SUCCOR quality: validation of ESGO quality indicators for surgical treatment of cervical cancer

Felix Boria ,[1] Luis Chiva ,[1] Enrique Chacon ,[2] Vanna Zanagnolo,[3] Anna Fagotti ,[4,5] Ali Kucukmetin,[6] Constantijne Mom,[7] Galina Chakalova,,[8] Aliyev Shamistan,[9] Mario Malzoni,[10] Fabrice Narducci,[11] Octavio Arencibia,[12] Francesco Raspagliesi,[13] Tayfun Toptas ,[14] David Cibula,[15] Dilyara Kaidarova,[16] Mehmet Mutlu Meydanli ,[17] Mariana Tavares,[18] Dmytro Golub,[19] Anna Myriam Perrone ,[20] Robert Poka ,[21] Petra L M Zusterzeel,[22] Igor Aluloski,[23] Frederic Goffin,[24] Dimitrios Haidopoulos,[25] Herman Haller,[26] Robert Jach,[27] Iryna Yezhova,[28] Margarida Bernardino,[29] Rasiah Bharathan,[30] Minna M Maenpaa,[31] Vladyslav Sukhin ,[32,33] Jean-Guillaume Feron,[34] Robert Fruscio ,[35,36] Kersti Kukk,[37] Jordi Ponce,[38] Fuat Demirkiran,[39] George Vorgias,[40] Natalia Povolotskaya,[41] Pluvio J Coronado Martín,[42] Tiermes Marina ,[43] Ignacio Zapardiel ,[44] Nicolò Bizzarri ,[45] Mikel Gorostidi ,[46] Monica Gutierrez,[1] Nabil Manzour ,[2] Arantxa Berasaluce,[47] Nerea Martin-Calvo,[48] On behalf of the SUCCOR study Group

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For numbered affiliations see end of article.

Correspondence to
Dr Luis Chiva, Department of Obstetrics and Gynecology, Clinica Universidad de Navarra, MADRID, Spain; lchiva@unav.es

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HIGHLIGHTS

⇒ The mean number of quality indicators compliance in this cohort was 13.6.
⇒ We observed that 479 women (57.2%) in the SUCCOR study were operated on at centers with high compliance with European Society of Gynaecological Oncology (ESGO) quality indicators.
⇒ Patients with cervical cancer operated on at centers with high compliance with ESGO quality indicators have a lower risk of recurrence and death from disease than those operated on at centers with low compliance.

ABSTRACT

Objective To evaluate whether compliance with European Society of Gynaecological Oncology (ESGO) surgery quality indicators impacts disease-free survival in patients undergoing radical hysterectomy for cervical cancer.

Methods In this retrospective cohort study, 15 ESGO quality indicators were assessed in the SUCCOR database (patients who underwent radical hysterectomy for International Federation of Gynecology and Obstetrics (FIGO) stage 2009 IB1, FIGO 2018 IB1, and IB2 cervical cancer between January 2013 and December 2014), and the final score ranged between 0 and 16 points. Centers with more than 13 points were classified as high-quality indicator compliance centers. We constructed a weighted cohort using inverse probability weighting to adjust for the variables. We compared disease-free survival and overall survival using Cox proportional hazards regression analysis in the weighted cohort.

Results A total of 838 patients were included in the study. The mean number of quality indicators compliance in this cohort was 13.6 (SD 1.45). A total of 479 (57.2%) patients were operated on at high compliance centers and 359 (42.8%) patients at low compliance centers. High compliance centers performed more open surgeries (58.4% vs 36.7%, p<0.01). Women who were operated on at centers with high compliance with quality indicators had a significantly lower risk of relapse (HR=0.39; 95% CI 0.25 to 0.61; p<0.001). The association was reduced, but remained significant, after further adjustment for conization, surgical approach, and use of manipulator surgery (HR=0.48; 95% CI 0.30 to 0.75; p=0.001) and adjustment for adjuvant therapy (HR=0.47; 95% CI 0.30 to 0.74; p=0.001). Risk of death from disease was significantly lower in women operated on at centers with high adherence to quality indicators (HR=0.43; 95% CI 0.19 to 0.97; p=0.041). However, the association was

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In ovarian cancer, adherence to clinical guidelines has proved to be associated with improved outcomes. However, in cervical cancer, literature investigating the influence of quality assurance is scarce.

WHAT THIS STUDY ADDS

⇒ Patients with early-stage cervical cancer operated on at centers with high compliance with European Society of Gynaecological Oncology (ESGO) quality indicators have a lower risk of recurrence and death.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study represents, to our knowledge, the first study to validate the quality indicators for cervical cancer surgery proposed by ESGO. Based on our study results, all centers should struggle to adhere to these quality indicators to provide the best quality assistance for their patients.

not significant after adjustment for conization, surgical approach, use of manipulator surgery, and adjuvant therapy.

