the widespread introduction of standardized structured pathology reporting in oncology.

was associated with increased completeness of reporting, increased reporting of quality indicators, and improved patient outcomes, we performed a population-based retrospective cohort study.

PATIENTS AND METHODS

Design, Data Sources, and Population

We conducted a population-based retrospective nationwide cohort study in which all surgically treated patients with primary CRC diagnosed between 2007 and 2014 from the Netherlands Cancer Registry (NCR) were included.¹⁵ Data from the NCR were used as all data were retrieved from both the NR and SSR for this registration. NR and SSR were compared for all outcome measures from the introduction of SSR in 2009 until 2014. To observe ongoing trends independent of the introduction of SSR, we used cohorts from 2007 to 2008 as a reference group. Linkage of the NCR with the Dutch Pathology Registry—PALGA¹⁶—and the Dutch ColoRectal Audit (DCRA; formerly the Dutch Surgical Colorectal Audit)¹⁷ was performed. PALGA is the nationwide network and registry of histo- and cytopathology in the Netherlands, with nationwide coverage since 1991. The DCRA is part of the Dutch Institute for Clinical Auditing and registers all patients who undergo surgery for CRC since 2009.

Patients were selected using International Classification of Diseases, Oncology codes (3rd edition¹⁸) C18.0 to C18.9 (colon, excluding appendix C18.1), C19.9 (rectosigmoid), and C20.9 (rectum). Rectosigmoid tumors were classified as either colon or rectum on the basis of the conclusions of the pathology reports. Patients with CRC who did not undergo resection, patients with multiple synchronous CRC or in situ carcinomas, and resection specimens without tumor were excluded, as well as those CRC cases that were reported with SSR before 2009 (minor pilot project, including 243 patients).

Variables retrieved from the NCR were as follows: gender, age at diagnosis, follow-up time, vital status, year of diagnosis, localization, histologic type, histologic grade, invasion depth (pT), nodal status (pN), presence of metastases

(pM), number of investigated and positive lymph nodes (LNs), CRM, and primary treatment of CRC. Three high-risk features, including EMVI data, obstruction, and bowel perforation were retrieved from the DCRA. Type of report (SSR or NR), date of resection, type of pathology laboratory (academic/university associated v nonacademic/nonuniversity associated), and random laboratory number were retrieved from PALGA.

The Dutch SSR is considered level six on the Ontario Scale.³

Completeness, Quality Indicators, and Patient Outcomes

We assessed the completeness of pathology reports using two different definitions: first, overall completeness—that is, the proportion of pathology reports that contained all mandatory pathology parameters—and second, parameter-specific completeness—that is, the proportion of pathology reports in which an individual parameter was reported. Parameters were selected according to the Dutch guideline¹⁴ in combination with availability in the NCR and DSCA. Six mandatory parameters—histologic type, histologic grade, pT, pN, LN count, and CRM—and one optional parameter—EMVI—were analyzed. Histologic grade was analyzed for patients who did not receive neoadjuvant therapy, and CRM was analyzed for patients with rectal resections only. As the NCR began registrations of CRM in 2008, we could not perform this analysis in the 2007 cohort reference group. EMVI was analyzed for patients who were diagnosed in 2009 to 2014, because the registration of this parameter by DCRA began in 2009. The other four parameters were analyzed for the whole study population.

The quality of pathology evaluation was defined as the proportion of pathology reports in which the informational content corresponded to Dutch and international quality standards. We examined the number of LNs,¹⁴ reporting of EMVI,¹⁹ and CRM. In addition, we used the prognostic power of these histologic factors as a surrogate marker for quality.

To evaluate the effects of SSR on patient care, we analyzed the proportion of patients with high-risk stage II colon cancer who received adjuvant chemotherapy. In addition,

we analyzed the effect of SSR on patient survival. Survival time was defined as the time from diagnosis until death or last follow-up date (January 31, 2016).

Statistical Analysis

Statistical analyses were performed using SAS Enterprise Guide 7 (SAS/STAT User's Guide; SAS Institute, Cary, NC), and all statistical tests were two sided. We used basic descriptive statistics to describe patient and tumor characteristics for NR, SSR, and the reference group. Annual and overall proportions were calculated for overall completeness, completeness of specific parameters, and quality indicators for NR, SSR, the reference group, and the total study population. We used univariable and multivariable logistic regression analyses to describe the association between the type of reporting and outcome measures using crude and adjusted odds ratios (OR) with corresponding 95% CIs. Year of diagnosis was selected as an a priori confounding factor and included in every model.

To investigate the impact of the implementation of SSR, we plotted relevant outcome parameters against the consecutive case numbers before and after the introduction of SSR. To allow for the interpretation of whether results were based on casemix, we also plotted predicted values that were based on the casemix parameters stated above. Per hospital, cases before the introduction of SSR received negative consecutive case numbers and case 0 represents the first case in which an SSR was used. Data from all hospitals were pooled and we performed exponentially weighted–moving average analysis to analyze changing trends in outcome parameters that could be explained by the implementation of SSR.²⁰

Proportions of patients with high-, low-, and undetermined-risk stage II colon cancer and the corresponding proportions of patients who received adjuvant chemotherapy were calculated for SSR and NR and analyzed using χ^2 analyses and adjusted ORs. We used Kaplan-Meier curves and log-rank tests to evaluate overall survival, stratified by the type of reporting. Survival was also calculated for the following quality indicators: EMVI (detected, not detected, or missing), CRM (negative, positive, or missing), and number of LNs (more or less than 10 or missing). The prognostic value of quality indicators in NR and SSR was assessed using the Akaike information content (AIC).²¹ Cox proportional hazards analyses were used to obtain hazard ratios (HR) and corresponding 95% CIs. Associations were adjusted in multivariable analyses for age at diagnosis, gender, year of diagnosis, localization of tumor (not for CRM analysis), histologic type, histologic grade, TNM stage, and type of pathology laboratory. We tested the proportional hazards assumption using Schoenfeld residuals and found it to be satisfied.

