


# The DGAV risk calculator: development and validation of statistical models for a web-based instrument predicting complications of colorectal cancer surgery

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## Abstract

**Purpose** The purpose of this study is to provide a web-based calculator predicting complication probabilities of patients undergoing colorectal cancer (CRC) surgery in Germany.

**Methods** Analyses were based on records of first-time CRC surgery between 2010 and February 2017, documented in the database of the Study, Documentation, and Quality Center (StuDoQ) of the *Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie* (DGAV), a registry of CRC surgery in hospitals throughout Germany, covering demography, medical history, tumor features, comorbidity, behavioral risk factors, surgical procedures, and outcomes. Using logistic ridge regression, separate models were developed in learning samples of 6729 colon and 4381 rectum cancer patients and evaluated in validation samples of sizes 2407 and 1287. Discrimination was assessed using *c* statistics. Calibration was examined graphically by plotting observed versus predicted complication probabilities and numerically using Brier scores.

**Results** We report validation results regarding 15 outcomes such as any major complication, surgical site infection, anastomotic

leakage, bladder voiding disturbance after rectal surgery, abdominal wall dehiscence, various internistic complications, 30-day readmission, 30-day reoperation rate, and 30-day mortality. When applied to the validation samples, *c* statistics ranged between 0.60 for anastomosis leakage and 0.85 for mortality after rectum cancer surgery. Brier scores ranged from 0.003 to 0.127. **Conclusions** While most models showed satisfactory discrimination and calibration, this does not preclude overly optimistic or pessimistic individual predictions. To avoid misinterpretation, one has to understand the basic principles of risk calculation and risk communication. An e-learning tool outlining the appropriate use of the risk calculator is provided.

**Keywords** Colorectal cancer · Risk calculator · Statistical prediction models · Model validation

## Introduction

Surgery for colorectal cancer (CRC) puts patients at a considerable risk of adverse events, such as surgical site infection, anastomosis insufficiency, or bladder voiding problems (in case of rectal cancer), as well as multiple other complications [1, 2]. The case fatality rate is substantial: reports of 30-day mortality vary between ca. 3% after elective surgery and over 40% after emergency operations [3, 4].

The individual risk of an adverse event depends on multiple factors, such as tumor characteristics (e.g., location and stage), type of surgery, socio-demographic variables like age and sex, comorbidity (e.g., diabetes mellitus, cardiovascular, or neurologic diseases), behavioral risk factors (smoking, alcohol abuse), and concomitant treatments (immunosuppression, glucocorticoids, radio-, radio-chemo-, and chemotherapy). Realistic preoperative assessment of complication

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probabilities is crucial for patient information, shared decision-making, and fine-tuning therapies [1].

Traditionally, risk estimates rely on the personal experience of the treating surgeon [5, 6]. Statistical models published in terms of formulas for calculating risk scores provide a more objective basis for decision-making, but are often felt cumbersome to apply in clinical practice [7]. This leads to the development of web-based risk calculators, often based on large databases from the US population [1]. Informal personal communications indicate that using these tools is common practice among surgeons in Germany, and thus, probably internationally. Herein lies a danger, since statistical prediction models cannot simply be transported from one population to another [8–10]. This motivated the development and validation of a new risk calculator based on a database of CRC surgery patients treated in German hospitals. In this paper, we describe the development and validation of the statistical models underlying the web tool.

## Patients and methods

### Data source

Model development and validation relied on subsamples from the Study, Documentation, and Quality Center (StuDoQ) database of the German Society for General and Visceral Surgery (Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie (DGAV)), a registry of CRC operations in participating hospitals throughout Germany. Inspired by the National Surgical Quality Improvement Program of the American College of Surgeons (ACS NSQIP), but not simply copying its database architecture, the StuDoQ database was implemented with the objective of documenting, assuring, and improving the quality of surgery in CRC patients.

Each StuDoQ database record consists of more than 200 patient variables, covering demographic characteristics, medical history, tumor features, comorbidity, behavioral risk factors, surgical technique, adverse events, and clinical outcomes. Data are entered via a web interface and automatically checked for completeness, plausibility, and consistency. Once obligatory patient data have been entered and passed the plausibility checks, records are flagged as analysis cases.

Our learning samples for model development consisted of all 6729 colon and 4381 rectum cancer patients flagged as analysis cases between 2010 and 2015. The corresponding validation sets consisted of 2407 colon and 1287 analysis cases documented between January 2016 and February 2017.

### Participants

Since the implementation of the StuDoQ database in 2010, the number of hospitals using the system has risen steadily.

Participating hospitals are primary care centers located in all 16 states of the Federal Republic of Germany. As of February 2017, 184 of approximately 750 surgical departments in Germany contribute patient records. The spectrum reaches from municipal hospital to university medical centers. All centers take part in an audit procedure by the DGAV to guarantee a functioning quality system. Documentation quality is also checked by routines inbuilt into the data management of the registry.

Eligible patients had to have first-time abdominal tumor resection for cure or palliation of CRC, either elective or in case of emergency. We included patients of both genders without age restriction.

### Outcomes

We developed and validated models for the following outcomes: severe complication (defined by a Clavien-Dindo score greater than three), surgical site infection requiring revision of the wound, 30-day mortality, anastomotic leakage, bladder voiding problems, bladder voiding disturbance after rectal surgery, abdominal wall dehiscence, ileus, bleeding requiring transfusions, unplanned ventilation, renal failure, myocardial infarction pulmonary embolism, stroke, 30-day hospital readmission, 30-day reoperation rate, and 30-day mortality.

