Evaluating the impact of COVID19-related healthcare disruptions on pathologic cancer staging: a retrospective cohort study

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Funding: LE Cipriano is supported by a Canada Research Chair in Healthcare Analytics, Management, and Policy (CRC-950-233070).

Competing Interests: None

Word Count: 2009

Abstract

Background: The COVID-19 pandemic has created significant disruptions in cancer care, with delays and reductions in diagnostic tests and treatments. We evaluated the impact of these healthcare-related changes on cancer staging, by comparing pathologically staged cancers before and during the pandemic.

Methods: We performed a retrospective cohort study at London Health Sciences Centre and St. Joseph's Healthcare, in London, Ontario. We evaluated all pathologically staged breast, colorectal, prostate, endometrial and lung cancers over a three-year period (March 15, 2018 to March 14, 2021). Cases were assigned to the pre-COVID group if the procedure was performed before March 15, 2020, or the COVID-period group with a procedure date on or after March 15, 2020. The primary outcome was cancer stage group, based on pathologic tumour, node, and metastasis (pTNM) stage. Univariate analyses were performed to compare demographic, pathologic features, and cancer stage group between pre-COVID and COVID-period cases. Multivariate ordinal regression analyses were performed for each cancer site, to evaluate whether cases staged during the COVID period were associated with a change in stage.

Results: There were 4 055 cases across the five cancer sites. Breast cancer staging procedures increased during the pandemic (41.3 vs 39.6 cases/30 days), while decreases were observed for endometrial (15.9 vs 16.4 cases/30 days), colorectal (21.8 vs 24.3 cases/30 days), prostate (13.6 vs 18.5 cases/30 days) and lung (11.5 vs 15.9 cases/30 days) cancers. For all cancer sites, there were no statistically significant differences in demographics, pathologic features, or cancer stage ($p>0.05$). In the multivariate regression analysis, cases staged during the pandemic were not associated with greater stage for all cancer sites ($p>0.05$).

Interpretation: Cases staged during the first COVID-19 pandemic year were not associated with greater stage, likely reflecting the prioritization of cancer procedures during times of reduced capacity.

Introduction

Throughout the COVID-19 pandemic, healthcare systems across Canada have grappled with significant fluctuations in healthcare service delivery. Notably, the first wave in March-June 2020 strained hospital capacity and supplies; to conserve limited resources, management of patients with COVID-19 and urgent non-COVID-19 conditions was prioritized (1). This shift in resource allocation, in addition to changes in patient behaviour, resulted in decreased hospital admissions, emergency visits, and medical services (2). In Ontario, there has been a series of province-wide states of emergency related to COVID-19, creating further potential gaps in care (3).

In the continuum of cancer care, patients may require access to a variety of medical services including ambulatory clinics, imaging and laboratory testing, oncologic treatments and supportive care (4). Previous studies have shown reductions in cancer screening, testing, and treatment during the COVID-19 pandemic (5–9), while modelling studies have projected greater cancer-related deaths as a result of the gaps in care (10,11). Despite these projections, it is unclear whether healthcare disruptions resulted in a change in cancer stage and characteristics in the initial pandemic period. This study sought to compare the pathologic stage and features of cancers staged before (March 15, 2018-March 14, 2020) and during the first year of COVID-related interruptions in hospital services (March 15, 2020-March 14, 2021).

Methods

Study Design and Data Collection

We performed a retrospective cohort study at London Health Sciences Centre (LHSC) and St. Joseph's Health Care (SJHC), located in London, Ontario, Canada. LHSC and SJHC are part of a network of academic tertiary care hospitals serving Southwestern Ontario and are affiliated with Western

University. We reported this study in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (12).

We first used our institutional cancer reporting data to identify the five most common cancers by site (excluding non-melanoma skin cancers), which included breast, colorectum, prostate, endometrium, and lung. Using our internal pathology database, we identified all cancer staging resections for these sites, performed over a three-year period (March 15, 2018 to March 14, 2021). We based the comparison groups on the surgery date; procedures performed before March 15, 2020 were included in the pre-COVID group, while the COVID-period group included all procedures performed on or after March 15, 2020. We used this date specifically because it was the start of the first province-wide ramping down of elective surgeries and non-emergent activities (13).

