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Feasibility and Safety of Robotic-Assisted Surgery for Rectal Cancer: Short-Term Outcomes of a Pilot Study with da Vinci Xi Platform During COVID-19

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Rezumat

Fezabilitatea și siguranța utilizării chirurgiei asistate robotic pentru cancerul rectal: rezultatele pe termen scurt ale unui studiu pilot cu platforma da Vinci Xi în timpul pandemiei Covid-19

Context: Cancerul colorectal este o cauză majoră de morbiditate şi mortalitate la nivel global. Aproximativ unul din trei cancere colorectale diagnosticate este un cancer rectal. Progresele recente în domeniul chirurgiei rectale au promovat utilizarea roboților chirurgicali. Exploatarea lor devine de mare importanță atunci când chirurgii se confruntă cu dificultăți anatomice, precum un pelvis masculin îngust, o tumoră voluminoasă sau pacienți obezi. Acest studiu îşi propune să evalueze rezultatele clinice ale chirurgiei robotice în cancerul rectal în perioada de introducere a unui sistem robotic chirurgical.
Metode: Din decembrie 2019, Departamentul de Chirurgie al Spitalului Universitar din Varna a devenit cel mai nou şi cel mai modern Centru de Competență în Chirurgia Robotică din Bulgaria, dotat cu cel mai avansat sistem chirurgical da Vinci Xi. Din ianuarie 2020 până în octombrie 2020, un număr total de 43 de pacienți au fost supuşi unui tratament chirurgical, dintre care 21 au avut proceduri asistate de robot şi restul au fost proceduri deschise.
Rezultate: Caracteristicile pacienților au fost similare între grupurile studiate. Vârsta medie a pacientului în chirurgia robotică a fost de 65 de ani, şase dintre aceşti pacienți fiind femei. În cazul intervenției chirurgicale deschise vârsta medie a fost de 70 de ani, 6 pacienți fiind femei. 66,7% dintre pacienții operați cu da Vinci Xi au avut tumori în stadiul 3 sau 4, iar aproximativ 10% au avut neoplasm

de rect inferior. Valoarea medie a timpului operator a fost de 210 min, în timp ce durata spitalizării a fost de 7 zile. Nu au fost observate diferențe semnificative ale acestor parametrii față de grupul de chirurgie deschisă. O diferență semnificativă este reprezentată de numărul de ganglioni limfatici excizați şi cantitatea de sânge pierdut, ambii parametri demonstrând avantaje pentru chirurgia asistată robotic. Cantitatea de sânge pierdut este de peste două ori mai mică în intervențiile robotice decât în cazul intervenției chirurgicale deschise.
Concluzii: Rezultatele au demonstrat introducerea cu succes a platformei asistate robotic în secția de chirurgie, în ciuda limitărilor create de pandemia COVID-19. Se aşteaptă ca această tehnică să devină principala alegere de abord minim invaziv aplicată tuturor intervențiilor chirurgicale pentru cancerul colorectal în Centrul de Competență în Chirurgie Robotică.

Cuvinte cheie: da Vinci Xi, chirurgie deschisă, rezultate clinice pe termen scurt, cancere rectale