RESULTS

The initial selection from the NCR resulted in 109,560 primary CRCs from 105,720 patients who were diagnosed

between 2007 and 2014 (Fig 1). After linkage with PALGA (n = 104,925; 95.8%) and exclusion of tumors of origin other than colon or rectum (n = 16), in situ tumors (n = 4,044), CRC without surgical intervention (n = 20,676), pT0 and pTx resections (n = 2,228), synchronous CRC (n = 3,913), and SSR from 2007 or 2008 (n = 243), a total of 73,805 CRCs that occurred in 72,859 patients were included for analysis. Table 1 lists patient and tumor characteristics of the study population. There were 17,489 pathology reports in the reference group (23.7%), 32,065 NR (43.4%), and 24,251 SSR (32.9%). Over time, use of SSR increased from 11.1% in 2009 to 78.3% in 2014 (Fig 2A). In the teaching setting of academic pathology laboratories, pathologists used NR more frequent than SSR, as was the case in stage IV CRC, rectal cancer, and those patients who were treated with neoadjuvant therapy. SSR was used more frequently than NR for low-grade tumors as well as for more adenocarcinomas, not otherwise specified.

Completeness

In the reference group, 90.5% of reports were already complete. As a result of the introduction of SSR, completeness increased (Fig 3A), whereas NR remained on the level of the reference group (95.8% v 89.8%; OR, 2.6; 95%

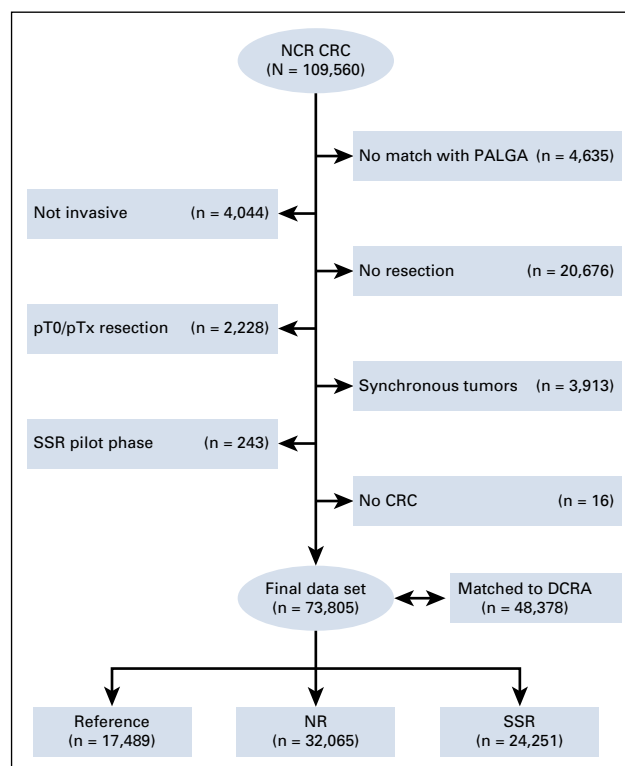


FIG 1. Flowchart of the patients with colorectal cancers (CRCs) who were included in the study. DCRA, Dutch ColoRectal Audit; NCR, Netherlands Cancer Registry; NR, narrative report; PALGA, Dutch Pathology Registry; SSR, standardized structured reporting.

TABLE 1. Patient and Tumor Characteristics

Characteristic	Total No.	Reference	NR	SSR	<i>P</i> *	<i>P</i> †
Patients, No.	72,859	17,315	31,566	23,978	—	—
Age, years, %						
< 50		5.2	5.6	4.4	.002	< .001
50-69		41.8	43.3	41.5	—	—
≥ 70		53.0	51.1	54.1	—	—
Male sex, %		53.7	54.9	54.3	.01	.20
CRC, No.	73,805	17,489	32,065	24,251	—	—
Localization, %						
Colon		73.5	69.5	79.1	< .001	< .001
Rectum		26.5	30.5	20.9	—	—
Type, %						
Adenocarcinoma		84.3	85.6	88.6	.001	< .001
Other		15.7	14.4	11.4	—	—
Grade, %						
Low		81.9	83.7	88.2	.001	< .001
High		18.1	16.3	11.8	—	—
Missing, No.		6733	14,579	7,674	—	—
TNM, %						
I		19.4	22.3	21.6	< .001	< .001
II		34.2	33.4	34.5	—	—
III		31.4	30.8	32.7	—	—
IV		15.0	13.5	11.2	—	—
Missing, No.		1,699	838	142	—	—
Neoadjuvant Tx, %						
Yes		22.3	28.1	14.6	< .001	< .001
Adjuvant Tx, %						
Yes		26.8	25.2	26.4	< .001	< .001
Pathology, %						
Academic laboratory		8.5	12.0	5.7	< .001	< .001

NOTE. Missing data are excluded from *P* value calculations.

Abbreviations: CRC, colorectal cancer; NR, narrative report; SSR, standardized structured reporting; Tx, therapy.

*Comparison of NR v reference.

†SSR v NR.