### Predictors

Besides age and gender, a set of potential predictors was selected from the available variables based on surgical literature and the judgment of surgical experts: age, sex, type of surgery (recorded as left vs. right colectomy, extended colon resection, low anterior resection, abdominoperineal rectum resection, and extended rectum resection), tumor location (right/left/transverse/other colon; rectum under 6, 6 to 12, or 12 to 16 cm from the anus, rectum without further specification), body mass index, emergency versus elective surgery, smoking, alcohol abuse, American Society of Anesthesiologists (ASA) category, need of care (none/partial/full), New York Heart Association (NYHA) Functional Classification, coronary artery disease, peripheral artery disease, diabetes mellitus (none, not insulin dependent, insulin dependent), dialysis, disseminated cancer, weight loss, radio- and chemotherapy, anticoagulatory medication (none/aspirin/clopidogrel/other), presence of distant metastases, presence and synchronous resection of liver metastases, chronic obstructive pulmonary disease, blood pressure medication, history of conditions with an increased risk of colorectal cancer (familial adenomatous polyposis, ulcerative colitis, Crohn's disease, hereditary non-polyposis colon cancer), corticosteroid medication, cerebrovascular disease (none, with/without neurologic deficit), elevated white blood cell count, anemia (none, mild with hemoglobin concentrations between 6 and 12 g/dL, severe with hemoglobin concentrations

**Table 1** Demographic and clinical characteristics of the colon and rectum cancer patients in the learning and the validation sets

	Colon cancer patients				Rectum cancer patients			
	Learning set		Validation set		Learning set		Validation set	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Total	6729	100.0	2407	100.0	4381	100.0	1287	100.0
Indicators								
Female sex	3219	47.8	1234	51.3	1697	38.7	473	36.8
Age (years)								
Under 65	1978	29.4	638	26.5	1366	31.2	355	27.6
65 to 74	2308	34.3	867	36	1116	25.5	336	26.1
75 to 84	713	10.6	264	11	218	5.0	79	6.1
85+	1730	25.7	638	26.5	1681	38.4	517	40.2
Type of surgery								
Extended colon resection	345	5.1	110	4.6				
Left colectomy	2904	43.2	1068	44.4				
Right colectomy	3480	51.7	1229	51.1				
Low anterior rectum resection					3453	78.8	1034	80.3
Abdominoperineal resection of the rectum					766	17.5	206	16.0
Extended rectum resection					162	3.7	47	3.7
Tumor location								
Right colon	3249	48.3	1168	48.5				
Transverse colon	615	9.1	205	8.5				
Left colon	2766	41.1	1023	42.5				
Other colon	99	1.5	11	0.5				
Rectum (< 6 cm from the anus)					1335	30.5	379	29.4
Rectum (6 to 12 cm from the anus)					1904	43.5	564	43.8
Rectum (12 to 16 cm from the anus)					1096	25.0	331	25.7
Rectum, not specified					46	1.0	13	1.0
Body mass index (kg/m <sup>2</sup> )								
Under 20	2335	34.7	842	35	1656	37.8	453	35.2
20 to 24.99	341	5.1	155	6.4	255	5.8	90	7.0
25 to 29.99	2575	38.3	892	37.1	1650	37.7	515	40.0
30+	1478	22	518	21.5	820	18.7	229	17.8
Emergency surgery	721	10.7	232	9.6	160	3.7	41	3.2
Smoking	128	1.9	66	2.7	320	7.3	105	8.2
Alcohol abuse	229	3.4	81	3.4	169	3.9	69	5.4
American Society of Anesthesiologists category								
ASA 1	442	6.6	181	7.5	449	10.2	146	11.3
ASA 2	3021	44.9	1119	46.5	2258	51.5	683	53.1
ASA 3	3015	44.8	1031	42.8	1594	36.4	436	33.9
ASA 4 or 5	251	3.7	76	3.2	80	1.8	22	1.7
Need of care								
None	6024	89.5	2157	89.6	4068	92.9	1208	93.9
Partial	600	8.9	212	8.8	265	6.0	73	5.7
Full	105	1.6	38	1.6	48	1.1	6	0.5
New York Heart Association Functional Classification								
No cardiac disease	5165	76.8	1894	78.7	3550	81.0	1072	83.3
I	354	5.3	99	4.1	271	6.2	48	3.7
II	669	9.9	243	10.1	347	7.9	111	8.6
III	351	5.2	106	4.4	144	3.3	25	1.9

Table 1 (continued)

	Colon cancer patients				Rectum cancer patients			
	Learning set		Validation set		Learning set		Validation set	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
IV	31	0.5	8	0.3	6	0.1	2	0.2
Unknown	159	2.4	57	2.4	63	1.4	29	2.3
Coronary artery disease	1256	18.7	439	18.2	625	14.3	181	14.1
Peripheral artery disease	165	2.5	71	2.9	105	2.4	37	2.9
Diabetes mellitus								
None	5286	78.6	1908	79.3	3612	82.4	1046	81.3
Not insulin dependent	957	14.2	331	13.8	501	11.4	172	13.4
Insulin dependent	486	7.2	168	7	268	6.1	69	5.4
Dialysis	50	0.7	21	0.9	21	0.5	5	0.4
Disseminated cancer	556	8.3	168	7	310	7.1	69	5.4
Weight loss	797	11.8	293	12.2	575	13.1	171	13.3
Radio- or chemotherapy								
None	6636	98.6	2373	98.6	2487	56.8	744	57.8
Radiotherapy only	25	0.4	5	0.2	112	2.6	46	3.6
Chemotherapy only	50	0.7	25	1	63	1.4	24	1.9
Both	18	0.3	4	0.2	1719	39.2	473	36.8
Anticoagulatory therapy								
None	5471	81.3	1893	78.6	3750	85.6	1080	83.9
Acetylsalicylic acid	802	11.9	310	12.9	402	9.2	134	10.4
Clopidogrel	90	1.3	34	1.4	44	1.0	16	1.2
Other	366	5.4	170	7.1	185	4.2	57	4.4
Distant metastases	905	13.4	300	12.5	573	13.1	131	10.2
Synchronous liver metastases								
None	5923	88	2164	89.9	3926	89.6	1174	91.2
Synchronous resection	219	3.3	52	2.2	129	2.9	33	2.6
No synchronous resection	587	8.7	191	7.9	326	7.4	80	6.2
Chronic obstructive pulmonary disease	393	5.8	139	5.8	208	4.7	58	4.5
Blood pressure medication	4235	62.9	1517	63	2369	54.1	691	53.7
Familial adenomatous polyposis	28	0.4	7	0.3	20	0.5	7	0.5
Ulcerative colitis	41	0.6	23	1	30	0.7	15	1.2
Crohn's disease	12	0.2	15	0.6	20	0.5	4	0.3
Hereditary non-polyposis colon cancer	61	0.9	18	0.7	28	0.6	7	0.5
Corticosteroid medication	93	1.4	47	2	46	1.0	4	0.3
Cerebrovascular disease								
None	6182	91.9	2207	91.7	4107	93.7	1203	93.5
Without neurologic deficit	313	4.7	132	5.5	180	4.1	62	4.8
With neurologic deficit	234	3.5	68	2.8	94	2.1	22	1.7
Elevated white blood cell count	1258	18.7	459	19.1	405	9.2	122	9.5
Anemia								
None	3529	52.4	1221	50.7	3180	72.6	931	72.3
Mild (hemoglobin 6 to 12 g/dL)	3171	47.1	1179	49	1193	27.2	356	27.7
Severe (hemoglobin < 6 g/dL)	29	0.4	7	0.3	8	0.2	0	0.0
C-reactive protein elevation	2776	41.3	916	38.1	1128	25.7	277	21.5
Creatinine elevation	845	12.6	325	13.5	388	8.9	97	7.5

