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Guideline adherence in ovarian cancer for surgical staging in the Netherlands

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ABSTRACT

Objective Previous studies have shown low adherence to surgical staging guidelines in patients with clinical early-stage ovarian carcinoma. The aim of this study was to identify guideline adherence for surgical staging and to show the distribution of each surgical item within the study population. In addition, we examined whether regional variation in the Netherlands exists for complete surgical staging.

Methods Patients with ovarian cancer and surgical staging registered in the Dutch Gynecological Oncology Audit between January 1, 2015 and December 31, 2019 in the Netherlands were included. Complete surgical staging was defined according to the Dutch evidence-based guideline. Surgical items were ranked and illustrated. Variation in complete surgical staging for eight regional cancer networks was shown in funnel plots. Manual validation of registered data was performed in three gynecological oncology centers.

Results 604 patients underwent surgical staging, 365 (60%) underwent an incomplete staging procedure, 295 (81%) were registered with early-stage disease (International Federation of Gynecology and Obstetrics I–IIA) and, of these patients, 115 (39%) received adjuvant chemotherapy. Patients with incomplete surgical staging were operated more often with minimal invasive techniques (laparoscopy or robot) compared with patients in the complete staging group ($p < 0.001$). Sampling of cytology/ascites was the most frequently lacking factor (29%). Manual validation of data in three gynecological oncology centers identified reasons for incomplete staging, the most common being ‘perioperative findings’ such as dense adhesions between tumor and peritoneum, consistent with advanced stage disease (\geq IIA). Regional variation for complete surgical staging showed two regions performing outside the confidence intervals (12.5% and 25.5%, mean 40%).

Conclusion Guideline adherence for staging was lower than expected and validation of data gave additional insights into the reasons that were contributing to incomplete surgical staging. Moreover, this analysis showed that regional variation for surgical staging exists, which forms a starting point to improve and harmonize staging procedures for these patients nationwide.

INTRODUCTION

In the past decade, guideline adherence and clinical variation has become a contemporary topic of interest. Simultaneously, evidence-based treatment has been

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Guideline adherence in surgical staging for ovarian cancer is lower than expected (internationally and nationally). It remains a subject of debate why these percentages remain low.

WHAT THIS STUDY ADDS

⇒ This study shows that guideline adherence for surgical staging in the Netherlands for ovarian cancer is lower than expected. Manual validation of data in three gynecological oncology centers identified several reasons for incomplete staging, the most common being ‘perioperative findings’ such as dense adhesions between tumor and peritoneum, already consistent with advanced stage disease (\geq IIA). Additionally, the study showed that there is regional variation in the Netherlands pertaining to surgical staging.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ By providing feedback on compliance with the guideline adherence per surgical item and its validated results, more insights can be gained into the use and registration of national guideline items in the Dutch Gynecological Oncology Audit.

recognized as a cornerstone to improve quality of care in relation to patient outcomes for ovarian cancer.^{1,2} Early-stage ovarian cancer requires surgical staging and, in case of inadequate staging, re-staging or adjuvant chemotherapy is recommended according to the Dutch guideline.³ In 2007, Sijmons *et al* investigated guideline adherence in early-stage ovarian cancer based on regional data in the Netherlands. Surgical guideline adherence was performed correctly in only 32.8% of the total study group.⁴ These numbers are not remarkable compared with other national and international studies on guideline adherence in surgical staging.^{5–8} Until now this remains a subject of debate as to why these percentages remain low.⁹ Yet strict conclusions cannot be drawn as many studies contain different population sizes, guidelines, and surgeons with different levels of experience.¹

In an attempt to assure and improve quality of care, quality improvement programs have been initiated by different countries such as Denmark, Sweden, Italy, and

