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Chapter

Centralization of Esophageal Cancer Surgery: Does It Improve Clinical Outcome?

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ABSTRACT

Background:

The volume-outcome relationship for complex surgical procedures has been extensively studied. Most studies are based on administrative data and use in-hospital mortality as the sole outcome measure. It is still unknown if concentration of these procedures leads to improvement of clinical outcome. The aim of our study was to audit the process and effect of centralizing esophageal resections for cancer by using detailed clinical data.

Methods:

From January 1990 till December 2004, five-hundred fifty-five esophagectomies for cancer were performed in eleven hospitals in the region of the Comprehensive Cancer Center Leiden, 342 patients were operated on before and 213 patients after the introduction of a centralization project. In this project patients were referred to the hospitals which showed superior outcomes in a regional audit. In this audit patient-, tumor- and operative details as well as clinical outcome were compared between hospitals. The outcome of both cohorts, patients operated on before and after the start of the project, were evaluated.

Results:

Despite the more severe comorbidity of the patient group, outcome improved after centralizing esophageal resections. Next to a reduction in postoperative morbidity and length of stay, mortality fell from 12 to 4% and survival improved significantly (p = 0.001). The hospitals with the highest procedural volume, showed the biggest improvement in outcome.

Conclusion:

Volume is an important determinant of quality of care in esophageal cancer surgery. Referral of patients with esophageal cancer to surgical units with adequate experience and superior outcomes (outcome-based referral), improves quality of care.

INTRODUCTION

The number of publications that report on the relationship between the volume of high-risk surgical procedures and patient outcome continues to grow¹. Most studies show better outcome with increasing number of operations performed by a specialized center or surgeon. However, there is still a debate about the level of evidence of these studies and the appropriateness of minimum volume thresholds for high-risk surgical procedures^{2 3 4}. For example, there are no randomized controlled trials that have compared outcome for complex surgical procedures between high and low volume hospitals. Despite this "lack of evidence", authors claim that many surgical deaths could be saved by centralizing these high-risk procedures⁵. However, studies that have analyzed the actual effect of centralization (or regionalization) on hospital volumes and outcomes are rare⁶.

It has been widely acknowledged that esophagectomy for cancer is a complex surgical procedure and that concentration in high-volume centers could lead to improved outcome ^{7 8}. However, translation of the conclusions of observational series to clinical practice is difficult. Cut-off values between high- and low volume esophageal surgery vary greatly between studies (Table I). In the Netherlands, van Lanschot *et al.* investigated the volume-mortality relationship for esophageal resections, analyzing data from the Dutch National Medical Registry ⁹. They also showed an inverse relationship between hospital volume and mortality. The purpose of our study was to analyze whether centralization of esophageal cancer surgery truly improves clinical outcome. Besides mortality, we were also interested in a more extensive set of outcome measures, including overall survival. As case-mix has also been shown to be an important predictor for treatment outcomes, we included detailed clinical data of individual patient and tumor characteristics¹⁰.

METHODS

Comprehensive Cancer Center Leiden

Eleven hospitals in the mid-western part of the Netherlands are affiliated with the Comprehensive Cancer Center Leiden (CCCL). In this urbanized area travelling distances between hospitals are not more than 45 kilometres (30 miles). In 1997, a Professional Network of Surgical Oncologists (PNSO) involving all affiliated hospitals was established, with the objective to improve the effectiveness and efficiency of surgical care for patients with cancer. Within the light of the increasing number of reports on a volume-outcome relationship for esophagectomies, the Network decided to evaluate the surgical care for patients with esophageal cancer treated in the CCCL region since the year 1990.

Retrospective registration

All surgically treated esophageal carcinomas from 1990 till 1999, were identified through the 'Cancer Registry' of the CCCL, in which all cancer patients diagnosed and treated in the mid-western part of the Netherlands (1.7 million inhabitants) are registered. All eleven hospitals formally gave their consent to participate in this audit and were subsequently visited by two investigators who retrieved the original patient files. Patient demographics, pathological notes, data on surgical and (neo)adjuvant treatments, co-morbidity as well as post-operative morbidity, mortality, length of stay and survival were extracted from the patients' files. Pathological notes were reviewed in detail by two independent researchers and all cancers were staged according to the TNM-staging system of the UICC 1997. The obtained pTNM stages were then cross-checked with the tumor stages in the 'Cancer Registry'. Discrepancies in tumor stage were discussed between the researchers and a trained data manager from the CCCL/Cancer Registry database. If consensus could not be reached, the tumor stage was classified as 'unknown'.

