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Surgical treatment of rectal cancer patients aged 80 years and older—a German nationwide analysis comparing short- and long-term survival after laparoscopic and open tumor resection

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ABSTRACT

Background: Minimally invasive removal of rectal tumors has proven to be a safe alternative to the open approach. Despite increased use of laparoscopy, its eligibility for older adults requires further exploration. This study compares perioperative mortality and 5-year overall, disease-free, and relative survival after laparoscopic and open surgery in rectal cancer patients aged ≥80 years.

Materials and methods: Data derive from 30 German regional cancer registries and cover approximately one quarter of the entire German population. All primary nonmetastatic rectal adenocarcinoma cases with surgery between 2005 and 2014 were eligible for inclusion. To compare survival rates, Kaplan–Meier analysis, a relative survival model, and multivariable Cox regression were applied; a sensitivity analysis assessed bias by exclusion.

Results: 1532 patients were included, of whom 17.1% underwent laparoscopic procedures. 30 days after surgery, 2.7% of the laparoscopy patients had died compared to 7.0% in the open surgery group. The multivariable analysis confirmed that minimally invasive procedures are followed by a lower 30-day postoperative mortality risk (odds ratio, OR, 0.352; 95% confidence interval, CI, 0.161–0.771; $p = 0.009$). With a 5-year disease-free survival rate of 52.0 vs. 47.6% ($p = 0.557$), only an nonsignificant long-term advantage of the minimally invasive approach was observed.

Conclusion: Given the results of this study, older rectal cancer patients are likely to benefit from the laparoscopic approach in the short term, and there are also no disadvantages in terms of long-term survival. Therefore, laparoscopy should be considered a standard procedure for older adults as well.

Introduction

Colorectal cancer is one of the most common neoplastic diseases worldwide. According to a survey conducted by the World Health Organization (WHO), approximately half a million people worldwide were diagnosed with rectal cancer in 2012 [1]. More than 50% of these patients received diagnosis after their 70th birthday [2]. Therefore, the treatment of older adults is gaining importance.

With rectal carcinomas, surgeons usually aim for radical resection of the tumor. For many years, open surgery was the gold standard for rectal resections, and even today the laparoscopy rates in many regions are relatively low [3,4]. Many surgeons still prefer the conventional approach, despite the fact that the noninferiority of laparoscopy in terms of overall- and disease-free survival has been proven by important randomized controlled trials such as COLOR II [5]. Other prospective and retrospective studies even observed slightly superior outcomes after minimally invasive surgery [6–10]. Nevertheless, there is an ongoing discussion on the topic [11]. Particularly where older adults are concerned, there is no clear recommendation regarding the minimally invasive approach.

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Higher age often comes with multimorbidity, which makes perioperative mortality a crucial issue in this special patient group. However, long-term survival after tumor resection is also gaining importance. Thanks to modern medicine, life expectancy has increased over the past decades. Today, a German citizen aged ≥80 years can expect to continue living for another 7.91 years on average [12]. Long-term survival data for elderly rectal cancer patients are scarce and large randomized trials on this topic are difficult to realize.

Based on a large pooled database of German cancer registries, this study describes short- and long-term survival of older adult patients, with special emphasis on the surgical approach. In Germany, rectal cancer treatment is highly influenced by evidence-based guidelines and elaborate quality management processes [13–15], which aim to ensure a patient's adequate treatment regardless of social or economic status. This situation guarantees ideal conditions to objectively examine oncologic outcomes after tumor resection in daily clinical practice.

Materials and methods

Data for the current publication derive from 30 regional cancer registries in south and east Germany, covering approximately 28% of the German population. In each registry, trained documentation officers systematically collect medical records of all tumor patients registered in their area. Before they may do so, all patients must formally consent to the use of their data. Information on vital status is regularly updated by official authorities or using death certificates issued by the Public Health Service. The anonymized unified dataset of all 30 registries was prepared by data analysts of the German Cancer Registry Association (*Arbeitsgemeinschaft Deutscher Tumorzentren*, ADT) [16] in strict accordance with the organization's high data protection standards.