Original research

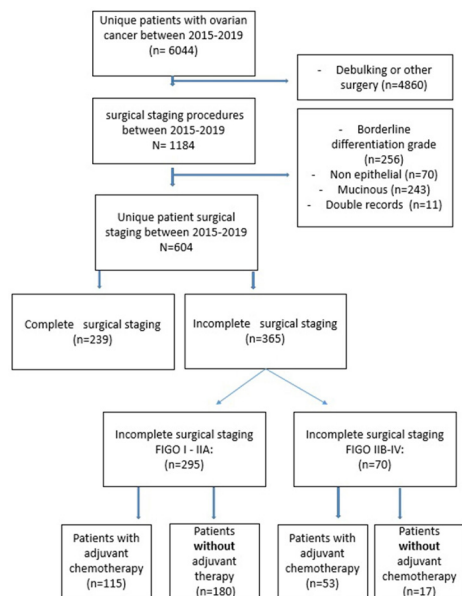


Figure 1 Flowchart of patients with ovarian cancer in the Netherlands.

more.^{10–12} Moreover, a systematic review of surgical staging in ovarian cancer recognized formal quality improvement programs resulting in high-volume centers as an important tool to improve quality of care.¹ A similar initiative was initiated in the Netherlands in 2014—the Dutch Gynecological Oncology Audit.¹³ Since 2016 a quality indicator has been developed for surgical staging of clinical early-stage ovarian cancer derived from the Dutch Gynecological Oncology Audit dataset.¹⁴ In recent years, this indicator has shown low compliance in the Dutch Gynecological Oncology Audit due to missing surgical items at the hospital level.

Since there is little information at the national level on adherence to guidelines for surgical staging of ovarian cancer, we aim to identify guideline adherence to the Dutch guideline for each surgical item in early-stage ovarian cancer and to illustrate the sequence of surgical items which contribute most often to incomplete surgical staging. Second, since care for these patients is organized per region, we aimed to identify whether there is variation between regions in the Netherlands. Last, data registered in the Dutch Gynecological Oncology Audit on surgical staging were validated in three gynecological oncology centers in the Netherlands to gain more insight into the reasons for not completing the staging procedure.

METHODS

All patients with ovarian cancer who had a surgical staging as registered in the Dutch Gynecological Oncology Audit between January 1, 2015 and December 31, 2019 in the Netherlands were included. The Dutch Gynecological Oncology Audit is a population-based clinical quality registry initiated in 2014.¹³ Registering patients in the Dutch Gynecological Oncology Audit has been mandatory for all patients with an ovarian malignancy since 2014. Patients with borderline, mucinous, and/or non-epithelial histology were excluded from this analysis. The International Federation of Gynecology and Obstetrics (FIGO) stage was acquired from the post-operative

pathology reports. Ethical approval or informed consent was not required for this study, according to Dutch legislation.

Organization of Care, Guidelines, and Procedures

Since 2010 the organization of care in the Netherlands for patients with ovarian cancer has been centralized, as directed by the health authorities. In practice, this meant that patients who were eligible for either a staging procedure or cytoreductive surgery should be referred to a center specializing in ovarian cancer. As a consequence, the number of hospitals providing this surgical care reduced gradually over time from 90 in 2010 to 20 in 2020.¹³ These are ovarian cancer-specialized center hospitals (one per region) and ovarian cancer-specialized general teaching hospitals (0–2 per region). The distinction between the two types of hospitals is defined by the employment of gynecological oncologists in the center hospitals. After regular training in gynecology followed by an accredited 2-year fellowship in gynecologic oncology, the Dutch Society of Gynecologic Oncology can certify members as gynecological oncologists. In ovarian cancer-specialized general teaching hospitals, gynecological oncologists from the center hospital participate in each staging or cytoreductive surgical procedure.¹⁵ Surgical staging was considered adequate and in line with the National Dutch guidelines when the following criteria were met: peritoneal washing or sampling of ascites, hysterectomy and bilateral oophorectomy (also if this was done in previous surgeries or left behind in case of fertility preservation); at least five peritoneal biopsies from several locations at risk for tumor implantation; adequate pelvic and para-aortic lymph node sampling; and biopsies of suspected lesions and adhesions. Lymph node sampling was considered adequate if at least 10 lymph nodes from five different loci were sampled including one or more lymph nodes collected from either the paracaval or para-aortic region together with two or more left-sided pelvic (iliac and obturator) lymph nodes and two or more right-sided pelvic lymph nodes.⁹