Intervention

In January 2000 the results of this retrospective analysis were presented at the PNSO meeting¹⁰. Differences in volume and outcome between hospitals were discussed and all surgeons agreed to participate in a prospective registration. Also all surgeons agreed upon the scenario of having to refer esophageal cancer patients to centers with a better outcome if their own results proved to be unfavorable (outcome-based referral). These referrals were on a voluntary basis, however, both for the patient and the surgeon.

Prospective registration

From January 2000 until December 2004 the same data were prospectively collected from the original patient files, and again all affiliated hospitals took part in this exercise. Completeness of the data was cross-checked with the independently collected information from the 'Cancer Registry'. Each year, the interim results were presented and discussed within the group of surgeons at the meeting of the PNSO.

Control group

To put the data of the CCCL in national perspective, we compared the outcome of the CCCL region with the results of the nearest referral center for esophagectomy outside the CCCL region. In this high volume university hospital, information of patients operated on for an esophageal carcinoma is prospectively collected from the original patient files by a data manager.

Statistics

Differences in patient, tumor and treatment characteristics, as well as in outcome measurements were assessed using the Kruskal-Wallis test for continuous variables and

the chi-square test for categorical variables. Patients with an 'unknown' status for a given variable were excluded for the analyses. Duration of survival was calculated as the difference between date of surgery and either the date of death or the date of last patient contact. To prevent the problem of differential follow up, for all groups follow-up was cut-off at two years after surgery. Observed survival rates were estimated by using the Kaplan-Meier method. The log-rank test was used to assess differences in survival between patients who were operated in different time-periods and in low-volume versus high-volume hospitals. The Cox proportional hazard model was used to calculate hazard ratios, adjusting for possible confounding variables. All analyses were conducted using SPSS software (version 12.0; SPSS inc., Chicago.IL).

RESULTS

Hospital volume

Between 1990 and 2004, the evaluation and treatment of patients with esophageal cancer was performed in eleven hospitals in the region of the CCCL (one university hospital, five teaching hospitals and five general hospitals). In 555 consecutive patients, an esophageal tumor was resected with curative intent. Figure 1a illustrates the distribution of surgical procedures within the studied time period for the 11 hospitals and Figure 1b shows the resection rates for esophageal carcinomas diagnosed in the CCCL region in three different time periods.

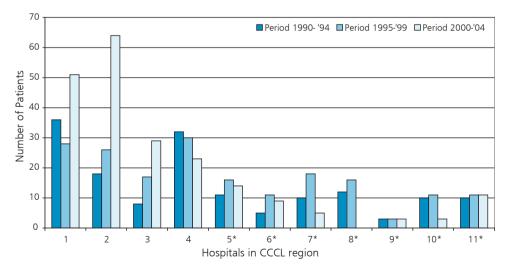


Figure 1a number of esophageal resections in hospitals in region of CCCLeiden per 5-years period (1990-1994, 1995-1999, 2000-2004) * Hospitals that abandoned esophageal resections during 2000-2004 period: 4 Hospital that abandoned esophageal resections after January 1st 2005



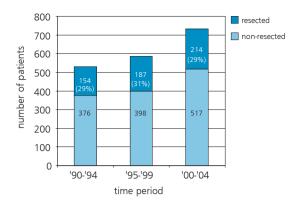


Figure 1b resection rates of newly diagnosed patients with esophagus carcinoma in hospitals in region of CCCL per 5-years period (1990-1994, 1995-1999, 2000-2004)

From 1990 till 1999, none of the hospitals performed more than seven esophageal resections per year (low volume hospitals; LVH). From the year 2000 onwards, a gradual concentration of esophageal resections has occurred, and in two hospitals (I and II) procedural volumes increased to more than 10 resections per year (high volume hospitals; HVH). In the same period of time, a mean annual number of 56 esophageal resections were performed in the nearest high volume center.

