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Research article

Impact of Diabetes Mellitus (DM) on Early Postoperative and Long-Term Outcomes in Colon Cancer Surgery

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Abstract

Background: A diverse number of patient related factors, tumor characteristics and treatment pathways are known to have a significant impact on tumor-driven outcomes. The aim of this study was to determine the impact of diabetes mellitus (DM) on post-operative short-term and long-term outcomes on patients with primary colon cancer with the use of prospectively collected data. Methods: Data was collected over a 3-year period from the ongoing prospective multicenter observational study of elective surgery for primary colon cancer using a registration form with 68 quality assurance items. Participation was voluntary and frequent follow-up was performed to obtain long-term data. Participants were divided into two cohorts: diabetic (DM) and non-diabetic (NDM). The diabetic cohort was further subdivided into non-insulin dependent diabetes (NIDDM) and insulin dependent diabetes (IDDM). Results: A total of 9,167 participants were enrolled, out of which 12.8 % had NIDDM and 7.7 % had IDDM. The mean age of the NDM group was 70.6 [95%-CI: 70.37; 70.91] years which was lower than that of the IDDM group at 74.2 [95%-CI: 73.57; 74.85] years and the NIDDM group at 73.5 [95%-CI: 72.97; 73.97] years; p<0.001). Tumors were staged using the UICC classification and were comparable among the groups (p=0.547). Participants with DM had a significantly greater number of comorbidities to include cardiac, pulmonary, renal and hepatic disease, as well as higher scores when using the ASA classification system of perioperative risk (p<0.001). Tumor site was assessed. There was no significant difference in tumor site distribution between the cohorts. Nor was there a difference in the conversion rate from a laparoscopic approach to an open laparotomy. Postoperative morbidity (p<0.001) and in-hospital lethality (p=0.005) were significantly higher in participants with DM compared to NDM. When subdivided, the IDDM group had a higher morbidity and mortality rate than NIDDM. The 5-year overall survival (OS) rate was lower in the IDDM group (44.9%) and NIDDM group (52.7%) when compared to the NDM group (59.7%; p<0.001). Similarly, the 5-year disease-free survival (DFS) rate was significantly lower in the IDDM group (p<0.001) and NIDDM group (p=0.042). In contrast, the 5-year local recurrence rate (LRR) was not influenced by either IDDM (p=0.631) or NIDDM (p=0.664). Conclusion: DM increases the risk of early post-operative morbidity and long-term mortality in patients undergoing oncological surgery for primary tumors of the colon. Furthermore, the 5-year overall survival rate was significantly lower in the IDDM group when compared to the NIDDM and NDM groups.

Keywords: Colon cancer, Diabetes mellitus (DM), Prospective multicenter observational study Research on clinical care Early postoperative outcome, Long-term oncosurgical outcome

Introduction

Colorectal cancer (CRC) is the third most common cancer in men and the second most common in women [1].

There is a global increase in the incidence of type-2 diabetes mellitus (DM), with an estimated total of 347 million adults suffering from type-2 diabetes in 2008 [3]. This warrants further ex-

amination of a potential link between type-2 diabetes and CRC.

Several epidemiological studies indicated that DM increases the risk of cancer-specific mortality in CRC [3-5]. Diabetes mellitus (DM) and hyperglycemia have significant negative effects on the incidence, chemoresistance, and prognosis of CRC, as well as on the outcomes of localized and metastatic CRC.

The dysregulation of insulin that occurs in diabetes with its ensuing hyperglycemia, insulin resistance and chronic inflammation may promote tumor growth, metastases, and chemoresistance in CRC. Additionally, diabetic patients frequently exhibit comorbidities such as cardiovascular disease and kidney disease which further complicates the management of cancer by increasing the likelihood of treatment-related complications.

The Aim of this study was to investigate the influence of DM onto the early postoperative and long-term oncologic outcome after surgery for primary colon cancer using data prospectively obtained in a representative number of 9,167 patients.

Materials and Methods

The procedures followed were in accordance with the ethical standards of the institutional and national guidelines.

Data was collected over a 3-year period of time in a prospective multicenter observation study performed by the Institute of Quality Assurance in Operative Medicine of the Otto-von-Guericke University at Magdeburg, Germany. Participation was voluntary. Patients included in the study were greater than 18 years old, had histologically confirmed colon cancer and had undergone elective primary surgery. Sixty-two items including pre, peri- and postoperative factors were reviewed for each participant.