In Germany, rectal cancer is defined as a malignant tumor located within 16 cm of the anocutaneous line. For the purpose of this analysis, all patients aged ≥80 years who were diagnosed with rectal cancer (ICD-10-GM: C20 [17]) between 1 January 2005 and 31 December 2014 were eligible for inclusion. Only patients with primary nonmetastatic adenocarcinoma and elective radical sphincter-preserving surgical treatment of their tumor were considered. Details on each patient include age, sex, Union for International Cancer Control (UICC) stage, grading, surgical procedure on intention-to-treat basis, and whether perioperative chemoradiotherapy was applied.

Perioperative mortality was defined as death within 30 days after surgery. To compare mortality rates, uni- and multivariable logistic regression models were used. All variables which were likely to have an influence on the outcome were regarded as potential confounders. For each of these, a χ-square distribution test was performed. All confounders which were more likely to be distributed unequally than equally in the open and laparoscopic surgery groups ($p < 0.5$) were included in the final model (sex, location, grading, and perioperative treatment).

The median follow-up time was 5.9 years (using Korn's Kaplan–Mayer potential follow-up method [18]) with an interquartile range (IQR) of 3.5–8.0 years, thus facilitating reliable long-term survival analyses. In order to compare overall and disease-free survival rates in patients with laparoscopic vs. open resections, a 5-year observation period after surgery was used. Moreover, a 30-day cutoff time was applied to eliminate the effect of perioperative mortality, which is analyzed separately. Patients with a survival or observation time of less than 31 days were excluded from all analyses on long-term survival. Accordingly, t = 31 days after surgery was set as the starting point for the observation time. In addition to Kaplan–Meier analysis, a multivariable Cox regression model was formulated [19]. Again, this was adjusted for all potential confounders that were unequally distributed in the open and laparoscopic surgery groups. Since the observed surgical procedures were performed during a considerable time span of 10 years, separate analyses for the operation years 2005–2008, 2009–2011, and 2012–2014 were performed to account for medical progress. To estimate cancer-specific survival rates, a relative survival model was computed [20]. The necessary data on general mortality of an age-, birth year-, and sex-matched cohort in the German population were provided by the Human Mortality Database of the Max Planck Institutes [21].

To account for bias due to missing data, a sensitivity analysis based on univariable logistic regression and Kaplan–Meier analysis with inclusion of initially excluded patients was performed. All significance tests were two sided with a significance level of 0.05; results are displayed as *p*-values or 95% confidence intervals (CI). The findings of this survey are presented in strict compliance with the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) statement [22]. During this study, IBM SPSS 25 (IBM Corp., SPSS for Windows, Armonk, NY, USA) as well as R version 3.3.2 (R Foundation for Statistical Computing, Vienna, Austria; http://www.R-project.org/) and the R package “relsurv” (Maja Pohar-Perme) were used.

Results

Between 1 January 2005 and 31 December 2014, 4240 patients aged ≥80 years received radical sphincter-preserving surgery due to rectal carcinoma (ICD-10-GM: C20). Of these patients, 29.2% had already developed distant metastases, suffered from syn- or metachronous colorectal malignancies, had tumors of an uncommon histological subtype, or underwent an emergency procedure. A further 18.9% lacked information on UICC TNM stage, grading, or tumor location, and in 15.7% of cases, the surgical approach was unknown. These patients were eliminated from further analyses (Fig. 1).

Of the 1532 included patients, 17.1% received a laparoscopic procedure, with an increasing rate over time (2005: 11.6%; 2014: 24.4%). There were no significant differences between the laparoscopic and open groups in terms of patients' baseline characteristics (Table 1) such as sex or tumor location. Mean and median age was almost identical in the two groups, with 83.8 years (median: 83.0 years) among laparoscopy and 83.9 years (median: 83.2 years) among open surgery patients. According to the χ-square test, UICC stages were distributed virtually identically within the two collectives ($p = 0.98$). Median follow-up time was 5.9 years (IQR: 3.5–8.0 years) in both groups.