**Table 2** Complications in colon and rectum cancer patients in the learning and the validation sets

	Colon cancer patients				Rectum cancer patients			
	Learning set		Validation set		Learning set		Validation set	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Total	6729	100.0	2407	100.0	4381	100.0	1287	100.0
Complications								
Any major complication	999	14.9	321	13.3	696	15.9	196	15.2
Surgical site infection	662	9.8	203	8.4	427	9.8	98	7.6
Anastomosis leakage	342	5.1	120	5.0	313	7.1	108	8.4
Bladder voiding problems					425	9.7	118	9.2
Abdominal wall dehiscence	274	4.1	97	4.0	133	3.0	28	2.2
Ileus	205	3.1	94	3.9	151	3.5	49	3.8
Bleeding requiring transfusions	172	2.6	38	1.6	120	2.7	22	1.7
Ventilation	223	3.3	69	2.9	142	3.2	29	2.3
Renal failure	89	1.3	37	1.5	58	1.3	13	1.0
Myocardial infarction	54	0.8	16	0.7	19	0.4	8	0.6
Pulmonary embolism	40	0.6	14	0.6	22	0.5	9	0.7
Stroke	15	0.2	8	0.3	18	0.4	4	0.3
30-day readmission	290	4.3	112	4.7	314	7.2	98	7.6
30-day reoperation	765	11.4	280	11.6	585	13.4	175	13.6
30-day mortality	198	2.9	69	2.9	78	1.8	18	1.4

below 6 g/dL), C-reactive protein elevation, and creatinine elevation.

Since all data were collected during clinical routine by the treating surgeons, documentation of the predictors was not blind for the outcomes under study and vice versa.

### Sample size

The learning set consisted of all available patients documented prior to 2016 (colon 6729, rectum 4381), the validation set of all patients treated between 2016 and February 2017 (colon 2407, rectum 1287). No formal sample size estimation was undertaken.

### Missing data

Missing data in categorical variables were imputed by majority voting, i.e., by replacing the missing information with the modal value. The R package *mice* (version 2.25) was used for multiple imputation of quantitative variables with missing values (C-reactive protein, hemoglobin, creatinine) prior to classification using the categories mentioned previously.

### Statistical methods

All analyses were performed using R version 3.3.0 [11]. Prediction models were based on logistic ridge using the *glmnet* package (version 2.0-5). Independent variables were

standardized to account for the different measurement scales used. The reported regression coefficients were back-transformed to the original scale. The optimal value of the penalty parameter  $\lambda$  was determined by a tenfold cross-validation based on the learning sample, using the mean squared error (MSE) as optimality criterion. Model discrimination in the validation set was assessed by means of ROC curves and the corresponding areas under the curves (AUC) using the R package *ROCR* (version 1.0-7). Model calibration was assessed graphically by splitting the validation set in groups defined by the deciles of the predicted event probabilities and plotting the observed frequencies in the resulting groups versus the predicted probabilities. Predictive accuracy was assessed using Brier scores. A perfect prediction produces a Brier score of zero. Predicting the exact opposite of what happened produces a Brier score of one. Predicting each event with the coin toss probability 0.5 produces a Brier score of 0.25.

### Results

Table 1 describes the demographic characteristics of the patients and the distributions of the predictor variables in the learning and the validation, stratified by main diagnosis. Table 2 gives an overview of the incidence of the complications modeled in the prediction models. The regression coefficients are displayed in Tables 3 (colon cancer) and 4 (rectal cancer).

**Table 3** Regression coefficients from the logistic ridge regression models for prediction of complications in colon cancer patients