Patient, tumor and treatment characteristics

Table 1 shows the patient, tumor and procedural characteristics of esophageal resections performed in three consecutive time periods. There was no significant difference in age, gender, histological type or location of the tumors. However, the number of patients with co-morbidities increased during the study period. Stage I tumors were more frequently seen in the later time periods and an increasing number of transhiatal resections were performed. The number of nodes evaluated by the pathologist changed in time, with a mean number of 6.3, 7.5 and 13.5 nodes reported on in the different time-periods. In the 2000-2004

	1990-1994	1994 1995-1999 2000-2004					
Characteristics	No. of patients	%	No. of patients	%	No. of patients	%	P value
Age (years)							0.19
Median	66		65		64		
Range	37-87		33-85		33-86		
Gender							0.70
Male	109	70.8	139	74.3	159	74.3	
Female	45	29.2	48	25.7	55	25.7	
Co-morbidity							0.25#,*
No	68	44.2	74	39.6	83	38.8	
1 organ system	51	33.1	61	32.6	85	39.7	
2 organ systems	19	12.3	30	16.0	41	19.2	
≥ 3 organ systems	4	2.6	7	3.7	4	1.9	
Unknown	12	7.8	15	8.0	1	0.5	

Table 1. Characteristics of	natients who	underwent esonhagea	resection hv	period of surgery
	patients who	underwent esophagea	resection by	period of surgery

	1990-199	4	1995-1999	9	2000-2004	4		
Characteristics	No. of patients	%	No. of patients	%	No. of patients	%	P value	
Histology							0.93#,**	
Adenocarc	107	69.5	130	69.5	144	67.3		
Squamous carc	45	29.2	51	27.3	52	24.5		
Barrets dysplasia	1	0.6	3	1.6	6	2.8		
Others	-	-	2	1.1	5	2.3		
Unknown	1	0.6	1	0.5	7	3.3		
Tumor localisation							0.97#,***	
Cervical esoph.	4	2.6	3	1.6	4	1.9		
Mid esoph.	23	14.9	30	16.0	32	15.0		
Distal esoph./ge-junction	127	82.5	152	81.3	177	82.7		
Unknown	-	-	2	1.1	1	0.5		
Stage (pTNM)							0.65#	
0	2	1.3	5	2.7	6	2.8		
1	10	6.5	26	13.9	31	14.5		
II	80	51.9	80	42.8	82	38.3		
	52	33.8	60	32.1	74	34.6		
IV	9	5.8	12	6.4	15	7.0		
Unknown	1	0.6	4	2.1	6	2.8		
Neo-adj. treatment							<0.001#,****	
No	150	97.4	165	88.2	160	74.8		
Chemo +/- radiother.	2	1.3	19	10.1	54	25.2		
Unknown	2	1.3	3	1.6	-	-		
Surgical approach							<0.001#,****	
Abdomino-cervical	53	34.4	97	51.9	156	72.9		
Thoraco-abdominal	62	40.3	34	18.2	11	5.9		
Abd-thor-cervical	16	10.4	27	14.4	27	12.6		
Abdominal	23	14.9	29	15.5	15	7.0		
Unknown	-	-	-	-	5	2.3		
Anastomoses							<0.001*****	
Cervical	69	44.8	126	67.4	187	87.4		
Thoracic	60	39.0	30	16.0	12	5.6		
Abdominal	25	16.2	31	16.6	15	7.0		
Total no. Of patients	154		187		214			

Table 1. Cont.

unknown category was excluded, * linear trend analysis, ** squamous versus adenocarcinoma plus barrets dysplasia, *** distal esophagus / GE-junction versus others, **** no neo-adjuvant therapy versus others, ***** abdomino-cervical versus others, *****cervical versus thoracic plus abdominal

time-period more neo-adjuvant chemotherapy was used, especially in patients with a tumor in the lower esophagus, included in a trial on peri-operative epirubicin, cisplatin and fluorouracil (ECF)¹¹.

Outcome

The outcome of esophagectomies in the CCCL region improved with time (Table 2). The percentage of patients with a microscopic radical resection (R0) improved from 69 % to

73%. The number of patients who left the hospital without adverse events was highest in the 2000 - 2004 period. Hospital stay was shortened significantly and in-hospital mortality was reduced almost three-fold. As shown in figure 2, a significantly better 2-yrs survival