Participants were divided into two cohorts which were diabetic (DM) and non-diabetic (NDM). The diabetic group was further subdivided into non-insulin dependent diabetes (NIDDM) and insulin dependent diabetes (IDDM).

Early postoperative and long-term oncosurgical outcomes were evaluated for each cohort. Morbidity and mortality data was collected for the early postoperative group. The morbidity data was subdivided into two groups: general and specific. General (medical) complications included but were not limited to pneumonia, thromboembolism and cardiac complications. Specific (surgical) complications included but were not limited to anastomotic insufficiencies, ileus and peritonitis.

Three long-term oncosurgical outcomes were studied: 5-yr overall survival (OS) rate, 5-year disease-free survival (DFS) rate and the 5-year local recurrence rate (LLR).

Data was analyzed using the Kruskal-Wallis test for continuous variables, the Chi-square test for cross tabulation, and the Kaplan-Meier estimation for survival and local recurrence rate. The Mantel-Cox log-rank test was used to compare the survival distribution between the NDM and DM groups. p-values < 0.05 were defined as significant and indicated that diabetes had an effect on the outcome.

Statistical analysis

Chi-square test was used to compare the DM and NDM cohorts. It was also used to compare IDDM and NIIDM which were subgroups of the DM cohort.

Rank correlation was used to analyze the long-term data of 5-yr-OS, 5-yr-DFS and 5-yr-LRR between participants with DM and NDM as well as between the subdivided groups, IDDM and NIDDM.

Binary logistic regression analysis was used to adjust for multiple potential confounders to determine whether the clinicopathological variables were jointly associated with the postoperative outcome. Potential confounders included gender, age, localization, T-staging, type of surgery, metastases, tumor differentiation, surgical procedures, histological diagnosis and prior abdominal surgeries.

The study was conducted in accordance with the guidelines of the Declaration of Helsinki for Biomedical Research from 1964 and its subsequent modifying provisions, as well as the requirements of the institutional ethics committee.

Results

Sample and admission findings

Over a 3-year period of time, 9,274 charts were reviewed. Charts with incomplete data were excluded from the study of which there were 107. A total of 9,167 were eligible for inclusion with a data capture rate of 98.8%.

Charts were obtained from 183 clinics. Each clinic contributed between 1 and 187 charts. The NDM cohort contained 7,279 participants which made up 79.5% of the total study population. The IDDM cohort had 705 participants which was 7.7% of the total. And, the NIDDM cohort had 1,770 participants which was 12.8% of the total. The male-to-female ratio was 52.9 % vs. 47.1 %.

The NDM cohort was younger than the IDDM and NIDDM cohorts. NDM participants had an average age of 70.6 years [95% CI: 70.37; 70.91], compared to IDDM patients with an average age of 74.2 [95% CI: 71.01; 72.35] yr and NIDDM patients with an average age of 73.5 [95% CI: 72.97; 73.97] yr ($p<0.001$) (Table 1).

Table 1: Patient Demographics

	Total		None DM		IDDM		NIDDM	
	n	%	*n*	%	*n*	%	*n*	%
Participants	9167	100	7292	79.5	705	7.7	1170	12.8
Male	4893	53.4	3843	52.7	398	56.5	652	55.7
Female	4236	46.2	3418	46.9	305	43.3	513	43.9
Not specified	38	0.4	31	0.4	2	0.2	5	0.4
Median Age	72.8 yrs		70.6 yrs		74.2 yrs		73.5 yrs	

Table 2: ASA classification

	Valid	Relative proportion	None DM		IDDM		NIDDM		*p value*
	n	%	*n*	%	*n*	%	*n*	%	
ASA I	9167	6.1	555	7.8	3	0.4	7	0.6	< 0.001
ASA II		44.1	3,501	49.5	157	23.1	385	34.9	
ASA III		42.1	2,756	39.0	451	66.2	656	59.4	
ASA IV		4.2	263	3.7	70	10.3	56	5.1	