CI, 2.4 to 2.7). After correction for year of diagnosis, the same effect remained (OR, 2.3; 95% CI, 2.2 to 2.5). For all parameters, SSR demonstrated a higher or similar percentage of completeness compared with NR (Fig 2B and Appendix Table A1). However, histologic type, invasion depth, LN count, and nodal stage were already reported in more than 99% of NR.

Quality Indicators

Introduction of SSR was associated with a remarkable increase in the number of investigated LNs (Fig 3B). As a consequence, there was a significant increase in the number of cases in which more than 10 LNs were

investigated (SSR, 89.3% vNR, 77.3%; OR, 1.8; 95% CI, 1.7 to 1.9, adjusted for year of diagnosis; Fig 2C). There was a small difference in the detection of EMVI (SSR, 17.1% vNR, 16.1%; *P* = .003). Although the reporting of the CRM increased over time (Fig 2D), there was no difference in the percentage of CRM positivity. To determine the adequacy of the histologic features reported, we compared the prognostic value of those features in the different settings applying AIC statistics. The prognostic model was better in the SSR cases for EMVI (AIC, 92,966 v 169,371; Appendix Figs A1, A2), CRM involvement (AIC, 12,322 v46,956; Appendix Figs A3, A4), and number of LNs (AIC, 80,397 v 1,123,778; Appendix Figs A5, A6).

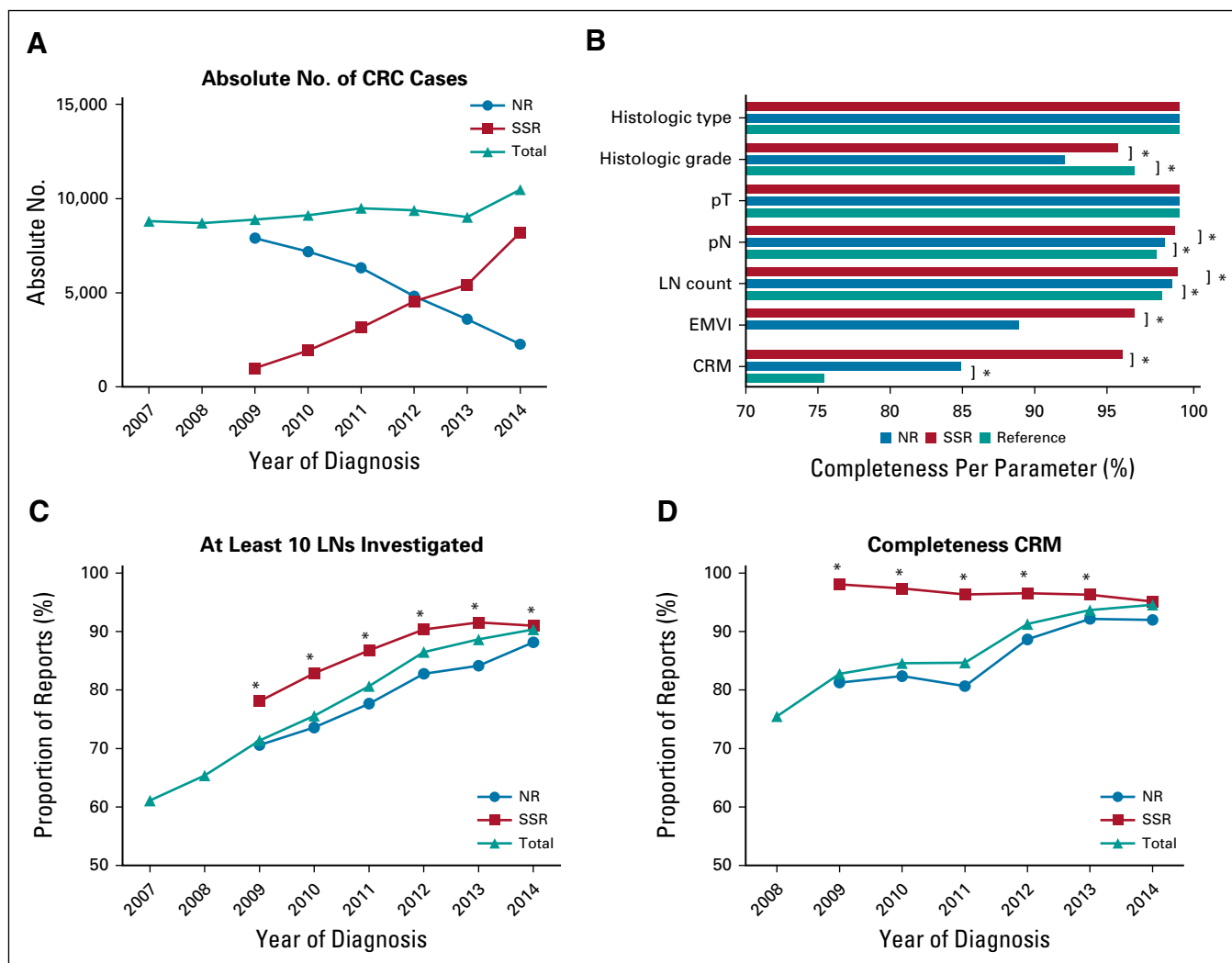


FIG 2. Effects of the introduction of standardized structured reporting (SSR) in the Netherlands. (A) Introduction of SSR in the Netherlands compared with the use of narrative report (NR). (B) Completeness per factor; NR and SSR are compared with the reference cohort. (C) Increased number of cases with more than 10 lymph nodes (LNs) examined over time; total numbers are compared with NR and SSR. (D) Completeness of circumferential resection margin (CRM) reporting over time; total numbers are compared with NR and SSR. CRC, colorectal cancer; EMVI, extramural vascular invasion. * $P < .001$.