Regarding postoperative mortality, 30 days after surgery, 2.7% of the laparoscopy patients had died compared to 7.0% in the open surgery group. Univariable logistic regression analysis showed that this difference is significant (odds ratio, OR, 0.364; CI 0.167–0.796; $p = 0.011$, Fig. 2a). After adjusting for sex, location, grading, and perioperative treatment, this difference remained significant (OR 0.352, CI 0.161–0.771; $p = 0.009$; Fig. 2b).

The following analyses of long-term survival were restricted to patients with a survival or observation time of 31 days or more, in order to nullify the effect of perioperative mortality. Follow-up started exactly 31 days after surgery.

Five years after tumor resection, 56.1% of the laparoscopic and 50.2% of open surgery patients were still alive; there was no statistically significant difference between the groups ($p = 0.471$; Fig. 3a). Multivariable Cox regression was performed adjusting for sex, location, grading, and perioperative treatment, yielding a hazard ratio (HR) of 0.941 (CI 0.758–1.167; $p = 0.578$; Fig. 3b) for laparoscopy patients. While between 2005 and 2008 laparoscopy

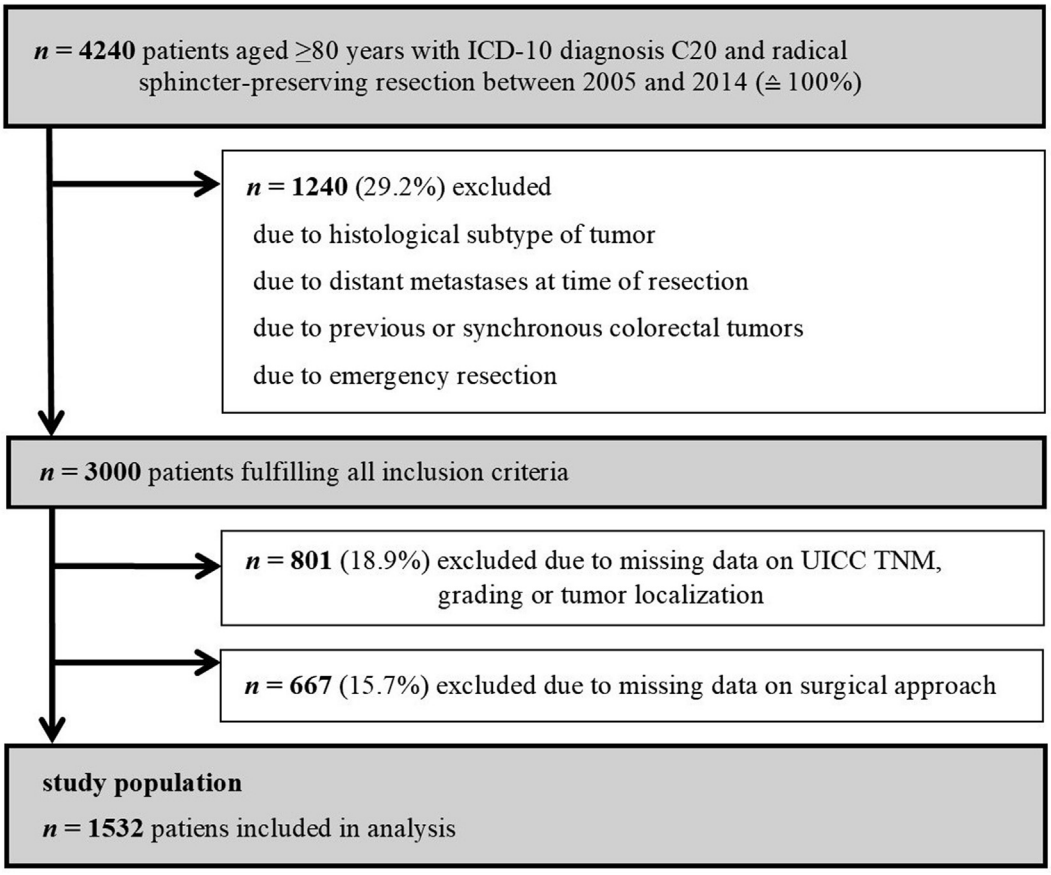


Fig. 1. Flowchart of study patient selection.

Table 1
Baseline characteristics of the study population according to surgical access. lower rectum ≙ 0–5.9 cm, mid-rectum≙ 6–11.9 cm, upper rectum ≙ 12–6 cm from anal verge.

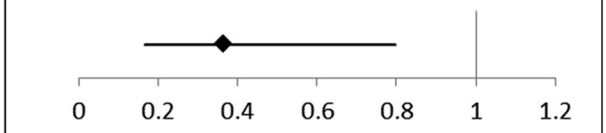
		Open ($n = 1270$)		Laparoscopic ($n = 262$)		χ^2
Age	mean	83.9 years		83.8 years		
	median	83.2 years		83.0 years		