	1990-1994	1	1995-1999)	2000-2004		
Outcome	No. of patients	%	No. of patients	%	No. of patients	%	P value
Margins							0.57#,*
RO	107	69.5	140	74.9	156	72.9	
R1	34	22.1	21	11.2	39	18.2	
R2	10	6.5	25	13.4	12	5.6	
Unknown	3	1.9	1	0.5	7	3.3	
Complications							0.20#
No	43	27.9	46	24.6	70	32.7	
Yes	106	68.8	140	74.9	143	66.8	
Unknown	5	3.2	1	0.5	1	0.5	
Re-intervention							0.27#,**
None	115	74.4	155	82.9	163	76.2	
1	27	17.5	21	11.2	32	15.0	
2	5	3.2	7	3.7	12	5.6	
≥ 3	2	1.3	3	1.6	3	1.4	
Unknown	5	3.2	1	0.5	4	1.9	
Hospital stay (days)+							0.002
Median	20		21		17		
Range	(9-92)		(9-125)		(8-273)		
In-hospital mortality							0.003#
No	131	85.1	160	85.6	204	95.3	
Yes	22	14.3	23	12.3	10	4.7	
Unknown	1	0.6	4	2.1	-	-	
Total no. of patients	154		187		214		

 Table 2. Outcome after esophageal resections in region of CCCLeiden (1990-1994, 1995-1999, 2000-2004)

+ patients who died during hospital stay were not included, # unknown category was excluded, * R0 versus R1 plus R2, ** no re-intervention versus others

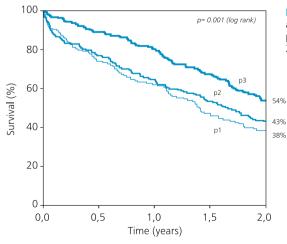


Figure 2. Two year survival after resection for all stages of esophageal carcinoma in 3 time periods (p1:1990-1994, p2: 1995-1999, p3: 2000-2004), incl. hospital mortality Table 3a. Cox multivariate model adjusted for the impact of covariates on the risk of dying (HR) for patients who underwent esophageal resection for cancer by period of surgery.

	HR	95% CI			
Univariate					
1990-1994	1.00				
1995-1999	0.89	0.69–1.14			
2000-2004	0.66	0.50-0.86			
Adjusted for stage# and co-morbidity#					
1990-1994	1.00				
1995-1999	0.82	0.61-1.11			
2000-2004	0.57	0.42-0.77			
Adjusted for stage#, co-morbidity# and surgical approa	ach#				
1990-1994	1.00				
1995-1999	0.85	0.62–1.15			
2000-2004	0.60	0.43-0.84			
Adjusted for stage#, co-morbidity#, surgical approach# and neo-adjuvant treatment#					
1990-1994	1.00				
1995-1999	0.85	0.63-1.16			
2000-2004	0.61	0.44-0.86			

HR: hazards ratio, 95% CI: 95% confidence interval, # unknown categories were excluded

Table 3b. Cox multivariate model adjusted for the impact of covariates on the risk of dying (HR) for patients who underwent esophageal resection by period of surgery (patients who died in-hospital excluded).

	HR	95% CI
Univariate		
1990-1994	1.00	
1995-1999	0.87	0.64-1.20
2000-2004	0.66	0.48-0.91
Adjusted for stage#		
1990-1994	1.00	
1995-1999	0.90	0.65-1.24
2000-2004	0.67	0.48-0.93
Adjusted for stage#, age and gender		
1990-1994	1.00	
1995-1999	0.88	0.64-1.22
2000-2004	0.67	0.48-0.93
Adjusted for stage#, age, gender and co-morbidity#		
1990-1994	1.00	
1995-1999	0.88	0.64-1.22
2000-2004	0.67	0.48-0.93
Adjusted for stage#, age, gender, co-morbidity# and surgical approach		
1990-1994	1.00	
1995-1999	0.92	0.66-1.29
2000-2004	0.75	0.52-1.07

HR: hazards ratio, 95% CI: 95% confidence interval, # unknown categories were excluded

is seen for the last time-period (p = 0.001). After exclusion of in-hospital mortality, this difference is still significant (p = 0.045).

Table 3a shows the results of a multivariate analysis for the risk of dying after surgery in the three time periods with adjustments for the impact of the covariates: stage, comorbidity, surgical approach and neo-adjuvant treatments. Somewhat higher stages of the disease and more patients with multiple comorbidities were operated in the last time-period. Although there are significant differences in surgical approach and the use of neo-adjuvant chemotherapy between time-periods, the survival benefit in the 2000-2004 period remains significant in multivariate analysis (HR 0.61). An analysis of the data after exclusion of patients who received (neo-)adjuvant treatment showed similar improvements in mortality rates and survival after 2000. Also, a multivariate analysis was performed after exclusion of the patients who died during hospital stay (Table 3b). Improvements in survival stayed (borderline) significant after adjustments for differences in stage, age, gender and comorbidities (p = 0.05), but after introducing surgical approach in the model, significance was lost (p = 0.25).