Table 3: Preoperative Presence of Risk Factors in Dependency on DM

	In total	Relative proportion	None DM		IDDM		NIDDM		*p value*
	n	%	*n*	%	*n*	%	*n*	%	
None	1,967	21.5	1,967	27.0	0	0	0	0	<0.001
Cardiac	5,194	56.7	3,833	52.6	546	77.4	815	69.7	<0.001
Pulmonary	1,448	15.8	1,099	15.1	152	21.6	197	16.8	< 0.001
Renal	832	9.1	545	7.5	133	18.9	154	13.2	<0.001
Hepatic	314	3.4	246	3.4	26	3.7	43	3.6	0.591
Nicotine abuse	437	4.8	352	4.8	29	4.1	56	4.8	0.594
Alcohol abuse	184	2.0	138	1.9	16	2.3	30	2.6	0.122
Varicosis	301	3.3	224	3.1	34	3.8	43	3.7	0.025

Table 4: Postoperative Morbidity in Dependency on DM

	Valid	Relative proportion	None DM		IDDM		NIDDM		*p value*
	n	%	*n*	%	*n*	%	*n*	%	
Morbidity (in total)	3,276	35.8	2,534	34.8	296	42.0	446	38.2	< 0.001
≥ 1 general complication		21.3	1,464	20.1	206	29.2	275	23.9	< 0.001
≥ 1 specific complication		23.9	1,719	23.6	185	26.2	282	24.2	0.290

The American Society of Anesthesiologists (ASA) Physical Status Classification System was used to assess each participant's preoperative risk. They were classified into 4 groups ranging from ASA I (healthy, low risk) to ASA IV (severe disease, high risk). None of the patients were classified into ASA V (moribund).

The IDDM cohort had the highest preoperative risk; 75.6% were classified as ASA III or IV (p<0.001). The NIDDM cohort also had significant preoperative risk; 64.5% were classified as ASA III or IV. The NDM cohort had the lowest preoperative risk; 42.7% were classified as ASA III or IV (overall, p<0.001).

The correlation between DM and a higher ASA classification was also reflected in the types of comorbidities that each cohort possessed. Participants with diabetes had a higher rate of cardiovascular disease, renal disease and obesity (p<0.001 each). IDDM participants had a significantly higher rate of cardiopulmonary disease (p<0.001) and "other" risk factors (p=0.040). Nicotine abuse was more common among non-diabetics (p=0.004).

There was no statistical difference among the cohorts when evaluated for alcohol abuse, liver disease and nicotine abuse.

Tumor location was analyzed. DM was associated with a significantly higher rate of transverse colon tumors (p=0.035) than NDM. There were no differences in other tumor locations between the DM and NDM participants.

Regarding metastatic disease, DM was associated with a significantly higher incidence of pulmonary metastasis (p=0.041). No significant differences were observed in tumor characteristics such as tumor entity, TNM classification, and grading (data not shown).

Depth of infiltration (T-category; p=0.018) and tumorous lymphangitis involvement (L-category), varied among the cohorts. DM correlated with a greater depth of infiltration than NDM. IDDM correlated with a greater depth than NIDDM.

Lymph node infiltration was similar among the cohorts. (N-stage; p=0.280).