Abstract

Background: Colorectal cancer is a major cause of morbidity and mortality in the world. Approximately, one of three diagnosed colorectal cancers is a rectal cancer. Recent developments in the field of rectal surgery have promoted the use of surgical robots, which are of great need when surgeons face anatomical difficulties, such as a narrowed male pelvis, bulky tumor, or obese patients. This study aims to evaluate the clinical results of robotic rectal cancer surgery during the introduction period of a surgical robot system. Moreover, the period of the introduction of this technique coincided with the first year of the COVID-19 pandemic.
Methods: Since December 2019, the Surgery Department of the University Hospital of Varna has become the newest and the most modern Robotic Surgery Center of Competence in Bulgaria, equipped with the most advanced da Vinci Xi surgical system. From January 2020 to October 2020 a total number of 43 patients have underwent surgical treatment, of which 21 had robotic-assisted procedures and the rest - open procedures.
Results: Patient characteristics were close between the studied groups. The mean patient age in robotic surgery was 65 years, as six of these patients were females, while in case of open surgery these values were to 70 and 6, respectively. Two thirds (66.7%) of the patients operated on with da Vinci Xi were with tumor stage 3 or 4 and approximately 10% had the tumor located in the lower part of the rectum. The median value of the operation time was 210 min, while the length of hospital stay was 7 days. These short-term parameters were not found to have a large difference in respect to the open surgery group. A significant difference is depicted for the number of lymph nodes resected and the blood loss, with both parameters demonstrating advantage for the robot-assisted surgery. The blood loss is more than twice less than the case of open surgery.
Conclusions: The results confidently showed the successful introduction of the robot-assisted platform in the surgery department despite the limitations caused by the COVID-19 pandemic. This technique is expected to become the main choice of minimally invasive technique applied to all types of colorectal cancer surgery in the Robotic Surgery Center of Competence.

Key words: da Vinci Xi, open surgery, short-term clinical outcomes, rectal cancers

Introduction

Colorectal cancer is a major cause of morbidity and mortality in the world. It is the fourth most incident and the third most deadly cancer in the world as well as Europe (1,2). Approximately, one of three diagnosed colorectal cancers is a rectal cancer (3). To date, the standard procedure for effective treatment is the total mesorectal excision, which may be performed by open surgery, recognised as the gold standard for rectal cancer surgery, and posteriorly by minimally invasive techniques. Laparoscopic surgery, one of the minimally invasive techniques, has been acknowledged as a safe and effective modality of rectal cancer surgery (4). A randomized controlled study, however, showed that the use of laparoscopic surgery in T3/T4 tumors may result in incomplete resection, affecting the oncological outcome in this group of patients (5). Often, an incomplete total mesorectal excision during laparoscopic surgery is encountered when surgery faces anatomical difficulties, such as a narrowed male pelvis, bulky tumor, or obese patients. Robotic rectal surgery might be used to successfully overcome these difficulties and evolves a preferred minimally invasive approach in some centers when surgical operations in the abdomen are concerned (6). The comparison of the results from these two minimally invasive techniques showed that the robotic-assisted surgery overcomes the limitations of laparoscopic surgery for cancers located in the deep pelvis (7). While for most of the parameters the two techniques have shown in general comparable outcomes, the operative time with robot-assisted surgery was found longer and the blood loss – more (8-10), a fact that is not supported by other research studies (11,12). Further, studies, concerning the cost analysis of these techniques showed that the costs of robotic-assisted surgery is higher compared to laparoscopic surgery due to operative costs and instruments (13). For instance, a study in South Korea showed that these costs are 2.34 times higher than the total charges in laparoscopic surgery in both cases without complications and cases with complications (7,14, 15).

The results from the introduction of robotic surgery in these studies however were obtained in non-pandemic times, assuring proper and uninterrupted training for the surgeons and a large number of patients operated with the robotic system. Unfortunately, the global epidemic of COVID-19 has created great challenges in both surgery activities. A study by Blanc et al. (16) showed more than 60% decrease in the volume of robot-assisted surgical procedures for the general surgery during COVID-19. This decrease influences the establishment of new robotic centers, as the one created in our country. Since December 2019, da Vinci surgical system Xi, installed at the Surgery Department of the University Hospital of Varna, has become the heart of the Robotic Surgery Center of Competence in Bulgaria. Three months later, on 13 of March 2020, the first complete lockdown was introduced and ended in May 2020, while the second lockdown was introduced on 27 of November for about three weeks, as the peak in November was the strongest one. For these two lockdowns, all planned surgical procedures in the Surgery Department were canceled and only the emergency cases were treated. This was a strong obstacle, which puts the development and the establishment of the innovative Center of Excellence in Robotic Surgery to face great challenges. The aim of this study is to present the short-term outcomes of robot-assisted surgery for rectal cancer during the COVID-19 pandemic in Bulgaria.