Conclusions Patients with early cervical cancer who underwent radical hysterectomy in centers with high compliance with ESGO quality indicators had a lower risk of recurrence and death.

INTRODUCTION

The estimated number of new cases of cervical cancer in Europe in 2020 was 58 169, with 25 989 deaths.[1] Surgery represents the main treatment in early stages (International Federation of Gynecology and Obstetrics (FIGO) 2018 IA–IB2) and the 5-year disease-free survival rate in the largest European cohorts ranges from 87.7% to 88.3%.[2 3] However, several differences in survival can be found across Europe. Five-year relative survival for European women diagnosed with cervical cancer in 2000–2007 was 62%, ranging from 57% to 67%.[4]

Lately, indicators of excellence in the treatment of cancer have been associated with better prognosis.[5–7] For this reason, the European Society of Gynaecological Oncology (ESGO) has been working through the guidelines committee in elaborating indicators to evaluate the quality of care provided in any gynecologic oncology center.[8] In ovarian cancer, adherence to clinical guidelines have been previously studied by several authors.[5 7 9 10] In a study conducted by Jochum, et al,[7] patients receiving suboptimal care (not adherent to European Society of Medical Oncology guidelines) had an increased risk of death of more than 100% compared with those treated according to the guidelines (HR=2.14). However, to our knowledge, no study to date has validated these indicators in a cohort of patients with cervical cancer.

To validate these surgery quality indicators for cervical cancer, we designed a retrospective study using the SUCCOR database. The primary endpoint of this study was to evaluate whether compliance with ESGO surgery quality indicators impacts the disease-free survival in patients undergoing radical hysterectomy for cervical cancer.

METHODS

Study Design and Endpoints

The SUCCOR study is a European, multicenter, observational, retrospective cohort study aimed at evaluating disease-free survival in patients with FIGO 2009 stage IB1 cervical cancer undergoing open versus minimally invasive radical hysterectomy between January first1, 2013 untiland December 31, 2014. Further detail on the study design is outlined elsewhere.[11]

Primary and Secondary Endpoints

The main objective of this study was to evaluate whether compliance with ESGO surgery quality indicators impacts disease-free survival in patients undergoing radical hysterectomy for cervical cancer. The secondary endpoint was to evaluate compliance with the different ESGO quality indicators in the centers participating in the SUCCOR database and to evaluate overall survival.

Evaluation of Quality Indicators Compliance

Quality indicators proposed by ESGO are categorized as process indicators, structural indicators, or outcome indicators.[12] Process and structural indicators are related to case load per center, overall management, and collection of adequate information. To calculate compliance with process and structural indicators we designed a survey with nine items (one for each quality indicator) (Online supplemental material)

Outcome indicators were calculated independently for every hospital using the database.

In February 2021, after institutional review board approval, an invitation to participate in the survey was sent via email to all the collaborators of the SUCCOR study. Three different emails (one per month for 3 months) were sent to the principal investigator of each center. All centers that answered the survey were anonymized and analyzed. In total, 15 quality indicators were assessed, each scored one point if fulfilled by the center. For the number of radical procedures (parametrectomies) per year, >15/year was given 1 point and >30 was given 2 points. Therefore, the final score ranged between 0 and 16 points. Participating hospitals were divided into two groups depending on their final score. Based on the ESGO recommendations for center certification in ovarian cancer,[13] we decided that centers with more than 13 points were classified as high-quality indicator compliance centers. The category of compliance centers (final score >13) was used as category of reference in all the analyses.

Inclusion and Exclusion Criteria in the SUCCOR Cohort

The SUCCOR database was collected in 2019 to better understand the treatment of cervical cancer in Europe. All ESGO members were invited to participate, and researchers from 126 institutions in 29 European countries contributed to the project.**1 12**

Patients were eligible if they had undergone radical hysterectomy for stage IB1 cervical cancer (FIGO 2009) in a European institution between January 1, 2013 and December 31, 2014. A total of 1156 patients were collected. The inclusion criteria of this database were as follows: (1) age≥18 years and (2) histologic type: squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma. Pelvic MRI confirming a tumor diameter ≤4 cm with no parametrial invasion and a pre-operative CT scan, MRI, or positron emission tomography PET/CT demonstrating no extracervical metastatic disease were mandatory. The operative report had to describe type B–C radical hysterectomy with bilateral pelvic lymphadenectomy by either minimally invasive surgery (laparoscopic or robotic) or open surgery, including at least 10 pelvic nodes. Women who underwent only sentinel lymph node mapping were included in the study, but data regarding tumor size, margins, and nodal status were required. Patients with any other histological type of cancer were excluded. Other exclusion criteria were as follows: (1) tumor size >4 cm, (2) final tumor stage IA, (3) history of any invasive tumor other than cervical cancer, (4) previous chemotherapy or radiation, and (5) conversion from minimally invasive surgery to open laparotomy (as stated in the SUCCOR study).