		n	**%**	***n***	**%**	***p*-value**
Sex	Male	589	46.4%	129	49.2%	0.40
	Female	681	53.6%	133	50.8%	
Location	Lower rectum	242	19.1%	39	14.9%	0.20
	Mid-rectum	534	42.0%	109	41.6%	
	Upper rectum	494	38.9%	114	43.5%	
UICC stage	I	372	29.3%	78	29.8%	0.98
	II	426	33.5%	88	33.6%	
	III	472	37.2%	96	36.6%	
Grading	G1/2	1060	83.5%	225	85.9%	0.33
	G3/4	210	16.5%	37	14.1%	
Perioperative chemoradiotherapy	Yes	222	17.5%	40	15.3%	0.39
	No	1048	82.5%	222	84.7%	

was nonsignificantly inferior (HR 1.17, CI 0.783–1.755; $p = 0.440$), the situation changed in later years: between 2012 and 2014, the HR was 0.73 (CI 0.493–1.078, $p = 0.114$) in favor of the minimally invasive approach.

Taking into account the baseline mortality of the German population, the 5-year relative survival rate of laparoscopic surgery patients was 91.9%, compared to 81.9% in the open resection group. However, the difference between the two relative survival curves did not reach the significance level ($p = 0.371$).

The 5-year disease-free survival rates were 52.0% after laparoscopic vs. 47.6% after open surgery ($p = 0.557$; Fig. 4a). Again, a multivariable Cox regression analysis with adjustment for sex, location, grading, and perioperative treatment was performed. The corresponding HR for laparoscopic patients was 0.958 (CI 0.781–1.177; $p = 0.684$; Fig. 4b). Similar to the situation with overall survival, the operation year-stratified analysis showed no significant advantage or disadvantage for one of the surgical approaches during any of the observed time periods, although the superiority