In Ontario, the pathological staging of primary cancers is reported using a standardized synoptic format, with mandatory reporting items established for different cancer sites. We used the pathology reports and electronic medical records to extract data for analysis, and all cases were deidentified using a unique study identifier. We used the pathological cancer stage group as the outcome variable, determined by the 8th edition of the American Joint Committee on Cancer Tumour/Node/Metastasis (pTNM) system (14). In cases where pathological staging was performed over multiple procedures, most commonly in breast cancers with separate sentinel lymph node sampling, we collated this information to determine the final stage group. We documented if the case was staged as a tumour recurrence, post-neoadjuvant therapy, or if there were multiple primary tumours. In the case of multiple primary tumours, the tumour with the most advanced stage was used for analysis.

For all cases, we collected demographic information including age and sex, as well as information regarding the specimen/procedure. For all primary cancers, we also extracted macroscopic and microscopic features that are included in the synoptic report but are not directly used for staging, with the variables specific to each cancer site. Generally, these features are used for risk stratification and may inform prognosis and/or guide treatment decisions. For breast and colorectal cancers, which have

population-wide screening programs, we reviewed the electronic medical records to determine the clinical presentation and whether the malignancy was initially detected via screening.

Statistical Analysis

We computed descriptive and summary statistics for the cohort. To compare cancer cases staged before and during the COVID periods, we included only primary surgically treated cancers. Neoadjuvant-treated and recurrent cases were excluded for multiple reasons: the stage would not be an accurate reflection of the original disease; complete microscopic evaluation is often limited by posttreatment changes, particularly in cases with minimal or no residual tumour; and, the case would not be reflective of a primary staging procedure because patients with neoadjuvant treatment or recurrence would already be in the cancer treatment pathway. We also excluded prostate cancer cases identified in radical cystoprostatectomy specimens, as these were all performed for primary bladder malignancies.

We performed univariate analyses to compare patient demographics, cancer features, and stage. We used the Mann-Whitney test to evaluate differences in ordinal and continuous variables. For ordinal variables, if there were less than 10 observations in a category, we combined those cases with the next lowest or highest group. For binary and categorical variables, we used χ^2 or the Fisher exact test, with the latter being used if there were less than 10 observations in a category.

To evaluate whether there was a statistically significant shift in cancer stage during the COVID period, we performed a multivariate ordered logistic regression analysis using cancer stage as the outcome variable. For each regression analysis, the model included COVID-period status, demographic variables, and site-specific risk features. We excluded binary variables from the model if there were less than 10 observations in one of the groups. Odds ratios and 95% confidence intervals were calculated for all variables. The Brant test was used to test the proportional odds assumption (15), and general variance-inflation factors were used to check for multicollinearity. A 2-tailed P value of <0.05 was used to define statistical significance. All statistical analyses were performed using R v.4.1.1.

Ethics Approval

Ethics approval was obtained from the Research Ethics Board at Western University and Lawson Health Research Institute (REB #119137).

Results

The cohort comprised 4055 cancer cases across the five cancer sites (Table 1). In the one-year COVID period, there was an increase in breast cancer cases compared to yearly pre-COVID average (41.3 vs 39.6 cases per 30 days, increase 4.3%), while decreases were observed for endometrial (15.9 vs 16.4 cases per 30 days, decrease 3.0%), colorectal (21.8 vs 24.3 cases per 30 days, decrease 10.3%), prostate (13.6 vs 18.5 cases per 30 days, decrease 26.5%) and lung (11.5 vs 15.9 cases per 30 days, decrease 27.7%) cancers. The baseline patient demographics and procedures were similar between both groups. There was a greater rate of neoadjuvant-treated cases for lung cancers (6.4% vs 3.1%), prostate (17.6% vs 7.8%), colorectal (26.0% vs 22.3%) and breast (17.9% vs 16.1%) in the COVID period.

In the univariate analysis, there were no statistically significant differences in cancer stage distribution, high-risk features, or demographics (Tables 2-6). The results of the multivariate ordinal logistic regression for all cancer sites are provided in Table 7. Across all cancer sites, having been staged in the COVID period was not statistically associated with higher cancer stage at diagnosis, after controlling for patient and disease-specific factors.