Statistical Analysis

We hypothesized 10% of relapse in the group with lower compliance with quality indicators. Assuming a two-sided α error of 5% and 90% statistical power, 342 women were needed in each group to detect differences of 9% in the risk of relapse. For descriptive purposes, we used mean (SD) for quantitative variables and frequencies or percentages for categorical ones. Demographic and clinical characteristics were compared between groups using

Student's t-test for quantitative variables and the χ^2 test for categorical ones. We constructed a weighted cohort using inverse probability weighting to adjust for the variables. The variables included in the propensity score were: body mass index, Eastern Cooperative Oncology Group (ECOG) score, smoking habit, history of autoimmune disease, macroscopic appearance of the tumor, and presence of nodal invasion.

Disease-free survival was defined as the time from the date of the radical hysterectomy to time of relapse, study end, or last contact, whichever came first. Overall survival was defined as the time from the date of the radical hysterectomy to time of death from the disease, study end, or last contact, whichever came first. We compared disease-free survival and overall survival using Cox proportional hazards regression analysis in the weighted cohort (model 1) and then plotted the differences using Nelson-Aalen survival curves. In further analyses we used multivariable models to adjust for surgery-related variables (model 2 was adjusted for variables in model 1 plus conization, surgical approach, and the use of uterine manipulator) and variables related with clinical evolution (model 3 was adjusted for variables in models 1 and 2 plus intra-operative complications and the use of adjuvant therapy). All p values were two-sided, and p below 0.05 was considered significant. The analyses were performed with STATA 16.0

In accordance with the journal's guidelines, we will provide our data for the reproducibility of this study in other centers if such is requested.

RESULTS

The survey was sent to 126 investigators. The response rate of the survey was 65% (82 responses). A total of 838 patients from 82 institutions in 24 countries were included in the study. The mean number of quality indicators compliance in this cohort was 13.6 (SD 1.45). The adherence to quality indicators is shown in Online supplemental material. Participant characteristics according to the center's compliance with the quality indicators are shown in Table 1. A total of 479 (57.2%) patients were operated on in high compliance centers (final score >13 points) and 359 (42.8%) patients were operated on in low compliance centers (final score ≤13 points). Women operated on in low compliance centers had higher body mass index, higher ECOG score, and were more likely to be a smoker. After inverse probability weighting, no differences were observed between groups (Table 1). No significant differences in tumor size, grade, and histology were observed between the groups (Table 1).

Nevertheless, in the weighted cohort we observed significant differences between groups in surgery-related variables. High compliance centers performed more open surgeries (58.4% vs 36.7%, p<0.01), more cone biopsies (45.4% vs 30.0%, p<0.01), more lymphadenectomies (84.7% vs 73.5%, p<0.01), and reported lower use of a uterine manipulator (15.5% vs 31.7%, p<0.01). Additionally, adjuvant treatment was administered more frequently in low compliance centers (48.4% vs 40.2%, p=0.01).

After a median time of follow-up of 49.7 months (range 1–79) in the low compliance group and 50.1 months (range 1–80) in the high compliance group, there were 59 (16.4%) relapses in 359 patients in the group of centers with low adherence to quality indicators and 36 (7.5%) relapses in 479 patients in the group of centers with high adherence to quality indicators. Compared with women operated on in low compliance centers, women who were operated on at centers with high compliance with quality indicators had a significant lower risk of relapse (HR=0.39; 95% CI 0.25 to 0.61; p<0.001) (Table 2). The association remained significant after further adjustment for conization, surgical approach, and use of uterine manipulator (HR=0.48; 95% CI 0.30 to 0.75; p=0.001) and adjustment for intra-operative complications and adjuvant treatment (HR=0.47; 95% CI 0.30 to 0.74; p=0.001).

Disease-free survival at 5 years of follow-up was 84% in the group of centers with low compliance with quality indicators and 92% in the group of centers with high compliance with quality indicators (p value for the adjusted difference <0.001) (Figure 1).

After a median time of follow-up of 53.5 months (range 1–82) in the low compliance group and 52.2 months (range 1–84) in the high compliance group, there were 25 (7%) deaths in 359 patients in the group of centers with low adherence to quality indicators and 14 (2.9%) deaths in 479 patients in the group of centers with high adherence to quality indicators. After adjusting for basal characteristics, the risk of death from the disease was significantly lower in women operated on at centers with high adherence to quality indicators (Table 3) (HR=0.43; 95% CI 0.19 to 0.97; p=0.041). The association became not significant after the adjustment for conization, surgical approach, and use of a urine manipulator (model 2) and adjustment for intra-operative complications and adjuvant therapy (model 3). Overall survival in the high adherence with quality indicators group was 97% at 5 years of follow-up compared with 93% in the low adherence with quality indicators group (p value for the adjusted difference=0.007) (Figure 2).