a	OR	CI	*p*-value
Open	1.000		
Laparoscopic	0.364	0.167–0.796	0.011



b	HR	CI	*p*-value
Open	1.000		
Laparoscopic	0.352	0.161–0.771	0.009

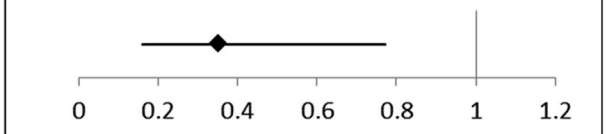
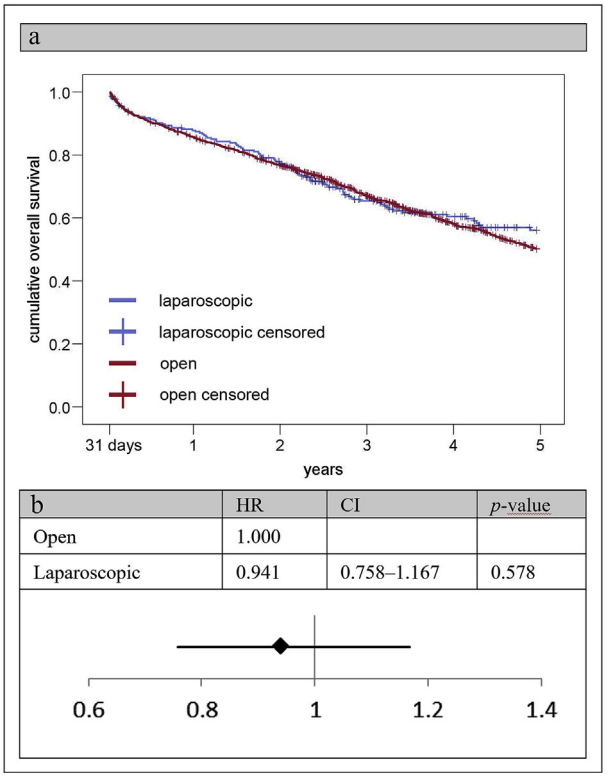
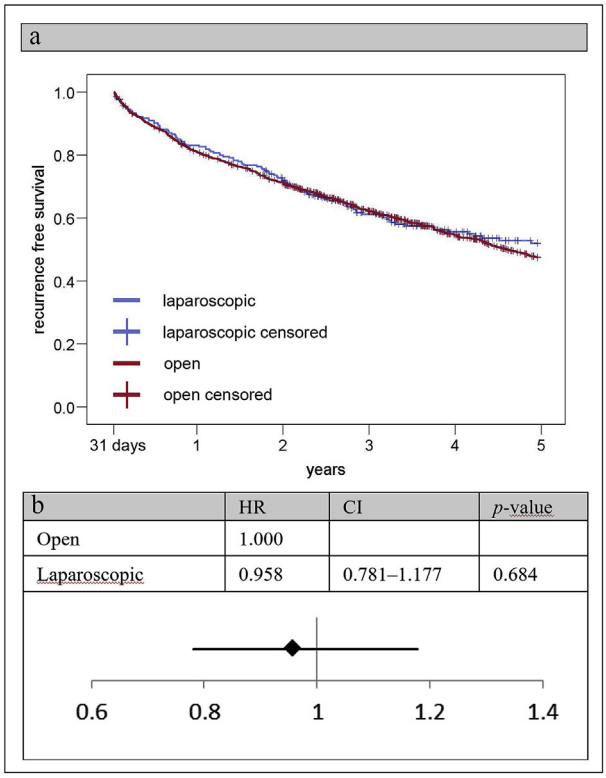


Fig. 2. Postoperative mortality (30 days).
OR: odds ratio, CI: two-sided 95% confidence interval. a Univariable logistic regression analysis comparing 30-day postoperative mortality rates open vs. laparoscopic surgery; reference: open approach. b Multivariable logistic regression analysis comparing 30-day postoperative mortality rates open vs. laparoscopic surgery, adjustment for sex, location, grading, and perioperative treatment; reference: open approach.



b	HR	CI	*p*-value
Open	1.000		
Laparoscopic	0.941	0.758–1.167	0.578

Fig. 3. Overall survival after perioperative period (31 days–5 years).
HR: hazard ratio, CI: two-sided 95% confidence interval. a Kaplan–Meier analysis: 5-year cumulative overall survival rate open vs. laparoscopic surgery: 50.2 vs. 56.1%; $p = 0.471$. b Multivariable Cox regression analysis, adjustment for sex, location, grading, and perioperative treatment; reference: open approach.