Impact on Patient Care and Outcome

The data set consisted of 12,366 patients with stage II colon cancer who were diagnosed between 2009 and 2014 and who were potentially eligible for adjuvant therapy. Of these, 7,202 patients were considered low risk (SSR, 64.2% v NR, 52.7%; $P < .001$) and 4,381 patients were high risk (SSR, 31.2% v NR, 39.4%; $P < .001$). Risk status could not be determined for 783 patients as a result of missing information on one or more risk factors (SSR, 4.6% v NR, 8.0%; $P < .001$). Of high-risk patients with SSR, 19.6% received chemotherapy compared with 15.1% of high-risk patients with NR ($P = .001$), even when corrected for year of diagnosis, gender, and age (adjusted OR, 1.29; 95% CI, 1.06 to 1.57). No difference in chemotherapy administration was observed for low-risk patients, nor for patients with an unknown risk status. Overall survival in the high-risk group was significantly better in patients with SSR (65.0% v

62.4%; $P = .026$; Fig 4A). No differences were observed for patients with low or unknown risk in relation to the type of report.

Crude 5-year overall survival for patients with an SSR was higher compared with patients with an NR (64.9% v 62.2%; $P < .001$; Fig 4B). As there were significant differences in stage, grade, and neoadjuvant therapy between SSR and NR (Table 1), we adjusted for these factors, as well as for age at diagnosis, gender, year of diagnosis, localization of tumor, histologic type, and type of pathology laboratory. The difference remained present after adjustment (HR, 0.94; 95% CI, 0.90 to 0.97).

DISCUSSION

We demonstrated that the nationwide implementation of SSR for CRC resection specimens resulted in improved completeness and quality of pathology reports, and we

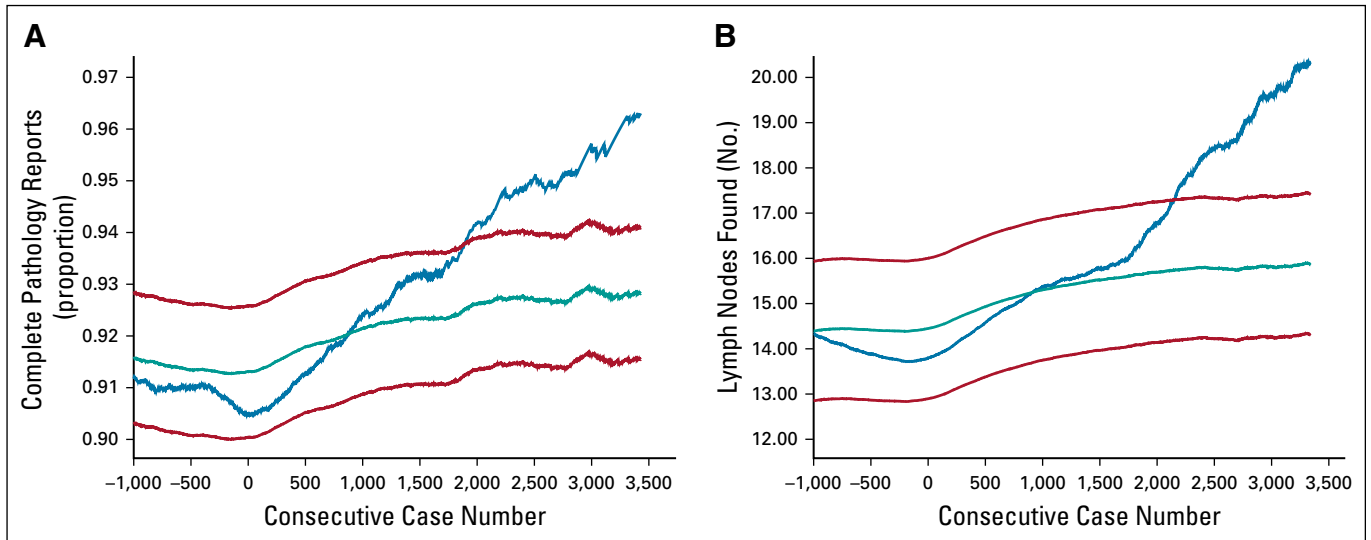


FIG 3. (A) Proportion of complete pathology reports after the introduction of standardized structured reporting (SSR). Blue, observed proportion of complete reports. Teal, expected proportion of complete reports. Red, 95% CI for the predicted proportion of complete reports. SSR is introduced at consecutive case number 0. After the observed proportion of complete reports exceeds the upper limit of the 95% CI of the expected proportion of complete reports, the increase of completeness can no longer be explained by casemix and is likely caused by the introduction of SSR. (B) Number of lymph nodes after the introduction of SSR. Blue, observed numbers of lymph nodes. Teal, expected number of lymph nodes. Red, 95% CI for the predicted number of lymph nodes. SSR is introduced at consecutive case number 0. After the observed number of lymph nodes found exceeds the upper limit of the 95% CI of the expected number of lymph nodes found, the increase can no longer be explained by casemix and is likely caused by the introduction of SSR.

have described the effects on patient care. Improved completeness was expected on the basis of previous studies⁴; however, these studies were relatively small, with only one study that included more than 1,000 SSR. Completeness for individual parameters was highly variable, but well below the 60% as a starting point for many parameters, such as resection margins^{6,12,22} and stage.^{10,11,13} Our reference group presented with more

than 90% total completeness; therefore, we expected a limited effect of SSR on completeness. This potentially limited the impact of the introduction on health care improvement; however, we demonstrated that SSR further improves reporting of all relevant items to 95% to 100%, which is in line with other publications.^{9,10,23,24} The improvement is particularly pronounced for more recently recognized parameters, such as EMVI and CRM.⁴