Variable	Major complication	Surgical site infection	Anastomosis leakage	Abdominal wall dehiscence	Ileus	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
Intercept	-2.153	-2.557	-3.246	-3.463	-3.398	-4.037	-3.797	-5.080	-5.323	-5.142	-6.315	-3.103	-2.313	-4.516
Type of surgery														
Extended resection	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Left colectomy	-0.002	-0.033	0.140	0.033	-0.100	-0.097	-0.093	-0.019	0.018	0.002	0.104	-0.001	0.049	-0.085
Right colectomy	-0.091	0.036	-0.193	-0.023	0.110	0.005	-0.099	-0.046	-0.018	-0.005	-0.109	0.002	-0.083	0.015
Tumor location														
Right colon	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Transverse colon	0.162	-0.077	0.230	0.037	-0.128	0.179	0.209	0.038	0.133	0.013	-0.028	0.000	0.118	0.124
Left colon	0.036	-0.012	0.193	0.019	-0.089	-0.066	0.063	-0.012	-0.051	0.002	0.116	-0.001	0.078	-0.080
Other	-0.186	-0.203	-0.305	-0.323	-0.355	-0.249	0.462	0.613	0.292	-0.032	-0.099	-0.001	-0.338	-0.094
Female sex	-0.241	-0.072	-0.239	-0.221	-0.307	-0.066	-0.251	-0.436	-0.035	0.000	-0.053	-0.002	-0.189	-0.154
Age (years)														
Under 65	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
65 to 74	0.087	0.041	-0.017	0.030	0.074	-0.010	0.174	-0.011	0.071	0.011	-0.042	0.000	0.013	0.289
75 to 84	0.148	-0.178	-0.224	0.062	0.027	0.072	-0.062	0.167	0.420	0.006	0.148	-0.002	-0.025	0.693
85+	-0.003	-0.018	0.022	-0.020	-0.029	0.036	-0.062	0.022	-0.144	-0.013	-0.084	0.002	0.006	-0.288
Body mass index (kg/m <sup>2</sup> )														
Under 20	0.077	-0.161	0.065	0.040	-0.122	-0.058	-0.037	-0.162	0.235	-0.001	-0.100	0.001	-0.004	-0.017
20 to 24.99	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
25 to 29.99	0.054	0.073	0.089	-0.023	0.064	-0.049	-0.009	0.037	0.037	-0.017	0.064	0.000	0.070	-0.048
30+	0.201	0.286	0.151	0.179	0.109	0.052	0.094	0.141	-0.104	0.028	0.065	0.002	0.159	-0.031
Emergency surgery	0.217	0.156	0.205	0.175	0.161	0.176	0.506	0.318	0.177	-0.003	-0.047	0.001	0.160	0.154
Smoking	0.059	0.162	0.299	0.365	0.386	0.271	-0.178	0.039	0.011	-0.033	-0.098	0.006	0.169	-0.170
Alcohol abuse	0.299	0.195	0.522	0.050	0.360	0.370	0.192	0.387	-0.227	0.040	-0.105	0.005	0.189	0.294
American Society of Anesthesiologists category														
ASA 1	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
ASA 2	-0.156	-0.077	-0.012	-0.173	-0.090	-0.099	-0.142	-0.050	-0.121	-0.018	-0.104	-0.001	-0.126	-0.286
ASA 3	0.160	0.083	0.140	0.132	0.054	0.068	0.101	0.018	0.120	0.018	0.067	0.000	0.136	0.162
ASA 4 or 5	0.552	0.092	0.247	0.051	-0.232	0.415	0.598	0.710	0.318	0.054	0.224	0.007	0.279	1.137
Need of care														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Partial	0.259	0.131	-0.109	0.167	0.206	0.183	0.163	0.236	0.204	-0.007	-0.058	0.001	0.086	0.639
Full	0.354	0.244	0.413	0.085	-0.374	0.334	0.425	0.658	-0.087	0.069	0.269	-0.001	0.235	0.661
New York Heart Association Functional Classification														
No cardiac disease	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I	0.155	0.086	0.151	0.209	0.056	-0.080	0.028	-0.034	0.006	-0.002	0.156	-0.004	0.147	-0.096
II	0.078	0.079	-0.024	0.108	-0.047	0.065	-0.042	0.296	0.277	0.017	0.023	-0.002	-0.026	0.300
III	0.180	0.214	0.001	0.203	0.076	0.160	0.176	0.239	0.221	0.045	0.247	0.002	0.070	0.505

Table 3 (continued)

Variable	Major complication	Surgical site infection	Anastomosis leakage	Abdominal wall dehiscence	Ileus	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
IV	0.631	0.146	0.510	0.545	-0.532	0.493	0.687	0.554	0.410	0.138	-0.134	0.004	0.261	1.151
Unknown	0.469	0.124	0.066	-0.236	-0.063	0.200	0.581	0.609	0.342	0.001	-0.120	0.001	0.096	0.641
Coronary artery disease	0.018	0.065	0.166	0.048	-0.083	0.163	0.229	0.188	0.275	0.012	0.108	0.000	0.071	-0.129
Peripheral artery disease	0.166	0.164	0.034	0.286	0.380	0.012	0.162	0.036	0.604	0.099	0.134	0.001	0.020	0.224
Diabetes mellitus														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Not insulin dependent	-0.029	0.134	0.011	-0.049	0.006	0.025	0.061	-0.021	0.091	0.001	-0.127	0.002	-0.045	0.030
Insulin dependent	0.016	0.033	-0.013	0.032	-0.266	0.065	-0.152	0.108	-0.010	0.000	0.065	0.003	0.073	0.114
Dialysis	0.029	-0.140	0.255	-0.163	0.103	-0.010	-0.083	0.336	0.529	-0.034	-0.132	-0.005	-0.062	0.910
Disseminated cancer	0.254	0.158	0.164	0.131	-0.036	0.131	0.081	0.251	0.058	-0.014	0.133	0.004	0.089	0.392
Weight loss	0.039	0.027	0.024	0.077	0.129	0.073	0.211	0.166	0.097	0.002	0.071	0.002	-0.013	0.268
Radio- or chemotherapy														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Radiotherapy only	0.628	0.283	1.077	0.304	0.132	0.611	0.007	-0.478	-0.237	-0.032	-0.110	0.008	0.644	-0.627
Chemotherapy only	0.291	-0.386	0.074	-0.012	0.185	-0.377	0.142	0.651	0.347	0.183	-0.111	-0.005	0.017	1.258
Both	-0.421	-0.604	-0.650	0.655	1.058	-0.309	0.508	-0.365	-0.176	-0.031	-0.097	0.003	0.020	-0.374
Anticoagulatory therapy														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Acetylsalicylic acid	0.061	0.055	-0.013	0.034	-0.076	0.002	-0.106	-0.072	0.214	0.001	0.116	0.000	0.068	0.006
Clopidogrel	-0.140	0.022	-0.039	-0.281	-0.341	0.056	0.113	-0.674	0.663	0.027	-0.124	0.005	-0.113	-0.188
Other	0.141	0.087	0.217	0.106	0.286	0.121	-0.012	0.246	-0.144	0.012	0.128	0.001	0.047	0.046
Distant metastases	0.036	-0.027	0.031	0.007	-0.027	0.012	-0.025	0.157	-0.052	0.004	0.098	0.002	0.014	0.070
Synchronous liver metastases														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Synchronous resection	0.153	-0.138	0.019	-0.142	-0.276	0.199	0.199	-0.170	-0.084	0.018	0.102	0.000	-0.031	0.017
No synchronous resection	-0.087	-0.024	-0.161	-0.009	-0.124	-0.063	-0.236	0.194	0.007	0.005	0.037	0.002	-0.107	0.230
Chronic obstructive pulmonary disease	0.246	0.031	0.185	0.156	0.295	0.103	0.366	0.044	-0.107	0.023	-0.004	0.000	0.159	0.386
Blood pressure medication	0.086	0.043	0.120	0.107	0.024	0.155	-0.027	0.200	0.142	-0.002	0.083	0.000	0.081	0.154
	0.236	-0.614	0.483	-0.370	-0.501	-0.348	-0.594	-0.338	0.722	-0.031	-0.092	0.006	0.159	-0.408