DISCUSSION

Summary of Main Results

The response rate of the survey was 65% (82 responses), comprising 838 patients (72% of the SUCCOR database). Disease-free survival and overall survival at 5 years of follow-up was 84% and 93% in the group of centers with low compliance with quality indicators and 92% and 97% in the group of centers with high compliance with quality indicators (p value for the adjusted difference <0.01). Patients with cervical cancer operated on in centers with high compliance with ESGO quality indicators have a lower risk of recurrence and death of disease than those operated on at centers with low compliance.

Results in the Context of Published Literature

Adherence to clinical guidelines and quality indicators have been promoted throughout societies, and referral to specialized centers and centralization of medicine in cancer is widely spread.[8 14] The ESGO quality indicators were created to help physicians to provide better quality in the care of patients with cancer. Previous studies have investigated the compliance with these indicators in other centers. In a retrospective study, including 5952 patients with cervical cancer that underwent surgery, Ding et al evaluated the compliance of quality indicators in a high-volume center between 2014 and 2019.[15] A total of 11 of 15 quality indicators were fulfilled. Quality indicators that were not fulfilled were: proportion of patients receiving adjuvant chemoradiotherapy after primary surgical treatment for a stage pT1b1 pN0 disease, proportion of patients

Table 1 Demographic and tumor-related characteristics by center quality score

	BEFORE inverse probability weighting			AFTER inverse probability weighting		
	QI≤13	QI>13		QI≤13	QI>13	
	n=359	n=479	P value	n=359	n=479	P value
Age (years) (mean (SD))	47.55 (9.96)	46.81 (11.39)	0.32	46.87 (9.86)	47.63 (11.87)	0.32
Age			0.63			0.23
<50 years	222 (61.8)	304 (63.5)		222 (65.2)	304 (61.1)	
≥50 years	137 (38.2)	175 (36.5)		137 (34.8)	175 (38.9)	
Body mass index (kg/m^2) (mean (SD))	25.65 (4.82)	24.90 (4.27)	0.02	25.51 (4.82)	25.28 (4.47)	0.48
BMI			0.016			0.65
I≤25	168 (46.8)	257 (53.7)		168 (48.4)	257 (50.0)	
>25	147 (40.9)	156 (32.6)		147 (38.5)	156 (37.2)	
Not reported	44 (12.3)	66 (13.8)		44 (13.1)	66 (12.8)	
ECOG Score			0.001			0.97
0	305 (85.0)	441 (92.1)		305 (89.3)	441 (88.4)	
1	29 (8.1)	15 (3.1)		29 (5.0)	15 (5.0)	
Not reported	25 (7.0)	23 (4.8)		25 (5.7)	23 (6.6)	
Smoker			0.013			0.84
Non-smoker	220 (61.3)	243 (50.7)		220 (56.8)	243 (55.4)	
Smoker	91 (25.3)	63 (13.2)		91 (18.6)	63 (18.9)	
Not reported	48 (13.4)	173 (36.1)		48 (24.6)	173 (25.7)	
Tumor volume (mean (SD))	8782.93 (11243.00)	7669.42 (11198.57)	0.16	8535.55 (11158.50)	7625.37 (11037.80)	0.24
Diameter in pathology			0.17			0.15
≤20 mm	186 (51.8)	271 (56.6)		186 (50.3)	271 (55.3)	
>20 mm	173 (48.2)	208 (43.4)		173 (49.7)	208 (44.7)	
Macroscopic appearance			0.004			0.86
Exophytic	143 (39.8)	220 (45.9)		143 (44.0)	220 (43.2)	
Endophytic ulcerative	86 (24.0)	93 (19.4)		86 (21.0)	93 (21.4)	
Endophytic barrel shaped	39 (10.9)	26 (5.4)		39 (7.1)	26 (7.2)	
Not reported	91 (25.3)	140 (29.3)		91 (28)	140 (28.2)	
Grade of differentiation			0.46			0.48
Grade I	52 (14.5)	57 (11.9)		52 (13.3)	57 (13.4)	
Grade II	160 (44.6)	200 (41.8)		160 (46.1)	200 (40.9)	
Grade III	105 (29.2)	151 (31.5)		105 (28.6)	151 (31.4)	
Not reported	42 (11.7)	71 (14.8)		42 (12)	71 (14.3)	
Final histology			0.84			0.46
Squamous carcinoma	246 (68.5)	319 (66.6)		246 (66.9)	319 (64.6)	
Adenocarcinoma	100 (27.9)	142 (29.6)		100 (29.8)	142 (31.8)	
Adenosquamous	13 (3.6)	18 (3.8)		13 (3.2)	18 (3.6)	
Lymph node metastasis			0.14			0.96
No	313 (87.2)	433 (90.4)		313 (89.3)	433 (89.4)	
Yes	46 (12.8)	46 (9.6)		46 (10.7)	46 (10.6)	
Lymphovascular space invasion			0.80			0.26
No	197 (54.9)	261 (54.5)		197 (58.6)	261 (54.9)	
Yes	122 (34.0)	168 (35.1)		122 (31.7)	168 (35.2)	