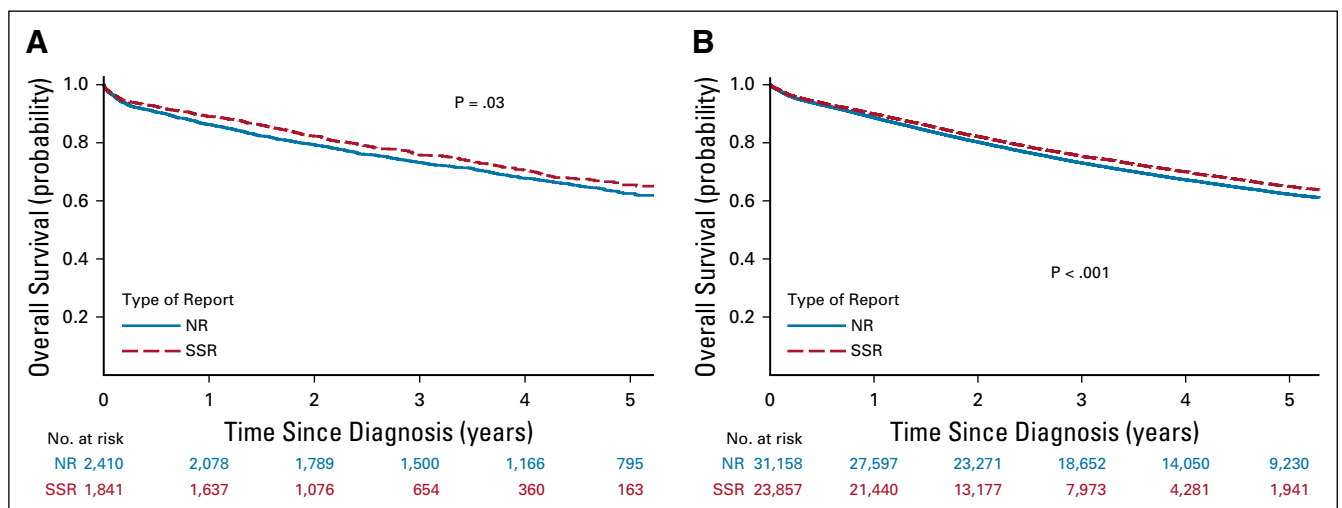


FIG 4. (A) Overall survival of Dutch patients with colorectal cancer (CRC) with high-risk stage II disease. There is a small but consistent overall survival benefit in the patients whose tumors were reported with standardized structured reporting (SSR). $P = .026$. (B) All stages CRC according to the type of pathology report. There is a small but consistent overall survival benefit in the patients whose tumors were reported with SSR. $P < .001$. NR, narrative report.

Of more importance, we also proved that the introduction of SSR leads to better-quality pathology reporting. Increased awareness of the critical issues in pathology assessment, such as CRM in rectal cancer and numbers of LNs in CRC, began before the introduction of SSR in the Netherlands, as can be observed in [Figures 2C and 2D](#), with increased reporting since 2007. The introduction of SSR accelerated this process, as can be observed from the rapid increase in the proportion of complete reports ([Fig 3A](#)) and the mean number of examined LNs per laboratory after they started with SSR ([Fig 3B](#)). To evaluate the improved quality of pathologic examination, the use of predefined quality indicators, such as LN count, EMVI detection remains to a certain extent artificial.

Numerous studies have examined the quality of microscopic evaluation by comparing the results of slide sets scored by different groups of pathologists²⁵⁻²⁸; however, clinical relevance is more directly investigated if the relation of a prognostic factor with outcome is evaluated. Therefore, we examined the prognostic value of the different histologic factors in both the SSR and NR settings and compared their AIC values, as is often used in comparing different staging systems.²⁹ We were able to show that for all relevant factors the prognostic value was better when SSR was used. This suggests that increased awareness, perhaps in combination with the possibility of directly checking the definitions (provided in SSR setting), leads to better histologic evaluation.

The effect of improved communication on patient care has been evaluated in the setting of multidisciplinary team meetings.³⁰ In general, these studies report higher rates of appropriate treatment, better adherence to clinical guidelines, and better survival.³¹⁻³³ In the current study, we have

focused on these items as a measurement of the effects on patient care. We demonstrated that the administration of adjuvant chemotherapy in patients with high-risk stage II disease was significantly higher in those with SSR. In addition, appropriate staging occurred in more patients, particularly with regard to discriminating patients with high-risk from low-risk stage II CRC. Use of SSR indirectly leads to outcome benefits, as demonstrated by the difference in overall survival between patients with SSR and NR, which remains present after adjustment for the year of diagnosis and patient and tumor characteristics. We realize that in the current setup, inherent biases are present that might reflect the higher quality of the multidisciplinary team rather than use of SSR. However, given the results from the figures that show changing trends before and after the introduction of SSR ([Fig 3](#)), this bias does not explain the whole effect.

Nevertheless, a randomized clinical trial is the most appropriate design to test the effects on patient outcomes; however, such a design is impractical under the current circumstances because of the widespread implementation of SSR in our country. Therefore, we adopted a whole population cohort study in which we controlled for potentially confounding factors, such as the type of hospital and the year of diagnosis. We therefore believe that our findings are robust.

In conclusion, the nationwide implementation of SSR for CRC resulted in increased completeness of pathology reports, higher-quality pathology evaluation, and better outcomes for patients. These findings support the widespread introduction of SSR in oncology.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated.