The higher rate of preoperative pulmonary metastases in DM

Table 5: General and Specific Postoperative Complications in Dependency on DM

	total	Relative proportion	None DM		IDDM		NIDDM		p value
General complications	*n*	%	*n*	%	*n*	%	*n*	%	
UTI	361	3.9	269	3.7	37	5.2	55	4.7	0.015
Pulmonary	405	4.4	304	4.2	47	6.7	54	4.6	0.022
Pneumonia	458	5.0	350	4.8	41	5.8	67	5.8	0.088
Cardiac	473	52	352	4.8	54	7.7	67	5.8	0.004
Thrombosis	29	0.3	24	0.3	3	0.4	2	0.2	0.668
Pulmonary embolism	63	0.7	49	0.7	5	0.7	9	0.8	0.726
Renal	234	2.6	160	2.2	34	4.8	40	3.4	< 0.001
Fever	300	3.3	230	3.2	38	5.4	32	2.7	0.208
Multi-organ failure	165	1.8	121	1.7	25	3.5	19	1.6	0.046
Diverse	625	6.8	471	6.5	63	8.9	91	7.8	0.007
None	7,196	78.7	5,811	79.9	499	70.8	886	76.1	< 0.001
Specific Complications									
Sepsis	129	1.4	95	1.3	9	1.3	25	2.1	0.094
Multi-organ failure	93	1.0	65	0.9	11	1.6	17	9.5	0.020
Aseptic wound healing disorder	234	2.6	165	2.3	25	3.5	44	3.8	< 0.001
AI	481	5.3	386	5.3	39	5.5	56	4.8	0.697
Mechanical ileus	84	0.9	68	0.9	5	0.7	11	0.9	0.749
Atony	474	5.2	387	5.3	32	4.5	55	4.7	0.246
Wound infection	455	5.0	353	4.9	39	5.5	63	5.4	0.285
Wound abscess	226	2.5	180	2.5	15	2.1	31	2.7	0.972
Burst abdomen	229	2.5	182	2.5	23	3.3	24	2.2	0.977
Postbleeding	85	0.9	68	0.9	5	0.7	12	1.0	0.918
Peritonitis	198	2.2	154	2.1	19	2.7	25	2.1	0.532
Colostomy complications	25	0.3	19	0.3	3	0.4	3	0.3	0.659
Intraabdominel abscess	91	1.0	68	0.9	8	1.1	15	1.3	0.251
Stool fistula	28	0.3	18	0.2	4	0.6	6	0.5	0.045
None	6,959	76.1	5,556	76.4	520	73.8	883	75.8	0.224

patients did not result in a higher rate of UICC stage IV (characterized by distant metastasis) (p=0.293).

The overall intraoperative complication rate was 2.7%. It did not vary among the cohorts (p=0.331). The most common complications were splenic injuries (1.0 %) and bleeding (0.5%). This is a low complication rate. However, bowel injury tended to occur more frequently in IDDM (0.7%) compared to NDM (0.2%) or NIDDM (0.3 %; p=0.088). Remaining complications occurred independently of DM (data not shown) (each p>0.05) and with occurrence rates of less than 1%.

Early postoperative outcome

The postoperative overall morbidity was 35.8 %. General (medical) complications occurred more frequently in the DM cohort (p<0.001); IDDM had a higher rate than NIDDM (p<0.001). The rate of specific (surgical) post-operative complications occurred more frequently in the DM cohort but it was not statistically significant (p=0.224); there was no difference between IDDM and NIDDM. As a result, overall morbidity was highest for the DM cohort when compared to the NDM cohort (p<0.001). Morbidity was higher for IDDM than NIDDM (p<0.001).

General (medical) postoperative complications occurred in 21.3 % of patients. IDDM had a complication rate of 29.2 %, and NIDDM had a rate of 23.9 %. These rates were higher than NDM which had a rate of 20.1 % (p<0.001).

Most of the general (medical) postoperative complications were higher in DM when compared to NDM with the exception of pneumonia, pulmonary embolism, thrombosis, and fever which did not show a statistical difference. (Table 5).

In contrast, there was no difference in the overall rate of specific (surgical) postoperative complications. When items were analyzed individually, wound healing complications such as stool fistulas and multiorgan system failure occurred more frequently in the DM cohort compared to the NDM cohort (Table 5).

Overall, 91.6 % of the patients were discharged. The mean hospital mortality was 4.2 %. DM participants exhibited a significantly higher mortality rate of 5.3 % compared to 3.9 % for

Table 6: Postoperative Morbidity and Mortality in Dependency on DM

	None DM		IDDM		NIDDM		total		*p value*
	n	%	*n*	%	*n*	%	*n*	%	
Morbidity	2,534	34.8	296	42.0	446	38.2	3,276	35.8	< 0.001
Mortality	283	3.9	41	5.8	59	5.0	383	4.2	0.005