Continued

Table 1 Continued

	BEFORE inverse probability weighting			AFTER inverse probability weighting		
	QI≤13	QI>13		QI≤13	QI>13	
	n=359	n=479	P value	n=359	n=479	P value
Not reported	40 (11.1)	50 (10.4)		40 (9.7)	50 (9.9)	
Parametrial invasion			0.21			0.98
No	342 (95.3)	446 (93.1)		342 (95.4)	446 (92.7)	
Yes	14 (3.9)	11 (2.3)		14 (3.7)	11 (3.6)	
Not reported	3 (0.8)	22 (4.6)		3 (0.9)	22 (3.7)	
Vaginal invasion			0.44			0.88
No	344 (95.8)	441 (92.1)		344 (95.4)	441 (92.4)	
Yes	11 (3.1)	10 (2.1)		11 (2.8)	10 (2.9)	
Not reported	4 (1.1)	28 (5.8)		4 (1.9)	28 (4.7)	
Uterine invasion			0.49			0.92
No	323 (90.0)	426 (88.9)		323 (90.8)	426 (89.3)	
Yes	25 (7.0)	27 (5.6)		25 (6.4)	27 (6.1)	
Not reported	11 (3.1)	26 (5.4)		11 (2.8)	26 (4.6)	

Results are shown as number (%) unless stated otherwise.
BMI, body mass index; ECOG, Eastern Cooperative Oncology Group ; QI, quality indicator.

discussed in a multidisciplinary tumor board, proportion of patients undergoing required pre-operative investigation, and proportion of patients t-upstaged (defined as detection of any involvement of parametria or vagina on pathology which was unknown before surgery, or a stage shift from T1b1 to T1b2 or higher, from pre-operative assessment to post-operative pathology).[15]

Literature investigating the influence of quality assurance in cervical cancer is scarce.[16] In a retrospective study conducted by Chiew et al,[17] adherence to clinical practice guidelines in cervical cancer was tested in 208 patients (stage I–IV receiving any type of treatment). Guideline-adherent care was associated with better outcomes in stages I and II (93.7% vs 69.7% 5-year disease, cancer-specific, survival). The authors concluded that patients who received guideline-adherent care have a lower risk of death (HR=0.22; 95% CI 0.07 to 0.75; p=0.015).

In a retrospective study by Fernandez-Gonzalez et al,[18] 215 patients undergoing radical robotic hysterectomy for early-stage cervical cancer were evaluated. The investigators divided hospitals according to their recurrence rates and observed that centers with the best survival outcomes had higher surgical volume, higher participation in clinical trials, higher rate of MRI use for diagnosis, and greater use of sentinel lymph node biopsies. They also audited 8 of 15 ESGO quality indicators and observed that these were fulfilled more frequently in hospitals with better survival outcomes. This is in agreement with the results of our study and highlights the importance of surgical volume, clinical trials, and pre-operative imaging work-up.

There were differences between groups in the surgical approach and in adjuvant treatment. Some of these (conization, surgical approach, use of manipulator) proved to be important prognostic

Table 2 Disease-free survival associated with center quality score

	QI≤13		QI>13		P value
Number of events/N	59/359		36/479		
Time at risk (person/months)	17 482		23 326		
Incidence rate (per 1000 person/month)	3.41		1.34		
	HR	95% CI	HR	95% CI	
Model 1	1.00	Ref.	0.392	0.25 to 0.61	<0.001
Model 2	1.00	Ref.	0.476	0.30 to 0.75	0.001
Model 3	1.00	Ref.	0.469	0.30 to 0.74	0.001

Model 1 is adjusted for body mass index, ECOG score, smoker status, presence of autoinmune disease, macroscopic appearance of tumor, and nodal status using the inverse probability weighting method.
Model 2 is adjusted for variables in model 1+surgery-related variables: conization, surgical approach, and uterine manipulator.
Model 3 is adjusted for variables in models 1 and 2+evolution-related variables: intra-operative complications, and adjuvant treatment.
ECOG, Eastern Cooperative Oncology Group; QI, quality indicator.