Interpretation

In our study, we evaluated the impact of the COVID-19-pandemic on cancer staging in a Canadian healthcare context. We did not find statistically significant differences in pathologic stage or high-risk features cancers staged in the first year of the COVID pandemic compared to those staged in the

two year per-pandemic period. In the first year of the pandemic, there was no evidence that surgically treated cancers were more advanced or aggressive.

Our analysis included the five most commonly staged cancers, all with a variety of risk factors, pathophysiology, and clinical characteristics. Although we did not observe any statistically significant differences, our findings provide insight into cancer care patterns during the pandemic. Despite disturbances in healthcare service delivery, the number of breast and endometrial cancers cases were similar to the pre-pandemic period, while a modest decrease of 10.3% was observed for colorectal cancers. These findings reflect the prioritization of oncologic surgeries during the lockdown period (16), and are consistent with previous studies showing that oncologic surgery volumes were not as severely affected compared to other surgery types (7,17). Furthermore, the COVID period also included extended times with resumed clinical activity, allowing greater capacity to treat patients waiting for surgery. Although there were service reductions, particularly at the beginning of the pandemic, the number of surgically treated cases over the one-year period was maintained for breast and endometrial cancers.

In contrast, there were markedly fewer staging procedures for prostate and lung cancers, likely because there are no population-wide screening programs for these cancers, and it is not uncommon for these patients to be asymptomatic at presentation (18–21). As a result, reductions in other types of clinical services may have limited opportunities to diagnose incident cases (2). Another possibility is that primary surgical staging may have been reduced for some cancers in favor of first-line drug or radiation therapy. During the pandemic, cancer treatment pathways have been modified, with triaging based on a combination of patient, disease, resource, and COVID-19-related risk factors (22), with variable impact. In another Canadian study, there was a significant decrease in lung cancer cases during the early pandemic period, along with a reduction in surgeries as the primary treatment modality (23). In our study, the greatest increase in neoadjuvant-treated cases during the COVID period was observed in prostate cancer.

For breast and colon cancers, we found that screening-detected cases were statistically significant predictors of lower stage, highlighting the role of these screening programs in detecting early-stage cancers. It is also important to emphasize the crucial role of screening in primary cancer prevention, through the detection and removal of pre-malignant lesions. We previously described how our institutional surgical pathology volumes changed during the first 4 months of the pandemic, with biopsy volumes more severely affected compared to surgical resections (24). Given that premalignant lesions in the breast and colon can take multiple years before progressing to cancer (25,26), the consequences from changes in screening utilization may not be observable for several years.

Cancer outcomes are not only influenced by stage, but are also affected by access to high quality diagnostic tests and treatments (27,28). Our findings indicate that early efforts to prioritize newly diagnosed cancer patients, even during significant strain on the health care system, appear to have protected patients from disease progression related to delays in care. Variable reductions in staging procedures were observed across different cancer sites, and it is important to elucidate whether this represents reductions in diagnoses and/or treatment. As healthcare systems allocate resources under continually changing conditions, addressing gaps in cancer care will be important to ensure that patients receive fair and equitable access to healthcare services, and to optimize patient outcomes.

Limitations

We used pathological staging data, which are based on the gross and microscopic examination of tissues. Pathological stage may differ from clinical stage if there are findings on imaging that are not assessed at the tissue level. Furthermore, some metastatic (stage IV) cancers may not be captured in our data, as these patients often do not undergo surgery. However, given the similar rates of cases, particularly for breast, colorectal and endometrial cancers, it is unlikely that a marked increase in metastatic cases would have arisen in the first year of COVID.

There is likely regional variation in how cancer staging has changed during the COVID-19 pandemic, depending on local infection rates, resource availability, and government and hospital policy. Temporal changes will also inevitably occur, as healthcare systems grapple with additional waves and fluctuations in clinical activity. Nonetheless, our study provides a broad overview of cancer patterns during the initial pandemic period and serves as valuable baseline data going forward.

Although we did not detect changes at the population level, there are no doubt individual patients who have experienced clinically meaningful delays in accessing cancer services. For patients with cancer during the pandemic, the healthcare changes and uncertainty have resulted in greater emotional and mental stress (29–31). We focused on cancer stage as the primary outcome, but resource planning must also include supportive treatments to address patient well-being, so that patients receive high-quality, comprehensive cancer care.