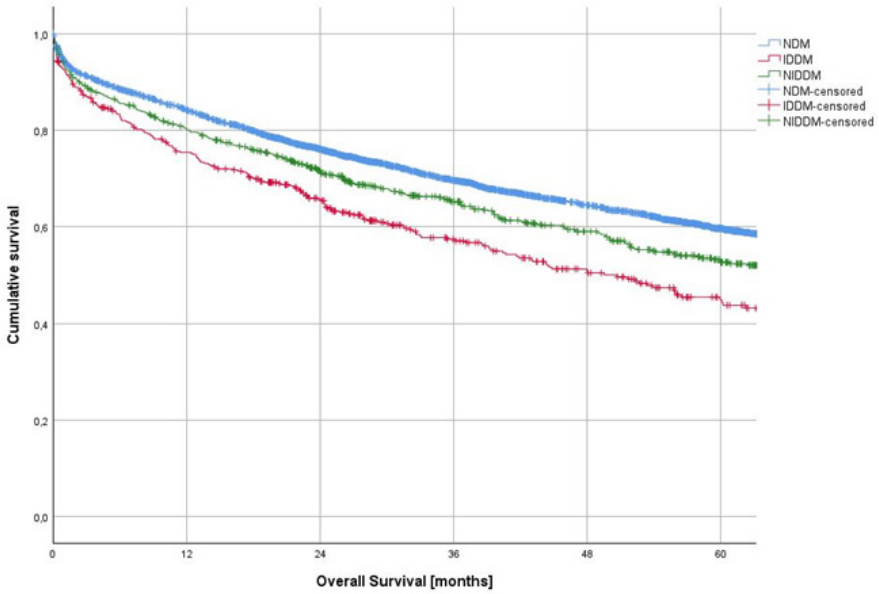

Figure 1. Influence of Diabetes Mellitus on the 5-Year Overall Survival Rate

NDM (p<0.001). Hospital mortality was highest in the IDDM cohort at 5.8 % (p=0.05; Table 6).

Long-term outcome

The impact of diabetes on the 5-year overall survival (OS) rate was analyzed. The initial sample size was 5,941 of which 3,724 (62.8%) were lost to follow up. In general, diabetes had a negative impact on long-term oncological surgical outcome. IDDM patients fared the worst with a 5-year OS rate of 44.9 % and an estimated median survival of 53.2 months [95% CI: not calculable]. NIDDM patients fared better than IDDM with a 5-year OS rate of 52.7 % (p=0.009) and lived a median of 64.0 [95% CI: 49.54; 78.46] months. NDM fared the best with a 5-year OS rate of 59.7 % (p<0.001 each) and had the longest median survival of 85.1 [95% CI: 53.32; 116.80] months (Figure 1).

The impact of diabetes on the 5-year disease-free survival (DFS) rate was analyzed. The initial sample size was 4,437 of which 3,087 (69.5%) were lost to follow up. The negative impact of diabetes that was seen on OS rate was also seen with DFS rate. The IDDM cohort had the lowest 5-year DFS rate of 52.5% (p=0.042). The NIDDM cohort fared better with a 5-year DFS rate of 60.5 %. The NDM cohort fared the best with a 5-year DFS rate of 67.6 % (Figure 2).

Uni- and multivariable influencing factors

In the multivariable analysis, both IDDM and NIDDM diabetics had more comorbidities than NDM (73 %). Regarding general (medical) postoperative complications, the IDDM group showed a significantly higher complication rate (29.2 %; p<0.001) than the NIDDM group (23.9 %; p<0.001) and the non-diabetic group (NDM) (20.1 %; p<0.001). In terms of specific (surgical) postoperative complications, there was no statistically significant difference among all three groups (23.6 % vs. 26.2 % vs. 24.2 %) for NDM vs. IDDM vs. NIDDM. Intraoperative complications were also not dependent on the presence of DM (Table 7).

Discussion

Methodological critique

The analysis includes 9,167 patients with histologically confirmed primary colon cancer, who underwent surgical treatment. Limitations include the potential for duplicate entries and errors due to the multicenter design (n=111 clinics and departments) and data collection in clinical practice. To minimize these "biases", validity criteria were applied within the database.

The multicenter study design is advantageous, as it allowed for the collection of numerous representative parameters to characterize the early postoperative and oncological long-term outcome of patients with primary colon cancer. Also beneficial is the high number of representative patient data. The data comes from clinics with various care profiles across Germany, making the analysis representative of the quality of care in Germany.