Table 3 (continued)

Variable	Major complication	Surgical site infection	Anastomosis leakage	Abdominal wall dehiscence	Ileus	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
Familial adenomatous polyposis	0.095	0.419	0.159	0.135	-0.512	0.954	0.652	-0.389	-0.165	-0.031	-0.080	0.001	-0.057	-0.338
Ulcerative colitis	-0.284	-0.070	-0.680	0.407	-0.538	-0.308	-0.547	-0.432	-0.172	-0.031	-0.079	0.008	-0.147	-0.485
Crohn's disease	-0.281	-0.263	0.198	-0.373	-0.531	-0.337	-0.570	-0.374	-0.161	-0.031	-0.086	-0.002	-0.130	-0.441
Hereditary non-polyposis colon cancer	0.161	0.361	0.457	0.123	-0.002	-0.178	0.059	0.355	-0.011	-0.033	-0.105	0.011	0.283	-0.022
Corticosteroid medication														
Cerebrovascular disease														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Without neurologic deficit	-0.108	-0.020	0.112	0.002	-0.367	-0.025	0.245	0.271	-0.076	0.001	0.315	0.000	-0.023	-0.206
With neurologic deficit	0.104	0.014	0.060	0.050	0.315	-0.089	0.612	0.627	-0.202	-0.034	0.258	-0.001	0.048	0.079
Elevated white blood cell count	0.154	0.170	0.066	0.127	-0.045	-0.041	0.257	0.032	-0.036	-0.008	-0.125	0.001	0.117	0.258
Anemia														
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Mild (hemoglobin 6 to 12 g/dL)	0.076	0.063	-0.009	0.084	-0.027	0.223	0.096	0.214	0.045	0.006	0.071	0.001	0.018	0.129
Severe (hemoglobin <6 g/dL)	0.170	-0.156	-0.570	-0.390	0.043	1.796	0.630	-0.352	1.178	-0.032	-0.086	0.005	0.001	0.533
C-reactive protein elevation	0.087	0.151	0.066	0.124	0.002	0.070	0.110	0.133	0.022	0.011	-0.039	0.002	0.099	0.193
Creatinine elevation	0.087	-0.057	0.009	0.071	0.091	0.097	0.215	0.544	0.172	0.020	0.045	0.001	0.058	0.286



**Table 4** Regression coefficients from the logistic ridge regression models for prediction of complications in rectum cancer patients

Variable	Major complication	Surgical site infection	Anastomosis leakage	Bladder voiding problem	Abdominal wall dehiscence	Ileus requiring transfusions	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
Intercept	-1.898	-2.649	-2.203	-2.510	-3.719	-3.313	-3.811	-3.969	-4.651	-5.850	-5.289	-5.562	-2.749	-1.987	-4.634
Type of surgery															
Low anterior rectum resection	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Abdominoperineal resection of the rectum	0.130	0.550	-0.253	0.500	0.003	-0.101	0.091	0.018	-0.040	-0.016	0.000	-0.031	0.062	0.138	0.042
Extended rectum resection	0.213	0.368	-0.041	1.028	0.257	0.228	0.482	0.561	0.316	-0.133	0.000	0.138	-0.204	0.020	0.390
Tumor location															
Rectum (< 6 cm from the anus)	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Rectum (6 to 12 cm from the anus)	0.018	-0.132	-0.012	-0.098	0.025	0.044	-0.008	0.087	-0.008	0.019	0.000	0.032	0.084	-0.038	-0.009
Rectum (12 to 16 cm from the anus)	-0.062	-0.130	-0.026	-0.367	-0.081	-0.175	-0.039	-0.162	0.004	-0.072	0.000	-0.029	-0.148	-0.063	-0.021
Rectum, not specified	-0.011	-0.092	-0.057	-0.650	0.045	-0.131	-0.089	0.057	-0.189	-0.122	0.000	-0.066	0.325	0.043	0.268
Female sex	-0.242	-0.082	-0.121	-0.640	-0.135	-0.366	-0.040	-0.348	-0.119	-0.057	0.000	-0.030	-0.073	-0.151	-0.101
Age (years)															
Under 65	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
65 to 74	0.148	0.018	-0.022	0.059	0.102	0.033	0.113	0.156	0.104	0.181	0.000	0.115	-0.019	0.048	0.198
75 to 84	0.041	-0.113	-0.097	-0.215	-0.056	0.046	0.004	0.271	0.158	0.199	0.000	-0.079	-0.100	-0.101	0.495
85+	-0.014	-0.018	0.065	0.108	-0.047	0.075	-0.092	-0.256	-0.123	-0.111	0.000	-0.083	0.042	0.050	-0.229
Body mass index (kg/m <sup>2</sup> )															
Under 20	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
20 to 24.99	0.088	-0.135	-0.023	-0.305	0.022	0.119	-0.073	-0.480	-0.023	-0.109	0.000	0.067	-0.092	0.084	0.184
25 to 29.99	0.007	0.078	-0.040	0.079	0.037	-0.001	-0.014	-0.019	0.029	0.072	0.000	0.019	-0.065	0.025	-0.073
30+	0.114	0.192	0.066	0.157	0.062	-0.070	0.007	0.346	0.065	0.087	0.000	0.038	0.092	0.070	0.076
Emergency surgery	0.220	0.138	-0.001	-0.145	0.190	0.035	0.100	0.645	0.348	0.354	0.000	0.031	-0.039	0.072	0.212
Smoking	0.049	0.083	0.056	-0.068	-0.017	0.083	-0.070	-0.066	0.023	-0.025	0.000	-0.070	0.178	0.094	0.044
Alcohol abuse	0.457	0.162	0.351	-0.122	0.214	0.753	0.380	0.717	0.233	-0.134	0.000	-0.072	0.171	0.277	0.667
American Society of Anesthesiologists category															
ASA 1	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
ASA 2	-0.085	-0.059	-0.051	-0.034	-0.115	0.087	-0.057	-0.133	-0.086	-0.130	0.000	-0.068	0.004	-0.047	-0.160
ASA 3	0.199	0.123	0.084	0.106	0.126	-0.026	0.079	0.235	0.084	0.148	0.000	0.044	0.015	0.105	0.183
ASA 4 or 5	0.638	0.077	0.160	-0.472	0.321	0.443	0.810	0.668	0.494	0.376	0.000	0.519	-0.033	0.209	0.912
Need of care															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Partial	0.221	0.247	-0.022	0.163	0.278	0.151	0.361	0.608	0.316	0.291	0.000	0.237	0.099	0.088	0.204
Full	0.034	-0.062	0.066	0.066	0.105	0.261	0.107	1.306	0.364	-0.229	0.000	-0.089	0.141	0.295	1.076
New York Heart Association Functional Classification															
No cardiac disease	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
I	0.009	-0.135	-0.013	-0.129	-0.054	0.081	0.075	0.164	0.004	0.071	0.000	0.054	0.044	-0.073	0.293
II	-0.014	0.246	-0.037	0.310	0.115	-0.153	-0.096	-0.151	0.025	-0.094	0.000	0.118	-0.046	0.057	0.075
III	-0.014	0.091	-0.035	0.342	-0.057	0.140	0.143	0.149	0.152	0.268	0.000	-0.092	0.030	0.078	0.081