Ranking Outcome

In order to illustrate which surgical item was left out most frequently, items required for complete surgical staging were ordered in relation to clinical outcome based on literature and expert opinion. Thereby, ranking was based on the complexity of the surgical procedure and defined as most easy to most difficult surgical staging item. This was illustrated in a bar plot with each bar showing raw percentages of the completed surgical item combined with a cumulative percentage leading to complete surgical staging.

Data Verification

As ‘completeness of surgical staging’ has traditionally been a quality indicator in the Dutch Gynecological Oncology Audit from the start of the registry in 2014, it was already known that completeness of surgical staging was low. In order to check correctness and completeness of data registration, data from the specific study population were reviewed in three gynecological oncology centers in three different regions. All items on surgical staging registered in the Dutch Gynecological Oncology Audit were compared with data present in the electronic patient file. Three authors (WJvD, MvH, RK) manually crosschecked the registered data and assessed accuracy and reasons why surgical staging was incomplete. During

Table 1 Patient and tumor characteristics

	Incomplete staging n (%)	Complete staging n (%)	P value
Number	365	239	
Age, n (%)			
<70 years	254 (69.6)	160 (66.9)	0.55
70+ years	111 (30.4)	79 (33.1)	
WHO classification, n (%)			
1	283 (77.5)	168 (70.3)	0.13
2+	9 (2.5)	7 (2.9)	
NA	73 (20.0)	64 (26.8)	
Body mass index, n (%)			
≤30 kg/m ²	276 (75.6)	199 (83.3)	0.08
>30 kg/m ²	83 (22.7)	38 (15.9)	
NA kg/m ²	6 (1.6)	2 (0.8)	
Operated by gynecologic oncologist, n (%)			
No	13 (3.6)	3 (1.3)	0.08
Yes	349 (95.6)	236 (98.7)	
NA	3 (0.8)	0 (0.0)	
Surgical approach, n (%)			
Laparoscopy	114 (31.2)	40 (16.7)	<0.001
Laparotomy	196 (53.7)	193 (80.8)	
Robot	53 (14.5)	6 (2.5)	
NA	2 (0.5)	0 (0.0)	
FIGO stage, n (%)			
IA	141 (38.6)	104 (43.5)	0.09
IB	11 (3.0)	11 (4.6)	
IC	4 (1.1)	0 (0.0)	
IC2	112 (30.7)	71 (29.7)	
IIA	20 (5.5)	9 (3.8)	
IIB	31 (8.5)	16 (6.7)	
IIIA	11 (3.0)	15 (6.3)	
IIIB	13 (3.6)	1 (0.4)	
IIIC	10 (2.7)	6 (2.5)	
IVB	5 (1.4)	2 (0.8)	
NA	7 (1.9)	4 (1.7)	
Grade, n (%)			
Not specified	52 (14.2)	35 (14.6)	0.77
Well	104 (28.5)	62 (25.9)	
Moderate	44 (12.1)	25 (10.5)	
Poor	164 (44.9)	117 (49.0)	
Undifferentiated	1 (0.3)	0 (0.0)	
FIGO stage and grade			
IA			
Well	38 (10.4)	33 (13.8)	
Moderate	20 (5.5)	11 (4.6)	
Poor	59 (16.2)	40 (16.7)	
Not specified	24	20	

Continued

Table 1 Continued

	Incomplete staging n (%)	Complete staging n (%)	P value
IB			
Well	4 (1.1)	3 (1.3)	
Moderate	0 (0.0)	1 (0.4)	
Poor	7 (1.9)	6 (2.5)	
Not specified	0	1	
IC			
Well	44 (12.1)	15 (6.3)	
Moderate	12 (3.3)	10 (4.2)	
Poor	41 (11.2)	38 (15.9)	
Not specified	19	13	
2A			
Well	2 (0.5)	3 (1.3)	
Moderate	4 (1.1)	0 (0.0)	
Poor	14 (3.8)	6 (2.5)	
Not specified	0	0	

FIGO, International Federation of Gynecologists and Obstetricians.

assessment of all the data, reasons for incomplete surgical staging were categorized.