b	HR	CI	*p*-value
Open	1.000		
Laparoscopic	0.958	0.781–1.177	0.684

Fig. 4. Disease-free survival (31 days–5 years).
HR: hazard ratio, CI: two-sided 95% confidence interval. a Kaplan–Meier analysis: 5-year cumulative disease-free survival rate open vs. laparoscopic surgery: 47.6 vs. 52.0%; $p = 0.557$. b Multivariable Cox regression analysis, adjustment for sex, location, grading, and perioperative treatment; reference: open approach.

of the minimally invasive approach missed the significance level only narrowly between 2012 and 2014 (HR 0.75, CI 0.522–1.081; $p = 0.124$).

Finally, a sensitivity analysis was conducted to quantify bias due to exclusion of patients with missing data. Concerning 30-day postoperative mortality, included patients had a slight yet significant advantage over excluded patients (OR 0.967, CI 0.935–1.000). Looking at 5-year overall survival rates, included patients did not have a significantly superior survival rate compared to patients excluded due to missing data (49.6 vs. 46.3%; $p = 0.105$).

Discussion

In past decades, tumor treatment for aged persons primarily sought to reduce the immediate impact on the frail patient's health. This will, of course, always remain an important aspect of individualized therapy for older adults, but with life expectancy increasing, long-term effects will doubtlessly gain more importance in the future [23]. Only a few publications on this special patient group address topics such as perioperative complications, blood loss, length of hospital stay, and postoperative mortality [24]. Even fewer deal with outcomes such as long-term and disease-free survival [25]. The present survey aimed to consider both aspects at the same time, thus painting a truly holistic picture. In the observed study population, older adults whose rectal carcinoma was removed laparoscopically had a significantly lower risk of perioperative mortality. Concerning long-term outcomes, no significant difference between the surgical approaches was observed. Before these key results are discussed in greater detail, the strengths but also the limitations of this study are emphasized below.

Data from 30 German national cancer registries representing more than a quarter of the entire German population were implemented in the current investigation. Although only patients aged ≥80 years were included, the study features a considerable sample size, allowing calculation of stable results for this special subgroup. This study is the first of its kind in a German-speaking country and even worldwide—very few publications on the topic with a comparable caseload exist, emphasizing the need for more research. Cancer registry research is the only possibility to obtain a reliable picture of daily clinical practice. While clinical trials normally take place in specialized hospitals, population-based studies include patients regardless of where they were treated. Although randomization can obviously not be part of such a study concept, the baseline specifications of laparoscopic and open surgery patients turned out to be very similar in this study. Moreover, if statistical tests could not entirely rule out the possibility of a potential confounder being distributed unequally, it was included in multivariable analysis. By adjusting for variables such as sex, grading, or perioperative therapy, it was possible to cover a lot of inhomogeneities. Unfortunately, no information was available on nononcologic comorbidities, as there is currently no consensus between the participating cancer registries on the issue; therefore, systematic documenting of the American Society of Anesthesiologists (ASA) or a different comorbidity score is not performed. This aspect could certainly be improved in the future.

Missing data is another important point. As stated above, the primary aim of this survey was to generate a holistic picture of national rectal cancer care, at least as far as surgically treated older adults are concerned. Therefore, information from as many regional cancer registries as possible was included. Nevertheless, some of these institutions are better established than others, leading to a somewhat inhomogeneous data quality level. Consequently, only variables with a high data completeness were considered for analysis, rendering it impossible to report on interesting process variables like operative time, intraoperative blood loss, or surgeon's experience. Some patients also suffered from information gaps concerning the core variables used in the present study and had to be excluded to meet mandatory statistical standards. However, sensitivity analysis could show that the necessary exclusion process only introduced a small amount of bias into the analysis of short-term survival, while results on long-term survival were not significantly influenced at all. Thus, all presented findings can be regarded as stable.