Table 4 (continued)

Variable	Major complication	Surgical site infection	Anastomosis leakage	Bladder voiding problem	Abdominal wall dehiscence	Ileus	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
IV	0.649	0.262	-0.352	0.567	1.357	0.864	0.654	1.209	-0.357	-0.207	0.000	-0.106	-0.403	0.527	0.701
Unknown	0.320	0.163	-0.098	0.172	0.253	-0.096	0.171	0.336	0.121	0.900	0.000	0.169	0.407	0.000	0.351
Coronary artery disease	0.025	-0.009	-0.031	-0.159	0.093	0.039	0.087	0.280	0.111	0.395	0.000	-0.006	-0.005	-0.019	0.148
Peripheral artery disease	0.463	0.191	-0.027	0.243	0.451	0.364	-0.034	0.013	-0.045	0.250	0.000	0.227	0.341	0.163	0.323
Diabetes mellitus															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Not insulin dependent	-0.001	0.088	-0.029	0.124	-0.018	-0.017	-0.047	-0.002	0.082	0.021	0.000	-0.009	0.128	0.040	0.077
Insulin dependent	0.035	0.090	0.076	0.093	-0.002	-0.114	0.058	0.107	0.054	0.319	0.000	0.048	-0.033	0.014	0.133
Dialysis	-0.026	-0.256	0.099	-0.476	0.243	-0.027	0.602	0.622	0.967	-0.254	0.000	-0.085	0.040	0.190	1.005
Disseminated cancer	0.014	0.151	-0.040	0.063	0.010	0.089	0.027	0.117	0.078	-0.037	0.000	-0.014	-0.081	-0.020	-0.028
Weight loss	-0.046	0.008	0.030	0.167	0.022	-0.117	0.102	-0.068	0.036	-0.042	0.000	-0.048	0.021	-0.017	0.119
Radio- or chemotherapy															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Radiotherapy only	0.293	0.350	0.002	0.312	0.560	0.472	0.089	0.512	0.013	0.084	0.000	0.217	0.004	0.315	0.030
Chemotherapy only	0.077	0.153	-0.068	0.432	0.132	0.506	-0.244	0.088	0.002	0.330	0.000	-0.064	0.149	0.108	-0.051
Both	-0.038	0.119	-0.050	0.232	-0.054	-0.011	-0.051	-0.162	-0.095	-0.086	0.000	-0.012	0.170	-0.035	-0.085
Anticoagulatory therapy															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Acetylsalicylic acid	-0.076	-0.006	-0.096	-0.036	0.186	-0.180	-0.159	-0.213	0.046	0.223	0.000	0.047	0.138	0.003	0.049
Clopidogrel	0.554	0.089	0.420	0.189	0.186	0.948	0.544	0.332	0.019	0.321	0.000	0.284	0.082	0.588	-0.111
Other	0.134	-0.085	-0.054	0.242	0.076	0.263	0.173	0.202	0.269	0.106	0.000	0.101	-0.073	0.189	0.150
Distant metastases	0.005	0.141	0.007	-0.006	0.061	-0.058	-0.025	0.037	0.080	-0.030	0.000	-0.010	0.059	0.017	0.116
Synchronous liver metastases															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Synchronous resection	-0.174	-0.034	0.078	0.149	-0.070	-0.186	0.033	-0.041	0.207	0.102	0.000	-0.067	-0.103	-0.234	0.079
No synchronous resection	-0.049	-0.071	0.024	-0.002	-0.137	-0.114	-0.062	-0.270	0.040	-0.037	0.000	-0.017	0.023	-0.079	0.110
Chronic obstructive pulmonary disease	0.206	0.127	-0.025	-0.213	0.212	0.109	0.110	0.526	0.037	-0.048	0.000	-0.002	0.051	0.288	0.178
Blood pressure medication	0.069	0.105	0.026	0.106	0.066	-0.065	0.063	0.277	0.153	0.083	0.000	0.084	0.034	0.004	0.116
Familial adenomatous polyposis	0.008	0.268	-0.048	-0.608	0.177	0.596	-0.238	-0.460	-0.136	-0.083	0.000	-0.061	0.182	-0.135	-0.197
Ulcerative colitis	0.054	0.211	-0.002	-0.674	0.443	-0.021	-0.018	-0.257	-0.176	-0.096	0.000	-0.066	-0.027	-0.481	-0.327
Crohn's disease	0.308	0.887	0.633	0.719	0.526	-0.377	0.198	-0.452	-0.129	-0.074	0.000	-0.056	0.089	0.301	-0.264
Hereditary non-polyposis colon cancer	0.160	0.444	0.353	-0.254	0.080	-0.419	0.093	0.267	-0.132	-0.082	0.000	-0.061	0.203	0.055	0.354
Corticosteroid medication	0.417	0.176	0.155	0.404	0.274	-0.182	0.195	0.748	0.292	-0.152	0.000	-0.076	0.398	0.438	0.664
Cerebrovascular disease															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