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APPENDIX

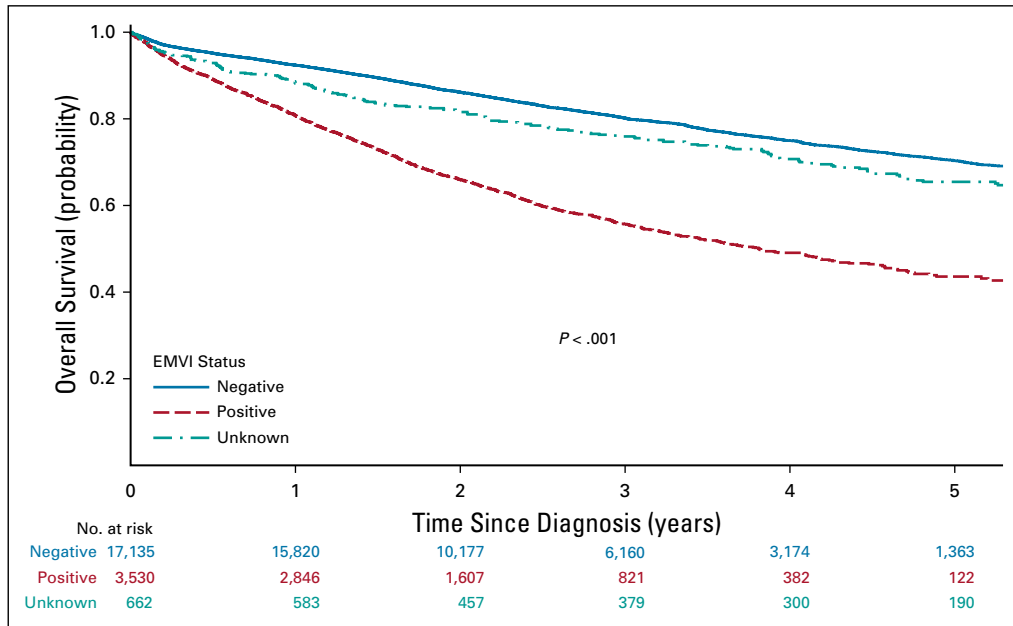


FIG A1. Survival curves to study the impact of positive, negative, and unknown extramural vascular invasion for standardized structured reporting.

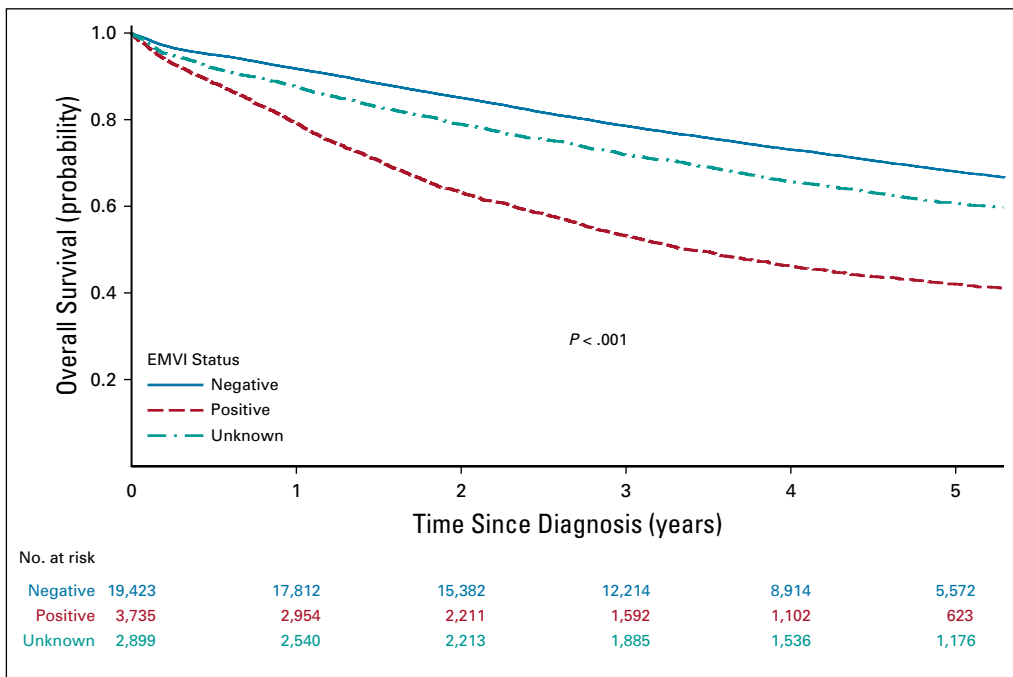


FIG A2. Survival curves to study the impact of positive, negative, and unknown extramural vascular invasion for standardized structured reporting and narrative report.