Concerning short-term survival, laparoscopic surgery patients showed a significantly lower postoperative mortality rate. This favorable outcome for the minimally invasive approach used for older adults might be explained by fewer perioperative complications after laparoscopy [26]. This explanation is supported by an analysis of the comprehensive American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database by Al-Refaie et al. [27]. These authors included 4162 patients aged ≥80 years and observed major postoperative complication rates of 23.5% after open and only 15.0% after laparoscopic resections (major complications were defined as, e.g., wound disruption, surgical site infection, or need for reoperation). Previous surveys on perioperative mortality of older adult patients have also indicated advantages for laparoscopy [28–30]. However, most previous studies suffer from small caseloads, prohibiting significant results. Most of the existing larger surveys do not separate colon from rectal carcinoma cases. For example, in 2018, Chern et al. published a large single-center study conducted in Taiwan including 1133 patients with a colorectal tumor in 2018 [31]. These authors observed a 30-day mortality rate of 1.8% in the open and 0.6% in the laparoscopic surgery group. The fact that these mortality rates are lower than those of the present study can be explained by the fact that Chern et al. included patients aged 75 years or older, while the cutoff used in this study was 80 years. This explanation is again supported by the findings of Al-Refaie et al. [27], who found an increased risk of morbidity and perioperative mortality in patients aged ≥80 years compared to younger patients. According to the latter study, 5.9% of older adults died within 30 days after surgery, compared to 0.7% of patients aged 55 years or younger.

In 2010, Jayne et al. published the 5-year follow-up data of the CLASICC trial [32]. In an exploratory analysis, these authors addressed the issue of long-term survival in older adult patients and found no significant difference in 5-year survival rates after open and laparoscopic surgery, with minor advantages for the open approach (open: 51.0 vs. laparoscopic: 47.0%; $p = 0.679$). The latter survey is almost 10 years old, while the minimally invasive surgery technique has improved considerably during the past decade. Two recent smaller studies, one prospective and one retrospective, also dealt with the issue [33,34]. One of the more notable investigations was published in 2014 by Hinoi et al. [35], who analyzed 282 rectal cancer patients aged ≥80 years by multivariable Cox regression analysis, as in the current study. These authors observed a nonsignificant advantage for laparoscopy in terms of overall (HR 0.895, CI 0.432–1.857; $p = 0.765$) and disease-free survival (HR 0.800, CI 0.406–1.574; $p = 0.516$); however, it must be noted that patients were recruited from 41 different hospitals over the course of 5 years, which does not allow for representative results. Nevertheless, these results support the findings of the present study based on more than 1500 patients. The observed advantages in overall and disease-free survival for older adults undergoing laparoscopy were not significant, but the operation year-stratified analysis revealed an interesting fact: while in earlier years laparoscopy for older adults tended to be slightly inferior, the situation changed later on—between 2012 and 2014, laparoscopy was somewhat superior both in terms of overall and disease-free survival. Notably, these findings missed the significance level only narrowly. This time-dependent gradient might have been caused by an underlying learning curve. Only surgeons performing a sufficient number of minimally invasive procedures can perform adequate laparoscopy. With laparoscopy rates still growing, future development towards even better results might be expected.

Conclusion

In the German observation cohort, laparoscopy is associated with significant perioperative survival advantages for patients aged ≥80 years. Concerning long-term overall, relative, and disease-free survival, the outcome after minimally invasive surgery seems to be noninferior to that of the open approach. Therefore, this study indicates no reason to withhold the laparoscopic technique from the special subgroup of older adult patients. At the same time, the authors recommend future (registry-based) research on the topic, with special emphasis on nononcologic comorbidities.

Research involving human and animal participants

This article does not contain any studies with human participants or animals performed by any of the authors.

Ethical approval

For the analysis of data from a clinical cancer registry, no ethics approval was necessary. This was confirmed by the Ethics Committee at the Regensburg University, Regensburg, Germany (approval no. 15-170-0000).

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Conflict of interest

The authors declare that they have no competing interests.

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