Comparisons Between Regions

Ovarian cancer care in the Netherlands is centralized per region. Each region consists of a gynecological oncology center and its referring hospitals. Staging procedures are performed in centers performing at least 20 cytoreductive surgical procedures for ovarian carcinoma annually, indicating that surgical teams had adequate surgical experience. For this study, we combined the results of referring hospitals with their gynecological oncology center. For each of the eight regions in the Netherlands, the percentage of patients with complete surgical staging was evaluated and depicted in a funnel plot.

Statistical Analysis

Patient and tumor characteristics were described using frequencies and percentages and were compared using a χ^2 test. Statistical significance was considered when $p < 0.05$. All analyses were performed with R Studio.

RESULTS

A total of 1184 patients who underwent surgical staging for ovarian cancer were registered in the Dutch Gynecological Oncology Audit. After excluding borderline, mucinous, and/or non-epithelial histology, 604 patients remained for analysis (Figure 1). Of these patients, 483 (80%) were registered with early-stage disease and 121 (20%) with advanced stage disease due to upstaging. The basic characteristics of both groups of patients (complete and incomplete staging) were comparable except for the surgical approach (Table 1). Patients with incomplete surgical staging were operated

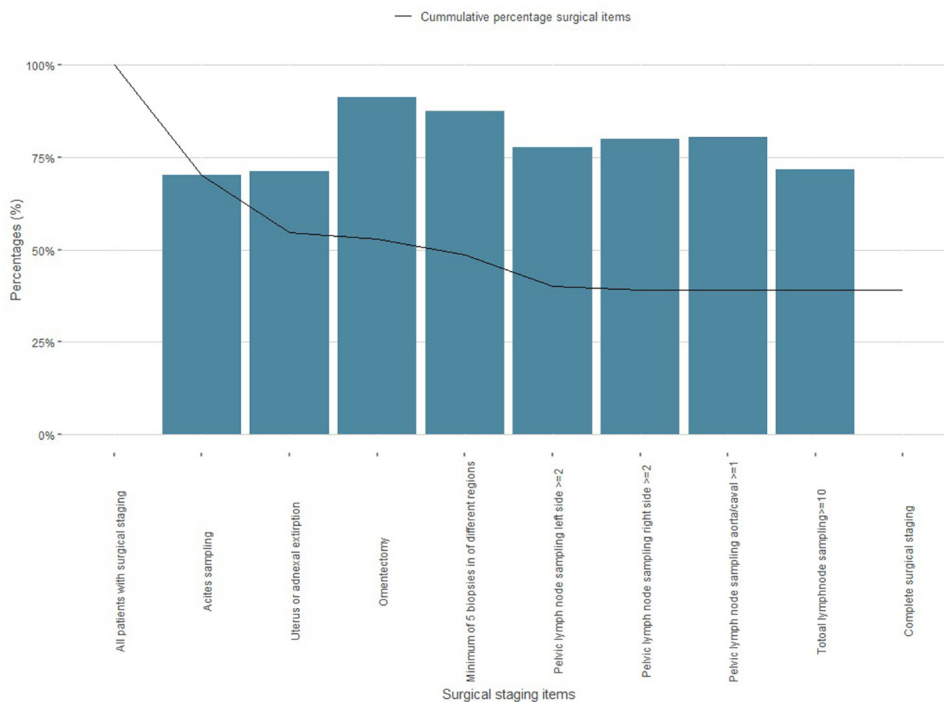


Figure 2 Bar plot and cumulative outcome of surgical staging items for patients with ovarian cancer.

more often with minimal invasive techniques (laparoscopy or robot) compared with patients in the complete staging group ($p < 0.001$).