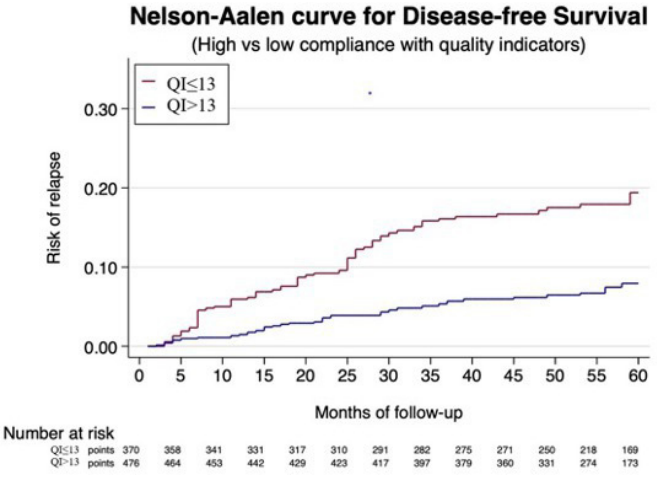

Figure 1 Nelson-Aalen cumulative hazard estimates for relapse. QI, quality indicator.

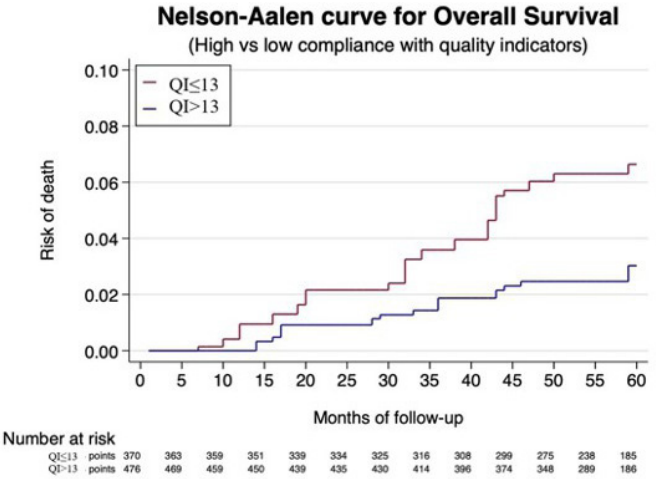

Figure 2 Nelson-Aalen cumulative hazard estimates for death. QI, quality indicator.

factors in the SUCCOR cohort. Moreover, adjuvant treatment may be a source of bias when analyzing survival. Although both factors are related to center quality care, we decided to conduct an exploratory analysis adjusting for these variables to evaluate solely the role of compliance with quality indicators. After adjusting for all these variables, the risk of relapse remained statistically lower for patients operated on at high compliance centers, which confirms the importance of the adherence to quality indicators. However, the difference was not significant when evaluating overall survival.

Strengths and Weaknesses

To our knowledge, this is the first study that validates the ESGO quality indicators for surgical treatment of cervical cancer. Moreover, a large number of patients from many institutions participated in the SUCCOR database, which give these data heterogeneity to measure the influence of quality assurance on prognosis. The main weakness of this study is the retrospective design of the data collection. There was no external audit of the data at the time of collection and some of the quality indicators were obtained by a survey filled individually in 2021 (the data were extracted from 2013 and 2014), which might have some discordance in hospital practices. The survey was sent only to the email of the principal investigator of each center, which might be a source of bias. Some of the data collected was not confirmed by a structured mechanism to evaluate compliance but it was rather opinion-based from the perspective of the respondents. However, all the outcome quality indicators were calculated directly from the cohort data.

Implications for Practice and Future Research

Based on our study results, all centers should adhere to quality indicators to provide the best quality care for their patients. Future research should pursue incorporating new quality indicators in our practice that allow us to improve our care for patients. Moreover, surgery-related variables associated with better prognosis were more frequently seen in the high adherence group, which correlates with the quality of the management. These variables may be added as quality indicators in the future as well.

CONCLUSIONS

Patients with cervical cancer operated on at centers with high compliance with ESGO quality indicators have lower risk of recurrence and death. High compliance centers performed more open

Table 3 Overall survival associated with center quality score.

	QI≤13		QI>13		P value
Number of events/N	25/359		14/479		
Time at risk (person/months)	18 836		24 053		
Incidence rate (per 1000 person/month)	1.12		0.48		
	HR	**95% CI**	**HR**	**95% CI**	
Model 1	1.00	Ref.	0.432	0.19 to 0.97	0.041
Model 2	1.00	Ref.	0.565	0.24 to 1.34	0.193
Model 3	1.00	Ref.	0.580	0.25 to 1.32	0.195

Model 1 is adjusted for body mass index, ECOG score, smoker status, presence of autoinmune disease, macroscopic appearance of tumor, and nodal status using the inverse probability weighting method.
Model 2 is adjusted for variables in model 1+surgery-related variables: conization, surgical approach, and uterine manipulator.
Model 3 is adjusted for variables in models 1 and 2+evolution-related variables: intra-operative complications, and adjuvant treatment.
ECOG, Eastern Cooperative Oncology Group; QI, quality indicator.

surgeries, more cone biopsies, and reported lower use of a uterine manipulator. Future studies may consider these variables also as quality indicators for surgical treatment of cervical cancer.