**Table 4** (continued)

Variable	Major complication	Surgical site infection	Anastomosis leakage	Bladder voiding problem	Abdominal wall dehiscence	Ileus	Bleeding requiring transfusions	Ventilation	Renal failure	Myocardial infarction	Pulmonary embolism	Stroke	30-day readmission	30-day reoperation	30-day mortality
Without neurologic deficit	-0.011	-0.036	-0.058	0.044	-0.028	-0.095	0.076	0.124	0.227	-0.033	0.000	0.013	-0.082	0.018	-0.112
With neurologic deficit	-0.241	-0.196	-0.258	-0.255	-0.044	0.108	-0.100	-0.230	-0.028	0.300	0.000	0.256	0.125	-0.055	0.174
Elevated white blood cell count	0.083	0.030	0.127	0.153	0.081	-0.049	0.071	0.094	0.244	0.128	0.000	0.013	0.128	0.096	0.292
Anemia															
None	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Mild (hemoglobin 6 to 12 g/dL)	0.076	0.118	-0.014	0.076	0.075	-0.007	0.164	0.070	0.126	0.135	0.000	-0.062	-0.021	0.072	0.178
Severe (hemoglobin < 6 g/dL)	-0.412	0.575	-0.313	0.821	-0.315	-0.518	0.532	0.447	-0.260	-0.177	0.000	-0.082	-0.392	-0.667	-0.428
C-reactive protein elevation	0.116	0.205	0.010	0.226	0.147	0.039	0.057	0.205	0.013	0.095	0.000	-0.017	0.044	0.054	0.151
Creatinine elevation	-0.051	-0.088	-0.048	-0.017	0.035	0.107	0.113	0.002	0.213	0.149	0.000	-0.040	0.085	-0.087	0.282

The regression coefficients can be used to weight the corresponding patient variables in the calculation of an additive risk score for the respective outcomes: starting with the intercept, weighted individual variable values add up to yield a sum score  $\eta_i$ . Higher scores indicate higher individual risks. The formula  $\exp(\eta_i) / [1 + \exp(\eta_i)]$  (where  $\exp$  is the exponential function with base  $e$ ) can be applied to transform risk scores into individual probability estimates.

Table 5 lists the  $c$  statistics and Brier scores of all models when applied to the learning and validation sets. In both the validation sets of colon and rectal cancer patients, the models predicting 30-day mortality exhibited the highest discriminatory power with  $c$  values of 0.844 and 0.846, respectively. The model predicting pulmonary embolism in rectal cancer patients did not contain a single non-zero regression coefficient and consequently failed to discriminate between persons with and without events ( $c = 0.500$ , Brier score 0.25). The majority of the Brier scores was less than 0.1.

The risk calculator can be accessed via the world wide web at <http://risikorechner.dgav.de/>. Figure 1 shows the graphical user interface of the program.