In table 4 patient, tumor and treatment characteristics of patients operated on in hospitals with less than 10 resections a year (low volume hospitals LVH) and with more than 9

	LVHs		HVHs		
Characteristics	No. of patients	%	No. of patients	%	P value
Age					0.24
Median (years)	64		63		
Range (years)	(33-86)		(43-80)		
Gender					0.53
Male	80	72.1	79	76.7	
Female	31	27.9	24	23.3	
Co-morbidity					0.001#,*
No	56	50.5	27	26.2	
1 organ system	35	31.5	50	48.5	
2 organ systems	18	16.2	23	22.3	
≥ 3 organ systems	1	0.9	3	2.9	
unknown	1	0.9	-	-	
Histology					0.98#,**
Adenocarc	73	65.8	71	68.9	
Squamous	27	24.3	25	24.3	
Barrets dysplasia	3	2.7	3	2.9	
Other	2	1.8	3	2.9	
Unknown	6	5.4	1	1.0	
Tumor localisation					0.61#,***
Cervical esoph.	2	1.8	2	1.9	
Mid esoph.	18	16.2	14	13.6	
Distal esoph./ge-junction	90	81.1	87	84.5	

Table 4. Characteristics of patients who underwent esophageal resection by hospital volume in the 2000-2004 time-period

	LVHs		HVHs		
Characteristics	No. of patients	%	No. of patients	%	P value
Unknown	1	0.9	-	-	
Stage (pTNM)					0.90#
0	3	2.7	3	2.9	
1	15	13.5	16	15.5	
11	43	38.7	39	37.9	
111	39	35.1	35	34.0	
IV	6	5.4	9	8.7	
Unknown	5	4.5	1	1.0	
Neo-adj. treatment					0.27#,****
No	90	81.1	70	68.0	
Chemo +/- radioth.	21	18.9	33	32.0	
Surgical approach					<0.001#,****
Abdomino-cervical	66	59.5	90	87.4	
Thoraco-abdominal	10	9.0	1	1.0	
Abd-thor-cervical	17	15.3	10	9.7	
Abdominal	14	12.6	1	1.0	
Unknown	4	3.6	1	1.0	
Anastomoses					<0.001*****
Cervical	86	77.5	101	98.1	
Thoracic	12	10.8	-	-	
Tbdominal	13	11.7	2	1.9	
Total no. of patients	111		103		

 Table 4. Characteristics of patients who underwent esophageal resection by hospital volume in the 2000-2004 time-period (Cont).

LVHs: Low Volume Hospitals (< 10 resections/yr) HVHs: High Volume Hospitals (\geq 10 resections/yr), # unknown category was excluded, ** adenocarcinoma / barrets dysplasia versus squamous and others, *** distal esophagus / GE-junction versus cervical / mid esophagus, **** no neo-adjuvant therapy versus others, ***** abdomino-cervical versus others, ****** cervical anastomoses versus others

resections a year (high volume hospitals HVH) are shown. Only patients operated in a year in which the procedural volume of the hospital concerned, exceeded 9 resections, were included in the HVH group. In this group more patients with more comorbidity were operated and the transhiatal approach was used more often, than the transthoracic approach. Significantly more adverse events occurred in the LVH group, with a mortality rate of 6.3% in the LVH group and 2.9% in the HVH group (table 5). After exclusion of the patients who died in-hospital, the median hospital stay was 8 days shorter in the HVH group. Survival analysis did not show a difference in 2-year survival between the LVH and HVH group (p = 0.63).

DISCUSSION

In the last decade, many studies have been published that have addressed the volumeoutcome relationship for complex surgical procedures^{1,12}. The results of these studies focus