Author affiliations
[1]Department of Obstetrics and Gynecology, Clinica Universidad de Navarra, Madrid, Spain
[2]Department of Gynecologic Oncology, Universidad de Navarra, Pamplona, Navarra, Spain
[3]Istituto Europeo di Oncologia, Milan, Italy
[4]Agostino Gemelli IRCCS, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy
[5]Catholic University of the Sacred Heart, Milano, Lombardia, Italy
[6]Queen Elizabeth Hospital, Gateshead, Gateshead, UK
[7]Amsterdam University Medical Centres, Amsterdam, Noord-Holland, The Netherlands
[8]University Oncologic Hospital, Sofia, Bulgaria
[9]National Center of Oncology, Baku, Azerbaijan
[10]Endoscopica Malzoni, Center for Advanced Endoscopic Gynecologic Surgery, Avellino, Italy
[11]Department of Gynecology, Centre Oscar Lambret, Lille, France
[12]Department of Gynecology, University Maternal Hospital Canary Islands, Las Palmas, Las Palmas, Spain
[13]Department of Surgery, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
[14]Department of Gynecologic Oncology, Saglik Bilimleri University Antalya Research and Training Hospital, Antalya, Turkey
[15]Department of Obstetrics and Gynecology, University of Prague, Prague, Czech Republic
[16]Department of Oncogynecology, Kazahskij naucno-issledovatel'skij institut onkologii i radiologii, Almaty, Kazakhstan
[17]Department of Gynecologic Oncology, Zekai Tahir Burak Women's Health Education and Research Hospital, Ankara, Turkey
[18]IPO-PORTO, Porto, Portugal
[19]Department of Surgery, LISOD - Israeli Oncological Hospital, Kyiv Region, Ukraine
[20]Division of Gynecologic Oncology, IRCCS Azienda Ospedaliero-Universitaria di Bologna Policlinico S Orsola-Malpighi, Bologna, Italy
[21]Department of Obstetrics and Gynecology, Unit of Gynecologic Oncology; Institute of Obstetrics and Gynecology; Faculty of Medicine, University of Debrecen, Debrecen, Hungary
[22]Department of Gynecological Oncology, Radboudumc, Nijmegen, Netherlands
[23]Department of Gynecologic Oncology, University Clinic of Gynecology and Obstetrics, Faculty of Medicine, Ss Cyril and Methodius University of Skopje, Skopjeskopje, Macedonia
[24]Department of Obstetrics and Gynecology, University of Liege, Liege, Belgium
[25]Division of Gynecologic Oncology, 1st Department of Obstetrics and Gynecology, Alexandra Hospital, National and Kapodistrian University of Athens, Athens, Greece
[26]Clinical Hospital Center Rijeka, Rijeka, Croatia
[27]Department of Gynecology and Oncology, Jagiellonian University, Krakow, Poland
[28]Lviv Oncology Center, Lviv, Ukraine
[29]Department of Gynecology, Instituto Português de Oncologia de Lisboa, Lisbon, Portugal
[30]University Hospitals of Leicester NHS Trust, Leicester, UK
[31]Department of Obstetrics and Gynecology, Tampere University Hospital, Tampere, Finland
[32]Department of Oncology, Radiology and Radiation Medicine, V N Karazin Kharkiv National University, Harkiv, Ukraine
[33]Department of Oncogynecology, Grigoriev Institute for Medical Radiology NAMS of Ukraine, Harkiv, Ukraine
[34]Institut Curie, Paris, Île-de-France, France
[35]Department of Medicine and Surgery, University of Milan–Bicocca, Milan, Italy
[36]Clinic of Obstetrics and Gynecology, Hospital San Gerardo, Monza, Italy
[37]North Estonia Medical Centre, Tallinn, Estonia
[38]Bellvitge University Hospital, L'Hospitalet de Llobregat, Catalunya, Spain
[39]Istanbul University Cerrrahpasa Medical Faculty, istanbul, Turkey
[40]Metaxa Cancer Hospital of Piraeus, Piraeus, Attika, Greece
[41]Department of Gynaecological Oncology, Queen Alexandra Hospital, Portsmouth NHS Trust, Portsmouth, UK
[42]Department of Obstetrics and Gynecology, Hospital Clinico San Carlos IdISSC, Complutense University, Madrid, Spain
[43]Department of Gynecologic Oncology, La Fe University and Polytechnic Hospital, Valencia, Spain
[44]Department of Gynecologic Oncology, La Paz University Hospital, Madrid, Spain
[45]UOC Ginecologia Oncologica, Dipartimento per la salute della Donna e del Bambino e della Salute Pubblica, Policlinico Agostino Gemelli IRCCS, Rome, Italy
[46]Hospital Universitario Donostia, San Sebastian, Spain
[47]Department of Preventive Medicine and Public Health, Clinica Universidad de Navarra, Pamplona, Navarra, Spain
[48],Department of Preventive Medicine and Public Health, Universidad de Navarra, Pamplona, Spain

Correction notice This article has been corrected since it was first published. The author Nerea Martin-Calvo was omitted from the manuscript in error and has now been added to the article.