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Table 1 – Summary characteristics of pre-COVID and COVID-period cancer cases

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)
Breast		
N	964	503
Cases per 30 days	39.6	41.3
Age, median (IQR)	63 (52-71)	64 (54-73)
Sex		
Female	957 (99.3%)	499 (99.2%)
Male	7 (0.7%)	4 (0.8%)
Specimen		
Mastectomy	300 (31.1%)	163 (32.4%)
Excision	662 (68.7%)	338 (67.2%)
Other	2 (0.2%)	2 (0.4%)
Neoadjuvant treatment	155 (16.1%)	90 (17.9%)
Recurrence	24 (2.5%)	29 (5.8%)
Multiple primary tumours	144 (14.9%)	69 (13.7%)
Colorectum		
N	592	265
Cases per 30 days	24.3	21.8
Age, median (IQR)	71 (61-78)	70 (60-78)
Sex		
Female	258 (43.6%)	113 (42.6%)
Male	334 (56.4%)	152 (57.4%)
Specimen		
Right colon	251 (42.4%)	116 (43.8%)
Left colon	78 (13.2%)	33 (12.5%)
Rectal	225 (38.0%)	100 (37.7%)
Subtotal/total colectomy or proctocolectomy	28 (4.7%)	11 (4.2%)
Other	10 (1.7%)	5 (1.9%)
Neoadjuvant treatment	132 (22.3%)	69 (26.0%)
Recurrence	6 (1.0%)	3 (1.1%)
Multiple primary tumours	19 (3.2%)	7 (2.6%)
Prostate		
N	449	165
Cases per 30 days	18.5	13.6
Age, median (IQR)	65 (59-68)	64 (59-68)
Specimen		
Radical prostatectomy	405 (90.2%)	141 (85.5%)
Radical cystoprostatectomy	44 (9.8%)	24 (14.5%)
Neoadjuvant treatment	35 (7.8%)	29 (17.6%)
Multifocal tumours	87 (19.4%)	36 (21.8%)
Endometrium		
N	398	193
Cases per 30 days	16.4	15.9

Age, median (IQR)	65 (59-72)	66 (58-72)
Specimen		
Hysterectomy Type		
Simple/Total	393 (98.7%)	190 (98.4%)
Other	5 (1.3%)	3 (1.6%)
NA	1	0
Bilateral salpingo-oophorectomy	369 (92.7%)	180 (93.3%)
<Bilateral salpingo-oophorectomy	16 (4.0%)	8 (4.1%)
Omentectomy	96 (24.1%)	46 (23.8%)
Neoadjuvant treatment	7 (1.8%)	3 (1.6%)
Lung		
N	386	140
Cases per 30 days	15.9	11.5
Age, median (IQR)	69 (63-75)	71 (66-76)
Sex		
Male	137 (35.5%)	63 (45.0%)
Female	249 (64.5%)	77 (55%)
Specimen		
Lobectomy	231 (59.8%)	80 (57.1%)
Wedge resection	89 (23.1%)	34 (24.3%)
Segmentectomy	15 (3.9%)	9 (6.4%)
Other	51 (13.2%)	17 (12.1%)
Neoadjuvant treatment	12 (3.1%)	9 (6.4%)
Recurrence	1 (0.3%)	2 (1.4%)
Multiple primary tumours	23 (6.0%)	12 (8.6%)

Table 2 – Univariate analysis comparing demographics, pathologic features, and stage between pre-COVID and COVID-period breast cancers

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)	p-value
n	788	387	
Cases per 30 days	32.4	31.8	
Age, median (IQR)	64 (54-72)	65 (55-73)	0.143
Sex			
Female	782 (99.2%)	383 (99.0%)	0.737
Male	6 (0.8%)	4 (1.0%)	
Screen			
No	462 (59.2%)	243 (62.8%)	0.236
Yes	319 (40.8%)	143 (37.0%)	
NA	7	1	
Histologic Subtype			
Ductal	559 (71.1%)	273 (70.9%)	0.282
Lobular	136 (17.3%)	60 (15.6%)	
Mucinous	31 (3.9%)	12 (3.1%)	
Other	60 (7.6%)	40 (10.4%)	
NA	2	2	
Grade			
1	189 (24.2%)	97 (25.5%)	0.236
2	369 (47.3%)	191 (50.1%)	
3	222 (28.5%)	93 (24.4%)	
NA	8	6	
Lymphovascular Invasion	142 (18.0%)	65 (16.8%)	0.663
Hormone Status			
Other	686 (87.4%)	342 (88.4%)	0.616
HER2-Overexpressed	39 (5.0%)	19 (4.9%)	
Triple-Negative	60 (7.6%)	26 (6.7%)	
NA	3	0 (0%)	
Positive Margin	72 (9.1%)	39 (10.1%)	0.680
Extensive intraductal component	78 (9.9%)	40 (10.3%)	0.896
Stage			
I	420 (53.5%)	199 (51.7%)	0.593
II	283 (36.1%)	145 (37.7%)	
III	82 (10.4%)	41 (10.6%)	
NA	3	2	