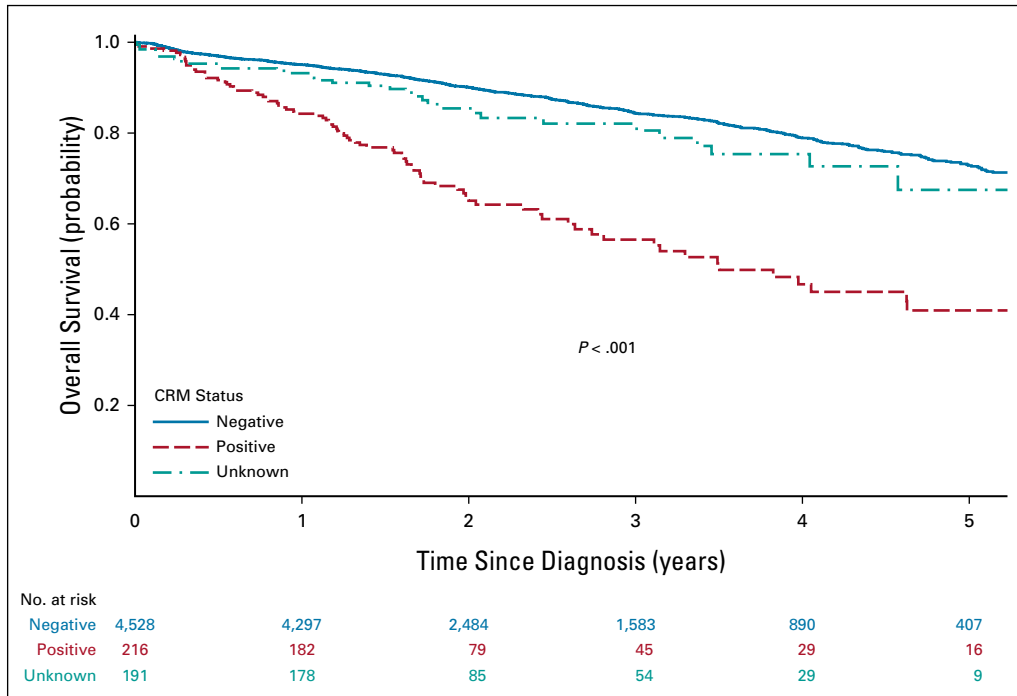


FIG A3. Survival curves for the impact of circumferential resection margin involvement for rectal carcinoma for standardized structured reporting.

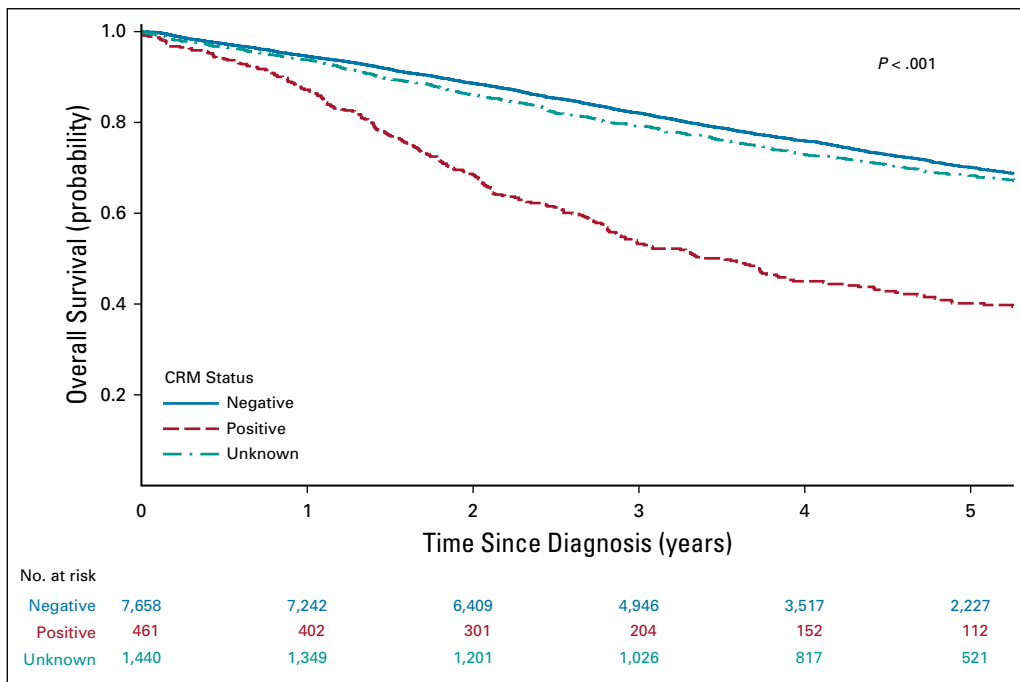


FIG A4. Survival curves for the impact of circumferential resection margin involvement for rectal carcinoma for narrative report.