Figure 2 shows the percentages of completed surgical staging items for the entire study population. Based on expert opinion, it was decided that ascites or fluid sampling was the first ranked item to gather during surgery. Surprisingly, obtaining cytology or collection of ascites was the most frequently omitted item (29%), and therefore contributed most to the decline in the percentage of complete staging. Subsequently, uterus and adnexa (28%), omentectomy (10%), biopsies (13%) and ≥ 10 lymph nodes (28%) additionally contributed most often to an incomplete staging procedure.

Patients with Incomplete Surgical Staging

In 365 of the total of 604 patients (60%) the surgical staging was incomplete (see Online supplemental table 1). Of these patients,

295 (81%) were registered with early-stage disease (FIGO I–IIA) and, of these, 115 (39%) received adjuvant chemotherapy. Patients registered with stage IC/IIA received adjuvant chemotherapy more often than those with stage IA/IB (61.0% vs 37.3%, $p < 0.001$). In addition, patients who received adjuvant chemotherapy more often had a poorly differentiated tumor compared with the group without adjuvant chemotherapy (70% vs 24.4%; $p < 0.001$). Online supplemental figure 1A shows the completed surgical staging items for patients both with and without adjuvant chemotherapy in case of registered early-stage disease. Overall, patients receiving adjuvant chemotherapy (39%) were less adequately staged than patients without adjuvant chemotherapy (61%). This is all the more evident for the items concerning staging of lymph nodes.

A total of 70 patients with incomplete staging were registered with advanced stage disease (FIGO stage $> \text{IIA}$). Of these patients, 53 (76%) received adjuvant chemotherapy. Online supplemental figure 1 shows the completed surgical items of patients with or without adjuvant chemotherapy. There were no marked differences between the degree of staging between both groups. The only statistically significant difference between adjuvant and no adjuvant chemotherapy was the World Health Organization (WHO) classification: patients with adjuvant therapy had a lower WHO classification ($p = 0.021$).

Regional Variation

Figure 3 shows a funnel plot for complete surgical staging in eight regional cancer networks in the Netherlands. Two cancer networks performed less complete surgical staging outside the 99% confidence interval (complete surgical staging in 12.5% and 25.5%, respectively).

Validation of Results

Table 2 shows the results of external validation of three gynecological oncology centers. The validated sample represented 26%

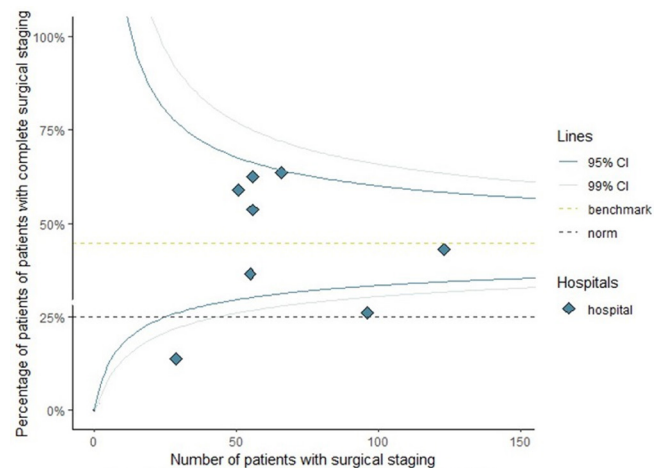


Figure 3 Complete surgical staging per region in the Netherlands between 2015 and 2019.