Table 3 – Univariate analysis comparing demographics, pathologic features, and stage between pre-COVID and COVID-period colorectal cancers

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)	p-value
n	455	193	
Cases per 30 days	18.7	15.9	
Age, median (IQR)	72 (64-80)	73 (61-79)	0.891
Sex			
Female	204 (44.8%)	90 (46.6%)	0.738
Male	251 (55.2%)	103 (53.4%)	
Screen			
No	376 (83.2%)	167 (87.0%)	0.275
Yes	76 (16.8%)	25 (13.0%)	
NA	3	1	
Histologic Subtype			
Adenocarcinoma	357 (78.6%)	152 (78.8%)	0.446
Mucinous adenocarcinoma	42 (9.3%)	13 (6.7%)	
Other	55 (12.1%)	28 (14.5%)	
NA	1	0	
Tumour size in cm, median (IQR)	4.5 (3.0-6.0)	4.3 (3.3-6.0)	0.712
Lymphovascular invasion	247 (54.3%)	110 (57.0%)	0.584
Perineural invasion	113 (24.8%)	50 (25.9%)	0.851
Positive margin	57 (12.5%)	19 (9.8%)	0.403
Tumour perforation	16 (3.5%)	8 (4.1%)	0.657
Stage			
I	102 (22.5%)	35 (18.1%)	0.174
II	164 (36.2%)	66 (34.2%)	
III	150 (33.1%)	79 (40.9%)	
IV	37 (8.2%)	13 (6.7%)	
NA	2	0	

Table 4 – Univariate analysis comparing demographics, pathologic features, and stage between pre-COVID and COVID-period endometrial cancers

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)	p-value
n	391	190	
Cases per 30 days	16.1	15.6	
Age, median (IQR)	65 (59-72)	66 (58-72)	0.785
Histologic Subtype			
Endometrioid carcinoma, NOS	244 (62.4%)	112 (58.9%)	0.613
Endometrioid carcinoma, other variant	56 (14.3%)	31 (16.3%)	
High-grade histologic subtype	88 (22.5%)	47 (24.7%)	
Other	3 (0.8%)	0	
Histologic Grade			
Low	272 (69.6%)	125 (65.8%)	0.411
High	119 (30.4%)	65 (34.2%)	
Lymphovascular invasion	115 (29.4%)	64 (33.7%)	0.342
Positive margin	6 (1.5%)	3 (1.6%)	1
Stage			
I	289 (73.9%)	145 (76.3%)	0.628
II	38 (9.7%)	13 (6.8%)	
III+IV*	64 (16.4%)	32 (16.8 %)	

*Grouped due to n<10 for stage IV cases

Table 5 – Univariate analysis comparing demographics, pathologic features, and stage between pre-COVID and COVID-period prostate cancers

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)	p-value
n	372	113	
Cases per 30 days	15.3	9.3	
Age, median (IQR)	64 (59-68)	63 (58-67)	0.411
Histologic Subtype			
Acinar adenocarcinoma	349	109	0.355
Acinar adenocarcinoma with mixed features	23	4	
Gleason Grade Group*			
1+2	274 (73.7%)	79 (69.9%)	0.508
3-5	98 (26.3%)	34 (30.1%)	
Intraductal carcinoma	102 (27.4%)	37 (32.7%)	0.328
Lymphovascular invasion	34 (9.1%)	14 (12.4%)	0.405
Perineural invasion	329 (88.4%)	105 (92.9%)	0.236
Margin status			
Negative	249 (66.9%)	73 (64.6%)	0.918
Limited pos	59 (15.9%)	25 (22.1%)	
Non-limited pos	64 (17.2%)	15 (13.3%)	
Stage†			
I+II	161 (43.3%)	44 (38.9%)	0.374
III	184 (49.5%)	59 (52.2%)	
IV	27 (7.3%)	10 (8.8%)	