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	LVHs		HVHs		
Characteristics	No. of patients	%	No. of patients	%	P value
Margins					0.35#,*
RO	77	69.4	79	76.7	
R1	19	17.1	20	19.4	
R2	10	9.0	2	1.9	
Unknown	5	4.5	2	1.9	
Complications					
No	24	21.6	46	44.7	0.001#
Yes	86	77.5	57	55.3	
Unknown	1	0.9	-	-	
Surgical complications					0.05#
No	54	48.6	64	62.1	
Yes	56	50.5	39	37.9	
Unknown	1	0.9	-	-	
General complications					0.001#
No	44	39.6	65	63.1	
Yes	66	59.5	38	36.9	
Unknown	1	0.9	-	-	
Re-intervention					0.39#,**
None	82	73.9	81	78.6	
1	19	17.1	13	12.6	
2	7	6.3	5	4.9	
≥3	1	0.9	2	1.9	
Unknown	2	1.8	2	1.9	
Hospital stay (days)+					<0.001
Median	22		14		
Range	(10-273)		(8-104)		
In-hospital mortality					0.24
No	104	93.7	100	97.1	
Yes	7	6.3	3	2.9	
Total no. of patients	111		103		

Table 5. Outcome after esophagea	I respections by bosnita	Lyolumo in the	2000 2001 time pariod
Table J. Outcome after esophagea	These clions by nospita	i volume in the	2000-2004 time-penou

LVHs: Low Volume Hospitals (< 10 resections/yr) HVHs: High Volume Hospitals (\geq 10 resections/yr), + patients who died during hospital stay were not included, # unknown category was excluded, * R0 versus R1 plus R2, ** no re-intervention versus others

on the rather high difference in mortality rates between high- and low-volume providers for esophageal resections for cancer⁷. As a consequence, these authors speculate that concentration of these high-risk surgical procedures in centres with adequate experience could avoid thousands of preventable deaths^{5,13}. However, the present study is the first that shows an actual improvement in outcome after the process of centralization of esophageal resections for cancer.

Chowdhury *et al.* reviewed 163 studies that looked at the volume-outcome relationship for complex surgical procedures¹. Seventy-three percent of these studies showed significant better outcomes in high volume hospitals and for high-volume surgeons. However, most

studies are registry-based and omit important case-mix adjustments from clinical data. Moreover, hospital mortality is often presented as the sole outcome measure, without presenting other dimensions of quality of care. Therefore, there is solid criticism on the methodological issues, which hampers centralization initiatives for complex surgical procedures, especially in the Netherlands. Despite the expected benefits of centralizing complex surgical procedures at high-volume providers, there are few studies that show an actual improvement in clinical outcome after centralization of a specific procedure¹⁴. As a part of a broader initiative, The Leapfrog group, a large coalition of private and public purchasers of health insurance in the United States, is referring their patients to high volume providers of esophagectomies since 2000. Although expectations about the beneficial effects of this intervention were high, no results have been published yet^{5,13}.

Our study adds clinical proof to the effectiveness of concentrating complex surgical procedures: not only hospital mortality was reduced to a third of the original value, but also other outcome indicators, like the number and severeness of adverse events, showed a significant improvement after centralization of esophagectomies in the CCCL region in the Netherlands. This was also reflected in a lower number of reinterventions and a lower length of stay. Remarkable is the significant improvement in survival that is already demonstrated after a limited concentration of esophageal resections (Figure 2). To our opinion overall survival, adjusted for differences in tumor stages, should be the most important performance indicator in surgical oncology, being even more valuable than operative mortality.

In an earlier article from our group we showed that case-mix is an important determinant of outcome and should be part of every study comparing outcome between providers¹⁰. Therefore, we tried to study the effect of differences in case-mix between the hospitals. The identification of more patients with multiple comorbid diseases and more patients with stage IV disease in the last time period (Table 1), supports our conclusion that outcome improved with centralization of esophageal resections.

However, our study has several limitations. First, the accuracy of the registry database should be confirmed. This was done by comparing the results with the data of the independently retrieved information in the Cancer Registry of the CCCL. Only 3% of the patients operated on for esophageal cancer in our region were missing from our prospective database. The treatment and outcome characteristics of this small group of patients did not differ significantly from the original group. An earlier report on a detailed medical audit confirms the accuracy of clinical outcomes databases on major fields like operative mortality, major complications, and significant factors in risk stratification¹⁵.