Impact of diabetes mellitus on patient characteristics and treatment

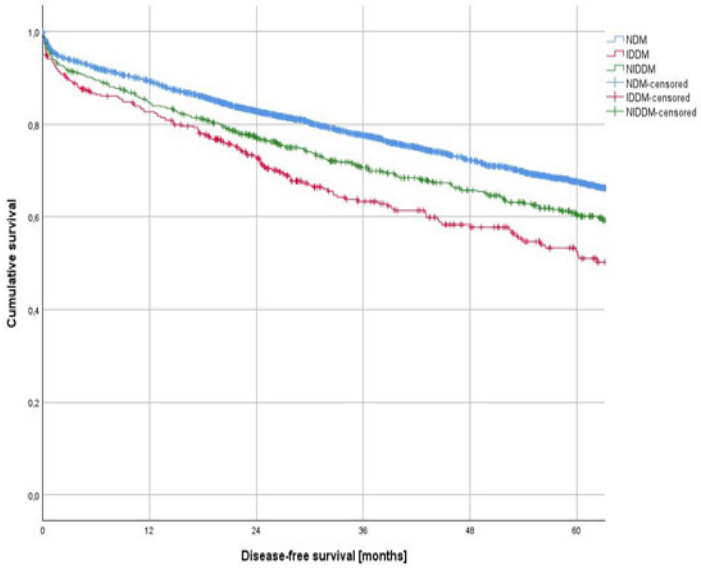

Figure 2. Kaplan-Meier Curve for the 5-Year Disease-Free Survival Rate Comparing NDM (blue), NIDDM (green), and IDDM (red)

Table 7: Multivariable Analysis

n (%)	None DM		IDDM		NIDDM		*p value*
	n	*%*	*n*	*%*	*n*	*%*	
At least one risk factor	5,325	73.0	705	100	1,170	100	< 0.001
At least one general postop. complication	1,464	20.1	206	29.2	275	23.9	< 0.001
At least one specific postop. complication	1,719	23.6	185	26.2	282	24.2	0.224
At least one intraop. complication	198	2.7	25	3.5	28	2.4	n. s.

In this analysis, 20. 5% of the study participants were diabetics. This figure is slightly higher than the 12-month prevalence of diabetes in people over the age of 60 [1]. As found in other studies, diabetics were significantly older and had a higher BMI [2, 4]. The tumor stages according to the UICC classification were comparable to those in other studies [2, 5]. Review of the literature reveals an increased incidence of colon cancer among diabetics [6]. Additionally, a higher BMI is associated with an increased relative risk of developing colon cancer, particularly in men [7].

Impact of diabetes mellitus on early postoperative outcomes

Postoperative morbidity was significantly higher in patients with IDDM and NIDDM compared to NDM.

Statistical analysis of significant influencing factors showed that diabetics were more likely to have at least one general (medical) postoperative complication ($p<0.001$). It was also evident that diabetics were more likely to have a higher ASA classification ($p<0.001$). Specifically, general (medical) complications occurred more frequently in IDDM patients ($p<0.001$). Interestingly, there was no significant difference in the occurrence of specific (surgical) complications between DM and NDM nor between IDDM and NIDDM, except for wound healing disorders, stool fistulas, and multi-organ failure.

It is well known that there is an increased incidence of wound infections following colorectal surgery in patients with elevated postoperative blood glucose levels [8]. So blood glucose levels should be strictly controlled peri- and postoperatively. The data set used for this analysis did not include postoperative blood glucose levels of the patients, which would be of interest for future studies.

General (medical) complications occurred more frequently in IDDM than NIDDM and occurred more frequently in DM than NDM. This finding is consistent with the preoperative risk profile of diabetic patients, particularly the increased cardiovascular morbidity associated with this patient cohort [2, 5, 9]. The only general (medical) complications were similar between DM and NDM pneumonia, pulmonary embolism, and fever.

Impact of diabetes mellitus on oncological long-term outcomes

The 5-year OS rate and the 5-year DFS rate were significantly lower in diabetics, especially in those with IDDM. This has been demonstrated in several meta-analyses which have highlighted the negative impact that diabetes has on overall mortality, cancer-specific mortality, DFS, and recurrence rates [10,11]. Postoperative blood glucose is an independent significant risk factor [1].