*Grouped due to n<10 for Gleason grade groups 1, 4 and 5

†Grouped due to n<10 for Stage I cases

Table 6 – Univariate analysis comparing demographics, pathologic features, and stage between pre-COVID and COVID-period lung cancers

	Pre-COVID (Mar 2018-Mar 2020)	COVID Period (Mar 2020-Mar 2021)	p-value
n	373	129	
Cases per 30 days	15.3	10.6	
Age, median (IQR)	70 (63-75)	71 (64-76)	0.396
Sex			
Female	240 (64.3%)	73 (56.6%)	0.144
Male	133 (35.7%)	56 (43.4%)	
Histologic Type			
Adenocarcinoma	236 (63.3%)	89 (69.0%)	0.316
Squamous cell carcinoma	70 (18.8%)	25 (19.4%)	
Carcinoid	36 (9.7%)	6 (4.7%)	
Other	31 (8.3%)	9 (7.0%)	
Lymphovascular invasion	57 (15.3%)	28 (21.7%)	0.123
Positive Margin	18 (4.8%)	5 (3.9%)	0.809
Stage			
I	239 (65.1%)	83 (64.3%)	0.904
II	72 (19.6%)	31 (24.0%)	
III+IV*	56 (15.3%)	15 (11.6%)	
Not applicable	6	0	

*Grouped due to n<10 for stage IV cases

Table 7 – Multivariate ordinal regression for pathological cancer stage

	OR	95% CI	p-value
Breast (n = 1150)			
COVID Period	1.071	0.826-1.388	0.603
Age	1.009	1.000-1.019	0.050
Screen-detected	0.246	0.186-0.324	<0.001
Grade	2.308	1.756-3.044	<0.001
Lymphovascular Invasion	5.522	3.968- 7.730	<0.001
High-risk hormone status	1.102	0.791-1.531	0.562
Extensive intraductal component	0.890	0.573-1.365	0.596
Positive margin	1.351	0.901-2.017	0.143
Colorectal (n = 638)			
COVID Period	1.201	0.869-1.661	0.268
Age	0.996	0.984-1.008	0.518
Sex (male)	1.119	0.828-1.512	0.465
Screen-detected	0.398	0.254-0.618	<0.001
Tumour size	1.178	1.105-1.259	<0.001
Lymphovascular invasion	3.799	2.731-5.314	<0.001
Perineural invasion	2.383	1.628-3.506	<0.001
Positive margin	3.764	2.261-6.334	<0.001
Endometrium (n = 572)			
COVID Period	0.792	0.495-1.252	0.324
Age	1.002	0.980-1.025	0.835
High Grade	4.922	3.173-7.700	<0.001
Lymphovascular Invasion	5.729	3.714-8.915	<0.001
Prostate (n = 485)			
COVID Period	1.171	0.765-1.794	0.603
Age	1.027	0.997-1.058	0.118
High Gleason Grade (3-5)	2.736	1.687-4.510	<0.001
Intraductal Carcinoma	2.744	1.795-4.243	0.001
Lymphovascular Invasion	17.849	8.423-39.749	<0.001
Positive margin	1.778	1.239-2.576	0.009
Lung (n = 496)			
COVID Period	0.826	0.535-1.262	0.383
Age	1.003	0.984-1.023	0.788
Sex (male)	1.888	1.292-2.761	0.001
Lymphovascular invasion	4.310	2.730-6.829	<0.001

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4-5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (*b*) For matched studies, give matching criteria and number of exposed and unexposed	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-6
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) If applicable, explain how loss to follow-up was addressed (*e*) Describe any sensitivity analyses	6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	7,14-21
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	14-20
Outcome data	15*	Report numbers of outcome events or summary measures over time	16-20

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	7,14-21
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	7-8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9-10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7-10
Generalisability	21	Discuss the generalisability (external validity) of the study results	NA
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	2

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.