Twitter Felix Boria @BoriaFelix, Enrique Chacon @Quique_ChC, Anna Fagotti @annafagottimd, Dilyara Kaidarova @r.bolatbekova@gmail.com, Rasiah Bharathan @RasiahBharathan, Tiermes Marina @Tiermes and Mikel Gorostidi @mgorostidi

Collaborators On behalf of the SUCCOR study group: Nabil Abdalla, Sedat Akgöl, Demirkiran Aksahin, Shamistan Aliyev, Maria Alonso-Espias, Claudia Andrade, Nikola Badzakov, Rosa Barrachina, Giorgio Bogani, Eduard-Aexandru Bonci, Hélène Bonsang-Kitzis, Cosima Brucker, Laura Cárdenas, Andrea Casajuana, Pere Cavalle, Jorge Cea, Benito Chiofalo, Gloria Cordeiro, Maria Cuadra, Javier Díez, Teresa Diniz da Costa, Santiago Domingo, Lukas Dostalek, Fuat Elif, Diego Erasun, Mathias Fehr, Sergi Fernandez-Gonzalez,Annamaria Ferrero, Soledad Fidalgo, Gabriel Fiol, Khadra Galaal, José García, Gerhard Gebauer, Fabio Ghezzi, Juan Gilabert, Nana Gomes, Elisabete Gonçalves, Virginia Gonzalez, Frederic Grandjean, Miriam Guijarro, Frédéric Guyon, Jolien Haesen, Gines Hernandez-Cortes, Sofía Herrero, Imre Pete, Ioannis Kalogiannidis, Erbil Karaman, Andreas Kavallaris, Lukasz Klasa, Ioannis Kotsopoulos, Stefan Kovachev, Uppin Arno Leht, Arantxa Lekuona, Mathieu Luyckx, Michael Mallmann, Gemma Mancebo, Aljosa Mandic, Victor Martin, María Belén Martín-Salamanca, Víctor Lago, Alejandra Martinez, Gesine Meili, Gustavo Mendinhos, Liliana Mereu, Milena Mitrovic, Sara Morales, Enrique Moratalla, Natalia R. Gómez-Hidalgo, Bibiana Morillas, Eva Myriokefalitaki, Maja PakižImre, Imre Pete, Stamatios Petousis, Laurentiu Pirtea, Natalia Povolotskaya, Sonia Prader, Alfonso Quesada, Mikuláš Redecha, Fernando Roldan, Philip Rolland, Reeli Saaron, Cosmin-Paul Sarac, Jens-Peter Scharf, Špela Smrkolj, Rita Sousa, Artem Stepanyan, Vladimír Študent, Carmen Tauste, Hans Trum, Taner Turan, Manuela Undurraga, Alicia Vázquez and Ignace Vergote.

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ORCID iDs
Felix Boria http://orcid.org/0000-0002-4761-6190
Luis Chiva http://orcid.org/0000-0002-1908-3251
Enrique Chacon http://orcid.org/0000-0001-8659-8602

Anna Fagotti http://orcid.org/0000-0001-5579-335X
Tayfun Toptas http://orcid.org/0000-0002-6706-6915
Mehmet Mutlu Meydanli http://orcid.org/0000-0001-6763-9720
Anna Myriam Perrone http://orcid.org/0000-0003-3140-4772
Robert Poka http://orcid.org/0000-0003-1836-1579
Vladyslav Sukhin http://orcid.org/0000-0002-4403-3707
Robert Fruscio http://orcid.org/0000-0001-5688-2194
Tiermes Marina http://orcid.org/0000-0002-3307-5346
Ignacio Zapardiel http://orcid.org/0000-0002-9175-7767
Nicolò Bizzarri http://orcid.org/0000-0002-1727-904X
Mikel Gorostidi http://orcid.org/0000-0001-5150-2797
Nabil Manzour http://orcid.org/0000-0002-4604-6042

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Correction: *SUCCOR quality: validation of ESGO quality indicators for surgical treatment of cervical cancer*

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The author Nerea Martin-Calvo was omitted from the manuscript in error and has now been added to the article.

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