Table 2 Validation of data registered in the Dutch Gynecological Oncology Audit from the staging procedure at three gynecologic centers

	Center A	Center B	Center C	Total
Sample size	47	40	69	156
Complete, n (%)	18 (38%)	10 (25%)	23 (33%)	
Incomplete, n (%)	29 (62%)	30 (75%)	46 (67%)	105
Reasons for incomplete staging				
Incomplete without reason	5	17	12	32%
Incomplete due to co-morbidities	2	0	5	7%
Wish of patient	4	1	1	6%
Advanced stage disease (>IIA) based on operative findings	12	6	20	36%
Fertility-sparing	2	3	3	8%
Various specified reasons	4	3	5	11%

of the entire study population. Registration of surgical items was cross-checked with the pathology and electronic patient records and showed 98% correctness. In case of incomplete surgical staging, reasons were drawn from the operative report. The most frequently occurring reason for incomplete staging was 'advanced stage disease (>IIA) based on per-operative findings' such as dense adhesions between tumor and pelvic peritoneum or specific histology results as assessed during frozen section, and accounted for 36% of the validated population size. Other reasons for incomplete surgical staging were: choice of the patient (patient did not want adjuvant chemotherapy anyway) (7%), comorbidities (6%), fertility-sparing surgery (8%), and various specified reasons (11%). The remaining 32% were incomplete without a specific reason.

DISCUSSION

Summary of Main Results

This first prospective nationwide study shows that, with respect to surgical staging of patients with clinical early-stage ovarian cancer, adherence to the Dutch evidence-based guidelines is lower than expected. Surprisingly, sampling of ascites was the item that contributed most often to an incomplete staging procedure. Furthermore, incompletely staged patients registered with advanced stage disease received adjuvant chemotherapy more often than patients registered with early-stage disease. This last aspect is important as incomplete staging without adjuvant chemotherapy may have a negative impact on prognosis.⁸ Additionally, it confirms the result of the validation in three centers where 'perioperative findings providing advanced disease' was one of the most frequent reasons for incomplete staging (36%). Finally, two regional cancer networks in the Netherlands performed outside the confidence intervals with significantly less frequent complete surgical staging procedures compared with the other regions. In addition, patients with incomplete surgical staging who received adjuvant chemotherapy more often had stage IC–IIA and a higher percentage of poorly differentiated tumors. This is concordant with the Dutch guideline stating that adjuvant chemotherapy is optional in patients with stage IC and poorly differentiated tumors even when a complete staging procedure is performed.

Results in the Context of the Published Literature

The rather high percentage of incomplete surgical staging (40%) is in line with previous literature.^{4–6} One of the statistically significant differences between complete and incomplete surgical staging was that patients with incomplete surgical staging were operated on more often through laparoscopy or robot surgery than patients with complete surgical staging. With regard to the sampling of ascites, a sub-analysis showed that, with laparoscopy or robotic surgery, this component was more frequently omitted in comparison to laparotomy (43%, 60%, and 18%, respectively). There was no clear explanation for this finding so it can only be speculated that, when a staging procedure is performed with a minimally invasive procedure (laparoscopy or robot), it is simply forgotten to obtain free fluid for cytology in spite of the fact that all surgeons were gynecological oncologists. Another explanation could be that the sampling of ascites was already done during an initial diagnostic procedure which, in that case, was often performed in a referring center. This is more difficult to register if the information is not available for the gynecologic oncology center which registers the patient. However, by giving this feedback to the gynecologic oncology centers, this is a measure to improve and will be evaluated in the future.

A similarity to previous literature is the rising percentage of lymph node sampling in recent years. The study by Kleppe et al described a trend in the Netherlands for the item 'more than 10 lymph nodes' from 2.3% in 2000 to 47.6% in 2012.¹⁶ Our study shows a continuous increasing trend to 73% in 2019. This trend could be explained by the fact that, during this period, staging procedures were increasingly performed in specialized hospitals due to more centralized care.¹⁶ Another study which evaluated the incomplete staging procedures in detail in 50 patients at five hospitals in the Netherlands (period 2010–2014) found that peritoneal biopsies were most often missing and the main reason for incomplete staging.⁸ The study identified an adequate sampling of peritoneal biopsies (≥ 5) in 32% compared with 87% in our study population. A possible explanation for this improvement over time is the aforementioned increased centralized care which started to be implemented in 2010 but took several years to be complete.