Material and Methods

Study Design

This was a single-center, non-randomized parallel group study comparing robot-assisted surgery and open surgery for patients with rectal cancer in the settings of national COVID-19 pandemic at First Clinic of Surgery St. Marina University Hospital, Varna, Bulgaria. The study was approved by the

Ethics Committee of the Medical University - Varna (Protocol# 82/28.03.2019). Informed consent was obtained from all participants included in the study.

Patients

The study included patients who underwent robot-assisted and open rectal cancer surgery between January 2020 and October 2020. In 2019-2020, due to the nation-wide declared state of COVID-19 pandemic, the scheduled admission and diagnosis of patients was interrupted. This reduced patient intake, putting the development of a start-up robotic surgery center ahead of major challenges. These are associated with both overcoming the learning curve and the risk of nosocomial infection with COVID-19. Performing surgery in centers that combine treatment of COVID-19 patients and specialized surgery poses a number of challenges to the team, theoretically increasing the risk of nosocomial infection to patients and operating personnel.

Data were prospectively collected in a specifically designed database. All patients were subjected to diagnostic protocol, which included colonoscopy, biopsy, magnetic-resonance imaging, endorectal ultrasound and positron emission tomography - computer tomography (PET-CT) with 2-deoxy-2-[fluorine-18] fluoro-D-glucose (18F-FDG). Tumor regression grade was estimated according to the Ryan score. In respect to the tumor location, the latter was classified as following: tumors in the (a) upper rectum, if their distal border is located more than 10 cm from the anal verge, (b) middle rectum, where the distal border of the tumor varies in the range 5 to 10 cm from the anal verge, and (c) lower rectum, where the distal border of the tumor is less than 5 cm from the anal verge (17). Patients with middle and low rectal cancer staged cT2-4N(any)M0 underwent neoadjuvant radiochemotherapy. We performed low tie technique and total mesorectal excision. The lower margin is set to minimally 1.5 cm below the tumor. The quality of the specimen is evaluated by the pathologist. The inclusion and exclusion criteria for the patients subjected to surgery in this study are as follows:

Inclusion criteria

- Signed informed consent;
- Age 18-85;
- Resectable rectal cancer stage T1-4N(any)M(0-1a).

Exclusion criteria

- Non-resectable rectal cancer;
- Recurrent cancer;
- Emergency surgery.

Informed consent was signed by each patient after it was ensured he/she meets the inclusion criteria. Patients for robotic and open surgery included in this study had the same inclusion and exclusion criteria. The selection for either approach was based on the surgeon's preference, as the surgeries were performed by different teams in the clinic.

Patient Admission

Each patient undergoes systematic screening for COVID-19 before admission in the form of questionnaire focused on clinical symptoms and epidemiological information (*Table 1*). In case of more than three positive answers on the questionnaire, any contact with confirmed SARS-COV-19 patient and a return travel from a high-risk zone in the previous two weeks were considered as indication for PCR testing. In case the test was negative, the patient proceeded to admission.

Surgery

The patient is placed in 25° Trendelenburg lithotomy position. In cases of anterior rectal resection, we used three robotic ports and one assistant port. The camera port is placed 2 cm above the umbilicus. The robotic ports were positioned with a distance of 8 cm between each other in linear fashion after target anatomy is defined. A low tie vessel ligation was performed with total mesorectal excision. Taking down the splenic flexure was not necessary as only mobilization of the descending

Table 1. Patient's systematic screening for COVID-19 before surgery.