Secondly, our dataset is still limited, though more (co)variables were included than in most volume-outcome studies. In contrast to the available data on case-mix variations, no information on structural changes in perioperative care was available. To our knowledge no important improvements in the treatment of esophageal cancer are known from the

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literature nor within the region of the CCCL. Nevertheless, progress in anesthesiologic techniques and postoperative care within the study period, could have interfered with our findings. In addition, limited data were available on the survival of patients in the later time-period (2-year survival). This could be insufficient to evaluate differences in disease control obtained by transthoracic and transhiatal procedures. Recently, the 5-year survival data of the Dutch randomized controlled trial comparing these surgical approaches were published¹⁶. No survival benefit was shown for either approach. Nevertheless, after introducing surgical approach in our multivariate analyses (Table 3b), the statistical difference in survival between the time-periods was lost, suggesting an important role for the choice of operative approach. To our opinion, the choice for a transhiatal or transthoracic procedure is made in a decision making process in which careful interpretation of diagnostic images and surgical experience is combined. The increase in hospital volumes, as a result of the concentration of esophagectomies in our study, might have lead to better surgical decision making, especially in the choice of operative approaches.

The beneficial effects of the centralization-process conducted in the last time-period is further supported by the comparison of outcome between LVHs and the hospitals that acquired the status of HVH (> 10 resections/ year) in the last time-period (Table 5). Although differences in operative mortality are not significant, they strongly suggest that the most important improvement in outcome is made in the HVHs, which now parallel the outcome in the nearest high-volume referral center (data not shown). Differences in case-mix, especially comorbidities, are also in favour of the HVHs (Table 4). A continuation of the centralization process and the outcome registration in our region will elucidate the mechanisms behind these improvements in patient outcome. From January 1st 2005 esophagus resections in the region of the CCCL are concentrated in three hospitals with a mean annual volume of more than 15 esophagus resections.

Finally, the feedback we gave to individual surgeons and hospital organizations on their performance (mirror-information) could in itself have influenced practice patterns and dedication of the professionals. When outcomes data are used for internal peer review within institutions, changes in the process of care can be initiated by surgeons or hospitals themselves. A good example is the Veterans Affairs National Surgical Quality Improvement Program (NSQIP) in which feedback to providers and managers lead to a decrease in the relative risk for postoperative mortality of 27% and a 45% decrease in postoperative morbidity¹⁷. However, this program was more detailed consisting of outcome-based annual reports, periodic assessment of performance, self-assessment tools, structured site visits and dissemination of best practices. Nevertheless, the observed improvements in outcome in our study could not only be a result of the concentration of services, but also of the introduced feedback on surgical performance. This could be the explanation for the improved outcome that was also demonstrated in the LVHs, though of a lesser magnitude than the improvements in HVHs (Table 5).

Some authors believe that procedural volume, as a proxy for quality, is preferable above direct outcomes measurement ^{18,19}. The availability and easy access of these data and the avoidance of the statistical 'problem of small sample size' are mentioned as important advantages ²⁰. However, in a study from our own country, van Heek *et al.* showed that, despite a 10-year lasting 'evidence-based' plea for centralization of pancreatic surgery, no reduction of mortality or change in referral pattern was seen in the Netherlands ²¹. The problem is that provider volume as a quality measure only holds true on average, and is a poor predictor of quality in individual hospitals or surgeons ^{22 23}.

In our opinion, a continuous monitoring of clinical outcomes has not only the ability to assess quality of care, but can actually improve surgical performance. A number of methods for surgical monitoring, that take into account different levels of prior risk, have been described in the literature ^{24,25}. A routinely conducted clinical audit, providing hospitals and surgeons with individualized and pooled outcome-information, can be a stimulus to the introduction of a range of improvements in hospital and surgical care ²⁶⁻²⁸. In addition, a national or regional approach, like the example for esophageal cancer surgery in our study, clarifies important differences in quality of care. In a peer review environment or when reliable, hospital specific outcome information is made available to the public, actual changes in referral patterns can be made (outcome-based referral).