Original research

Strengths and Weaknesses

One of the strengths of this study is that data from all patients undergoing surgical staging are collected in a prospective manner. This study also provides insight into all the difficulties in collecting the necessary data when procedures and adjuvant chemotherapy are performed in different centers, in spite of the registration rules that apply in the Dutch Gynecological Oncology Audit.¹³ For countries with similar health systems, this study may help to identify these registration issues and to consider using other data sources (pathology data) to verify which part of the staging procedure is lacking. Moreover, providing information on completeness of staging procedures and giving this feedback to participating hospitals can make gynecologic oncologists aware of the gaps in their procedure. Additionally, to understand possible errors in data collection, we validated the data in three large gynecological oncology centers (reflecting 26% of all patients). The results of this validation provided insight into reasons for an incomplete staging procedure. In addition to correct registration (98% correctness), a reason for incomplete staging was given in 67% of patients, with the most common reason being 'advanced stage disease (>IIA) based on per-operative findings'.

A limitation of the study lies in the challenging nature of data collection and includes the registration of adjuvant chemotherapy. Since care for patients with ovarian cancer is organized within regions, the surgical procedure is performed in a gynecological oncology center and adjuvant chemotherapy may be administered in the referring hospitals. Although the Dutch Gynecological Oncology Audit has registration rules (the hospital that performs surgery must monitor the chemotherapy status), this may not always be met. As a consequence, adjuvant chemotherapy may be under-reported. However, since the percentage of patients receiving adjuvant chemotherapy with incomplete surgical staging in our study is similar to that reported in the study by Laven et al (39% vs 38%), we estimate that the risk of under-reporting adjuvant chemotherapy is low.⁸ We did not apply any case-mix correction, so we cannot exclude the possibility that, in the regional comparison, the two regions that performed less surgical staging could be explained by a high percentage of patients with excessive co-morbidity and/or performance status. Further evaluation in this respect should be performed to gain more insight into these observed differences. Unfortunately, the Dutch Gynecological Oncology Audit registry does not yet contain sufficient data on survival, which makes it impossible to correlate inadequate versus adequate staging and chemotherapy.

Last, in our study we have analyzed all procedures which are registered as surgical staging procedures. Although we are aware of the fact that surgical staging is not indicated for advanced ovarian cancer, FIGO stages IIB and IIIA may result from upstaging related to microscopic metastases outside of the pelvis identified by the pathologist. Patients registered as FIGO IIB–IVB (n=28) are probably based on an incorrect registration. This finding is also noteworthy to describe, since it identifies an inadequate way of registering these patients (either the operation code or the stage).

Implications for Practice and Future Research

The identification of regional variation allows the possibility of identifying differences leading to a better outcome and, by sharing these best practices (benchmarking), will eventually improve the overall care for patients with early-stage ovarian carcinoma nationwide. Additionally, for other health systems who are planning to set up a quality

registry for surgical care on patients with ovarian carcinoma, this study could give guidance on how to set up an audit, make registration rules, consider manual validation to validate the data and, if available, to make use of other data sources to minimize registration burden.

CONCLUSION

The results of this study give insights into surgical staging at a national level, the items of the surgical staging procedure leading to incomplete staging, and the reasons for incomplete staging. It was identified that the registry lacked reasons for incomplete staging. Subsequently, this variable will be added to the registry, allowing more insight into guideline adherence regarding staging procedures on a national level in the future.

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from the first to the last version. The Dutch Gynecology Oncology Collaborator Group: collecting data for the Dutch Gynecological Oncology Audit and reviewing and approving the final version of the manuscript.

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