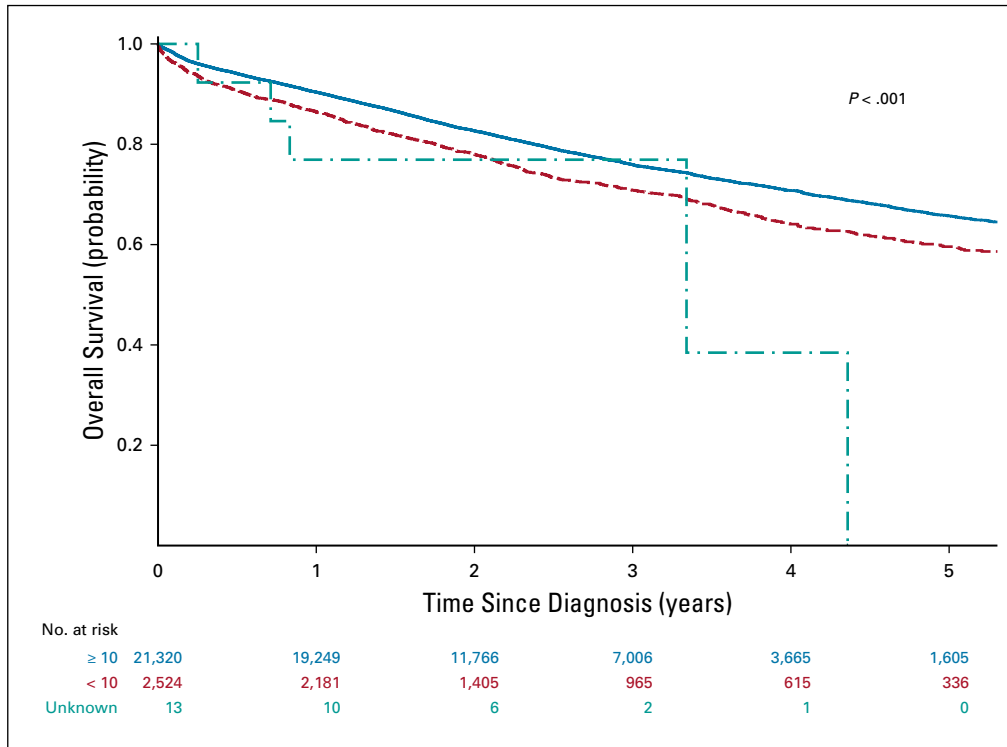


FIG A5. Survival curves for the impact of 10 or more examined lymph nodes for standardized structured reporting.

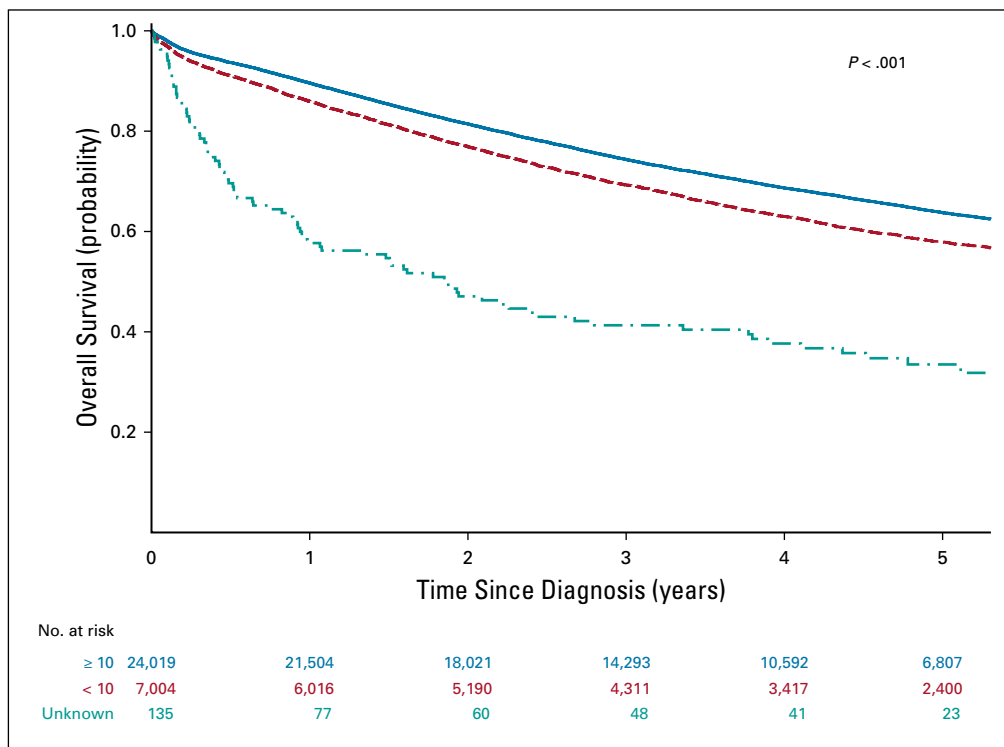


FIG A6. Survival curves for the impact of 10 or more examined lymph nodes for narrative report.

TABLE A1. Effects of SSR on Completeness and Quality Indicators

Variable	Reference, %	NR, %	SSR, %	Crude OR (95% CI)	Adjusted OR (95% CI)	<i>P</i> Reference v NR	<i>P</i> NR v SSR
Overall completeness	90.6	89.8	95.8	2.58 (2.40 to 2.78)	2.33 (2.15 to 2.52)	.006	< .001
Parameter-specific completeness							
Histologic type	100	100	100	NA	NA	NA	NA
Histologic grade	96.9	92.1	95.8	1.96 (1.80 to 2.14)	1.97 (1.79 to 2.18)	< .001	< .001
Invasion depth	100	99.9	100	NA	NA	.20	.07
Nodal status	98.4	99.0	99.7	3.38 (2.61 to 4.39)	2.98 (2.24 to 3.96)	< .001	< .001
Lymph node count	98.8	99.5	99.9	6.24 (3.83 to 10.2)	4.56 (2.69 to 7.73)	< .001	< .001
EMVI	—	88.9	96.9	3.86 (3.55 to 2.41)	2.17 (1.98 to 2.38)	NA	< .001
CRM	75.5	84.9	96.1	4.34 (3.73 to 5.06)	3.63 (3.06 to 4.30)	< .001	< .001
Quality indicators							
At least 10 lymph nodes investigated	63.3	77.3	89.3	2.46 (2.34 to 2.58)	1.77 (1.68 to 1.87)	< .001	< .001
Presence of EMVI	—	16.1	17.1	1.08 (1.03 to 1.13)	1.08 (1.02 to 1.14)	NA	.003
Negative CRM	88.5	94.3	95.5	1.27 (1.08 to 1.50)	1.13 (0.94 to 1.37)	< .001	.004

NOTE. Adjusted OR is corrected for year of diagnosis.

Abbreviations: CRM, circumferential margin; EMVI, extramural vascular invasion; NA, not assessable; NR, narrative reporting; OR, odds ratio; SSR, standardized structured reporting.