Fever ☐ Runny nose ☐	Muscle pain ☐	Sore throat ☐
Redness and burning in the eyes ☐	Dry cough ☐	Difficulty breathing ☐
Prolonged chest pain ☐	Skin blushing ☐	Nausea, vomiting, upper abdominal pain and / or diarrhea ☐
Prolonged dizziness ☐	Loss of taste and smell ☐	Progressive fatigue, exhaustion ☐
Have you resided in another country in the last 28 days? ☐	Have you had contact with people who tested positive for COVID-19 in the last 28 days? ☐	Have you had contact with a person quarantined for COVID-19 in the last 14 days? ☐

colon provided enough length. The anastomosis was performed with circular 29 mm stapler in termino-terminal fashion. As a standard procedure diverting ileostomy was created in cases of resection of middle and low rectal cancer and closed one month postoperatively after follow-up endoscopy. In cases of abdomino-perineal resection we used again three robotic ports and one assistant port. The colostomy was placed on the left lateral robotic port. The new pelvic floor was covered by the surrounding peritoneal flaps. The perineal wound was closed primarily with drainages.

The criteria for hospital discharge are set by the clinical pathway imposed by the Bulgarian National Health Insurance Fund and are as follows: lack of fever in the last 48 hours before discharge, primary healing operative wounds or such that allow outpatient care; complete postoperative mobilization; normal bowel function; hemoglobin level above 100 g/l; prothrombin time between 11 and 13.5 sec; C-reactive protein < 80 mg/l.

Surgeons' Training

The surgery operations were performed by four surgeons with experience between 8 and 15 in colorectal and laparoscopic surgery procedures. While the surgeons had a significant experience with both open and laparoscopic operations, they did not have a previous experience with a robotic surgery system. The training started in November 2019 and was divided into two steps. The on-site technology training included hands-on tissue lab, development of technical skills, introduction to procedure skills and system skills, port placement and patient selection. Progress to the next step was allowed after assessment Skills simulator™ focused on camera targeting, depth perception, non-tactile visual feedback, coagulation, and suturing. The second step included certification at Intuitive training center. All members of the team passed their certification and in December 2019 the first cases were scheduled. In February 2020, two months after the launch of the robotic center, the most experienced patient-side assistant was chosen to undergo a console surgeon training. This proved to be troublesome during the developing pandemics. The on-site training was completed easily following the same structure. The certification of completion for system skills training using the daVinci Surgical system was delayed on several instances due to temporary closure of certification centers and flight delays. Supervision by an experienced trainer was available for the first three rectal cancer patients. Due to the COVID-19 travel restrictions no further supervision was possible. Besides the experience in colorectal surgery with da Vinci Surgical system, the surgeons received significant practical experience in cholecystectomy, hiatal, and inguinal hernias during the pandemics.

Intraoperative and Postoperative Clinical Outcomes

The following clinical outcomes were selected for monitoring and further analysis: operation time, blood loss, conversion to open surgery, number of lymph nodes resected, tumor size, selected immediate postoperative outcomes and length of stay in hospital, distal and cir-

cumferential margin. Patients were followed-up for one month after surgery. Follow-up concerning the oncological results was performed (for a period of 5 years), but it is not an objective of this study. The results were compared in respect to the clinical outcomes of the open surgery procedures as well as outcomes selected from the literature. All analyses were performed on MatlabR2020a, by using the Statistics and Machine Learning Toolbox. The approach of Morgan (18) in analysing small sample size data was followed. Visual results for selected parameters are given along with the numerical results. P-values were computed using t-test (for normal distributions) and Wilcoxon test for the rest.

Results

Patient characteristics

In the studied period, the total number of patients who underwent rectal robotic surgery with da Vinci robotic system was 21, while the patients who underwent rectal open surgery were 22. Patient characteristics (except age at surgery and sex) as well as tumor characteristics are summarized in *Table 2*. In addition, patient's age, body mass index (BMI) and tumor location distributions are summarized in *Fig. 1*. Distal and circumferential margins were evaluated by a pathologist.

The mean age of patients in the robotic surgery group was 65 years, while in the open surgery group was 70 years. In robotic surgery

Table 2. Characteristics of the patients enrolled in the study.