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REFERENCES

- Chowdhury MM, Dagash H, Pierro A. A systematic review of the impact of volume of surgery and specialization on patient outcome. *Br J Surg* 2007; 94:145-61.
- Urbach DR, Austin PC. Conventional models overestimate the statistical significance of volumeoutcome associations, compared with multilevel models. J Clin Epidemiol 2005; 58:391-400.
- Metzger R, Bollschweiler E, Vallbohmer D, Maish M, DeMeester TR, Holscher AH. High volume centers for esophagectomy: what is the number needed to achieve low postoperative mortality? *Dis Esophagus* 2004; 17:310-4.
- Holscher AH, Metzger R, Brabender J, Vallbohmer D, Bollschweiler E. High-volume centers-effect of case load on outcome in cancer surgery. *Onkologie* 2004; 27:412-6.
- Birkmeyer JD, Finlayson EV, Birkmeyer CM. Volume standards for high-risk surgical procedures: potential benefits of the Leapfrog initiative. *Surgery* 2001; 130:415-22.
- Gandjour A, Bannenberg A, Lauterbach KW. Threshold volumes associated with higher survival in health care: a systematic review. *Med Care* 2003; 41:1129-41.
- Birkmeyer JD, Siewers AE, Finlayson EV et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002; 346:1128-37.
- Killeen SD, O'Sullivan MJ, Coffey JC, Kirwan WO, Redmond HP. Provider volume and outcomes for oncological procedures. *Br J Surg* 2005; 92:389-402.
- van Lanschot JJ, Hulscher JB, Buskens CJ, Tilanus HW, ten Kate FJ, Obertop H. Hospital volume and hospital mortality for esophagectomy. *Cancer* 2001; 91:1574-8.
- Wouters MW, Wijnhoven BP, Karim-Kos HE et al. High-Volume versus Low-Volume for Esophageal Resections for Cancer: The Essential Role of Case-Mix Adjustments based on Clinical Data. Ann Surg Oncol 2007.
- Cunningham D, Allum WH, Stenning SP et al. Perioperative chemotherapy versus surgery alone for resectable gastresophageal cancer. N Engl J Med 2006; 355:11-20.
- Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. *Ann Intern Med* 2002; 137:511-20.
- Dudley RA, Johansen KL, Brand R, Rennie DJ, Milstein A. Selective referral to high-volume hospitals: estimating potentially avoidable deaths. JAMA 2000; 283:1159-66.
- O'Connor GT, Plume SK, Olmstead EM et al. A regional intervention to improve the hospital mortality associated with coronary artery bypass graft surgery. The Northern New England Cardiovascular Disease Study Group. JAMA 1996; 275:841-6.

- Herbert MA, Prince SL, Williams JL, Magee MJ, Mack MJ. Are unaudited records from an outcomes registry database accurate? Ann Thorac Surg 2004; 77:1960-4.
- Omloo JM, Lagarde SM, Hulscher JB et al. Extended transthoracic resection compared with limited transhiatal resection for adenocarcinoma of the mid/ distal esophagus: five-year survival of a randomized clinical trial. Ann Surge 2007; 246:992-1000.
- Khuri SF, Daley J, Henderson WG. The comparative assessment and improvement of quality of surgical care in the Department of Veterans Affairs. Arch Surg 2002; 137:20-7.
- Dimick JB, Birkmeyer JD, Upchurch GR, Jr. Measuring surgical quality: what's the role of provider volume? *World J Surg* 2005; 29:1217-21.
- Birkmeyer JD, Dimick JB, Staiger DO. Operative mortality and procedure volume as predictors of subsequent hospital performance. Ann Surg 2006; 243:411-7.
- Dimick JB, Welch HG, Birkmeyer JD. Surgical mortality as an indicator of hospital quality: the problem with small sample size. JAMA 2004; 292:847-51.
- van Heek NT, Kuhlmann KF, Scholten RJ et al. Hospital volume and mortality after pancreatic resection: a systematic review and an evaluation of intervention in the Netherlands. *Ann Surg* 2005; 242:781-8, discussion.
- Rathore SS, Epstein AJ, Volpp KG, Krumholz HM. Hospital coronary artery bypass graft surgery volume and patient mortality, 1998-2000. Ann Surg 2004; 239:110-7.
- Birkmeyer JD, Dimick JB, Birkmeyer NJ. Measuring the quality of surgical care: structure, process, or outcomes? J Am Coll Surg 2004; 198:626-32.
- Lovegrove J, Valencia O, Treasure T, Sherlaw-Johnson C, Gallivan S. Monitoring the results of cardiac surgery by variable life-adjusted display. *Lancet* 1997; 350:1128-30.
- Steiner SH, Cook RJ, Farewell VT, Treasure T. Monitoring surgical performance using risk-adjusted cumulative sum charts. *Biostatistics* 2000; 1:441-52.
- Jarman B, Bottle A, Aylin P, Browne M. Monitoring changes in hospital standardised mortality ratios. *BMJ* 2005; 330:329.
- Wright J, Dugdale B, Hammond I et al. Learning from death: a hospital mortality reduction programme. J R Soc Med 2006; 99:303-8.
- Reilly J, Mitchell A, Blue J, Thomson W. Breast cancer audit: adapting national audit frameworks for local review of clinical practice. Health Bull (Edinb) 2001; 59:60-2.