Research suggests that glucose can affect biochemical mark-

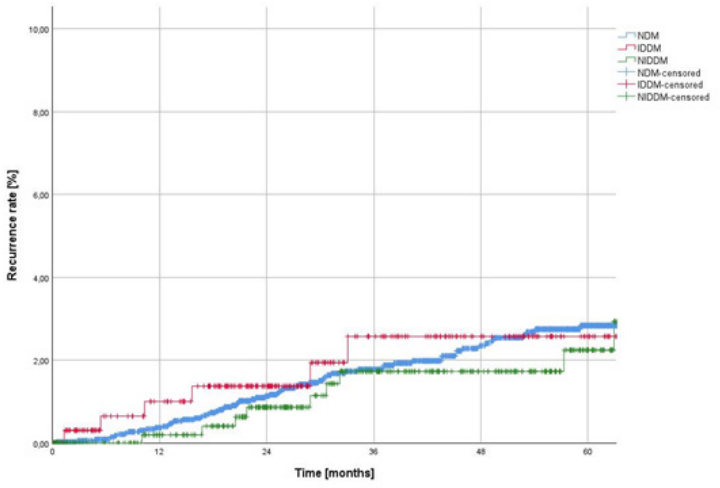

Figure 3. Kaplan-Meier Curve for the 5-Year-Local Recurrency Rate Comparing NDM (blue), NIDDM (green) und IDDM (red)

ers (microRNA-16, VEGFR2) and pathways. It is theorized that elevated serum glucose can induce specific signaling cascades that contribute to tumor and recurrence development [1]. These processes offer interesting research pathways for future projects, and it remains to be seen which additional biochemical signaling cascades with pro-carcinogenic potential or roles in carcinogenesis will be identified.

Comparison with rectal cancer

In 2018, Gebauer et al. published data on the early postoperative and oncological long-term outcomes in rectal cancer with a similar study design. Their findings showed higher rates of both general (medical) and specific (surgical) postoperative complications in diabetic patients when compared to the results of this study. Specifically, IDDM had the highest rate of complications [14].

Comparison of the impact of BMI on colon cancer

Regarding overall morbidity, patients with a BMI > 30 kg/m² without diabetes, as well as the overall cohort with a BMI > 30 kg/m², had a significantly higher risk of morbidity. In patients with type-II diabetes, the BMI did not show a significant impact on overall morbidity in the logistic regression analysis conducted. In contrast, several studies have already demonstrated the impact of BMI on early postoperative and long-term oncological outcomes in patients with colon cancer. For example, the systematic review by Dolemann et al. showed that both obese and underweight patients had an increased risk of mortality, cancer-specific mortality, and local recurrence rates. They also demonstrated worse DFS [15].

Gebauer et al. found that in patients with rectal cancer, BMI had a significant impact on postoperative morbidity and 5-year OS rate. Specifically, underweight and obese patients showed significantly higher rates of postoperative morbidity. Cachectic patients had a lower 5-year OS rate, while overweight and obese patients had a higher 5-year OS rate compared to normal-weight patients ($p<0.001$). No differences were found regarding local recurrence rates (LRR) [16].

Conclusion

Diabetes has a significant negative impact on the outcome of oncosurgical treatment of primary colon cancer. The negative impact is a result of diabetes as a metabolic disorder as well as its association with comorbidities such as cardiovascular and renal disease. It is associated with increased postoperative morbidity and mortality and decreased oncological survival. Insulin dependent diabetics have poorer outcomes when compared to those with noninsulin dependent diabetes and those who do not have diabetes. Thus, diabetes not only increases the risk that is related to surgery and anesthesia but also negatively impacts both short-term (early postoperative) and long-term (oncological) surgical outcomes, as reflected by relevant outcome parameters.

This underscores the need for exemplary management of diabetes, especially in the setting of insulin dependency. This applies for all aspects of colon cancer treatment from the perioperative and postoperative, to the management of complications and the follow-up period. These considerations should be urgently addressed in certified cancer centers and facilities with designated expertise.

Abbreviations

AI: Anastomotic Insufficiency; ASA: American Society of Anesthesiologists “Grading of patients for surgical procedures”; CI: Confidence interval; CRC: Colorectal Cancer; DFS: Disease free survival; DM: Diabetes mellitus; IDDM : Insulin dependent Diabetes mellitus; LRR: Local Recurrence Rate; NDM: Non- Diabetes mellitus; NIDDM : Non-insulin dependent Diabetes mellitus; N.S.: not significant; OS : Overall Survival; RKI: Robert-Koch-Institiut, TNM: TNM-staging system, 6th edition 2002; UICC- Union Internationale Contre le Cancer; UTI: Urinary tract infection; WHS- Wound healing disorder; YR-year

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Conflicts of Interest

The authors declare no conflict of interest.

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