Parameter	Robotic	Open surgery	P-value
Age at surgery (years)*	65.10 (8.48)	70.45 (6.68)	0.05
Sex			
Male [No.(%)]	15 [71.43%]	16 [72.73%]	
Female [No.(%)]	6 [28.57%]	6 [27.27%]	
Weight, kg*	76.95 (9.67)	82.18 (8.07)	0.06
BMI kg/m^2**	25.5 [22.6-35.2]	27.1 [22-33.1]	0.05
Histology	21 G2	1 G1 18 G2 3 G3	
Tumor location			
Lower	2	4	
Middle	8	1	
Upper	11	17	
Preoperative radiochemotherapy	19	18	
Distance from anal verge, cm**	12 [2.5 - 15]	17 [1 – 20]	0.003
Previous abdominal surgery		6	
lap chole	1		
Appendectomy	2		
Pre-operative stage			
I	2	0	
II	5	2	
III	14	16	
IV	0	4	
Tumor stage			
1	1	2	
2	6	1	
3	13	18	
4	1	1	
N-stage			
0	15	13	
1	4	3	
2	2	6	

*values are mean values (standard deviation); **values are the median [range of values].

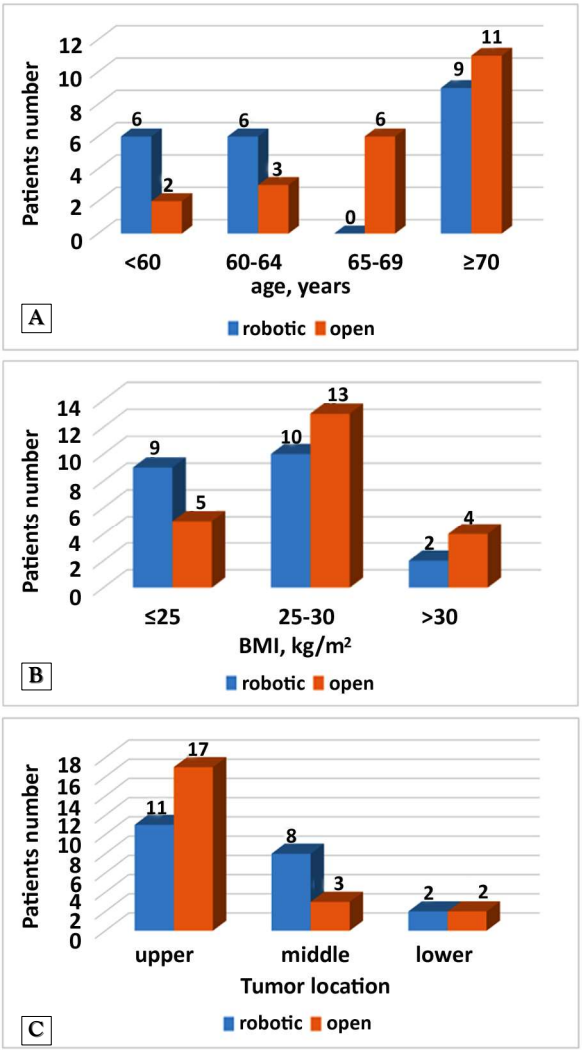

Figure 1. Summary of main patient's characteristics for the two robotic and open rectal surgery groups: **(A)** patient age, **(B)** BMI and **(C)** tumor location.

group, 90.5 % of the patients had BMI below 30 kg/m², while the other 9.5 % had BMI above 30 kg/m². The average BMI was 25.5 kg/m² for this group. In the open surgery group, the average BMI was 27.1 kg/m², while 81.8 % of the patients had BMI below 30 kg/m², and the rest 18.2 % had BMI above 30 kg/m².

More than half of the patients who were operated on with da Vinci Xi (66.7 %) had a tumor stage 3 or 4, while in 9.5 % of them the adenocarcinoma was located in the lower part of the rectum, in 38.1% in the middle part, and in 52.4% in the upper part. A similar percentage result is reported for the open surgery patient group, with more than half of the patients (specifically 86.4%) having tumor stage 3 or 4.