### Discussion

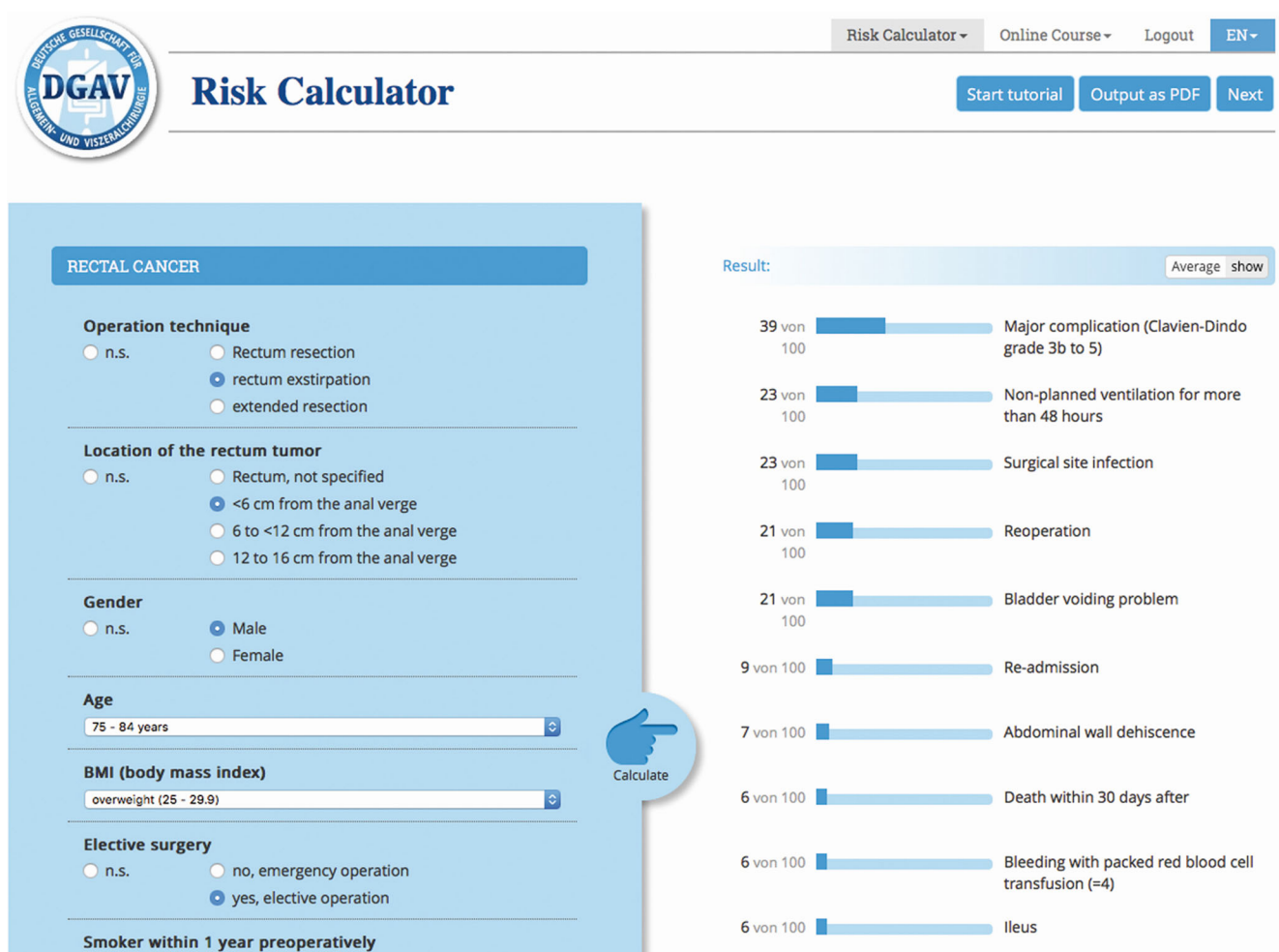
Most of our models show satisfactory discriminatory power and calibration. There are, however, exceptions from this rule, namely the prediction model for post-operative pulmonary embolism in patients with rectal cancer. It should be noted that good discrimination and calibration do not preclude individual predictions that are far off the mark. The vast majority of the analyzed patients (and most future cases) presented risk factor patterns effecting only low complication probabilities. It follows that, while predictions for low-risk persons tend to be stable, those for the small, yet particularly interesting, subpopulation of high-risk patients tend to be unreliable.

Our study has some limitations. It is unclear whether the contributing hospitals are a representative sample of the population of all surgical centers. Regarding the selection of patients, there is only a low potential of bias, since documentation quality and completeness are monitored regularly. There is some doubt, however, regarding the completeness of follow-up after hospital discharge. The 30-day mortality in the StuDoQ sample is lower than the values reported in the international literature and in hospital remuneration data for the population of German statutory health insurance members available at the German Federal Bureau of Statistics. While mere underreporting of outcomes unavailable at the time of hospital discharge need not have biased the regression slopes for the predictors, but must have resulted in risk estimates biased too low.

Surgical decision-making is a difficult process. Traditionally, it uses intuition and experience, but studies have shown that

**Table 5** *c* statistics and Brier scores for the prediction models

	Colon cancer patients				Rectum cancer patients			
	Learning set		Validation set		Learning set		Validation set	
	<i>c</i>	Brier score	<i>c</i>	Brier score	<i>c</i>	Brier score	<i>c</i>	Brier score
Model								
Any major complication	0.669	0.120	0.671	0.110	0.650	0.128	0.602	0.127
Surgical site infection	0.640	0.087	0.611	0.076	0.706	0.084	0.696	0.068
Anastomosis leakage	0.677	0.049	0.650	0.049	0.629	0.086	0.595	0.098
Bladder voiding problems					0.713	0.082	0.683	0.080
Abdominal wall dehiscence	0.697	0.038	0.690	0.038	0.730	0.029	0.639	0.021
Ileus	0.684	0.029	0.579	0.037	0.735	0.032	0.633	0.036
Bleeding requiring transfusions	0.723	0.024	0.719	0.016	0.731	0.026	0.613	0.017
Ventilation	0.736	0.031	0.721	0.027	0.820	0.029	0.683	0.022
Renal failure	0.801	0.012	0.677	0.015	0.807	0.013	0.845	0.010
Myocardial infarction	0.842	0.008	0.774	0.007	0.936	0.004	0.714	0.006
Pulmonary embolism	0.718	0.006	0.622	0.006	0.500	0.005	0.500	0.007
Stroke	0.864	0.002	0.678	0.003	0.884	0.004	0.703	0.003
30-day readmission	0.597	0.041	0.531	0.044	0.651	0.065	0.548	0.070
30-day reoperation	0.640	0.098	0.636	0.101	0.618	0.113	0.560	0.117
30-day mortality	0.857	0.025	0.844	0.026	0.864	0.016	0.846	0.013

**Fig. 1** Screenshot of the user interface of the DGAV risk calculator

both physicians and patients often overestimate benefits and underestimate harms from medical interventions [12, 13]. Especially in complex situations like cancer surgery, where the level of uncertainty is high, a more analytical approach would be helpful to support the decision-making process [14]. The DAGV risk calculator is such a decision aid. It enables patients and surgeons to balance risks and expected outcomes and arrive at a decision together.

To prevent potential misuse and misinterpretation of the predictions from the risk calculator, we have complemented it with a web-based e-learning course raising consciousness for the statistical issues, untoward clinical consequences, and the appropriate application of the tool. One of the major challenges for patients and physicians is understanding and dealing with the inherent prognostic uncertainty. The e-learning tool not only provides practical tips to communicate percentages and probabilities in a comprehensible way but also encourages to integrate the patients' values, preferences, and their current situation in the decision-making process.

Future research will have two major foci. Firstly, as the number of eligible patients documented in the StuDoQ database rises, models will have to be revised updated regularly, steadily increasing the reliability of the predictions. Secondly, the likely benefits and possible perils of using the risk calculator will have to be investigated systematically. We are confident that we are providing a tool that facilitates and supports shared decision-making, but clinical evidence for a beneficial effect has yet to be provided.

## Other information

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