Intraoperative and Postoperative Clinical Outcomes

Intraoperative and postoperative clinical outcomes are summarized in *Table 3*. Three short-term characteristics: operation time, blood loss, duration of hospital stay, and immediate postoperative outcomes are shown for both robotic and open surgery groups in *Fig. 2*.

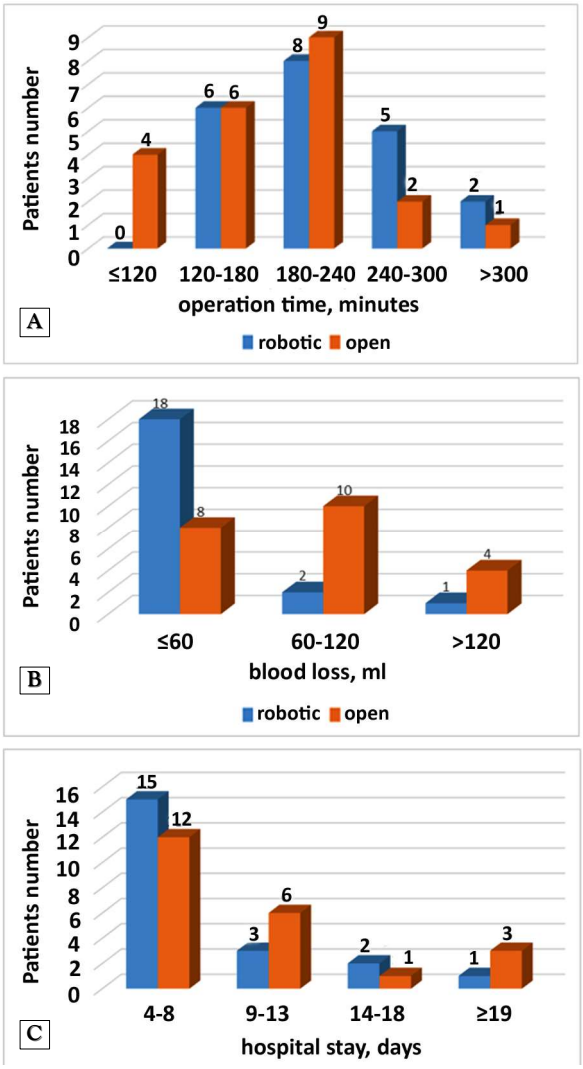

Figure 2. Selected short-term clinical outputs of the study: **(A)** operation time, **(B)** blood loss, and **(C)** hospital stay.

Table 3. Short-term clinical outcomes.

Parameter	Robotic	Open surgery	P-value
Operation time, minutes*	210 [160-420]	198 [100-420]	0.17
Blood loss, ml*	40 [20-200]	100 [20-150]	0.001
Conversion to open surgery, %	1	-	
Number of lymph nodes resected*	11 [4-14]	9 [4-18]	0.007
Resection margin			
R0	0	0	
R1	1	0	
R2	0	0	
Distal resection margin (cm)	1.8 [1.4-3]	2.1[1.8-3.1]	0.11
Anastomotic leakage	1	1	
Ileus	0	0	
Clavien Dindo			
Grade I			
Grade II	1	3	
Grade III			
Grade IIIa	1		
Grade IIIb	1	1	
Grade IV		1	
Grade V	1	1	
Deaths within 30 days	1	1	
Tumor size, mm*	38 [5-85]	36.5 [15-65]	0.88
Tumor regression grade scale	2 - 2 Ryan scale	1	
Length of stay in hospital, days*	7 [4 - 22]	8 [4-30]	0.01
Immediate postoperative outcomes			
First flatus, days	1.2 (0.1)	1.8 (0.4)	<0.05
First stool, days	1.3 (0.2)	2.1 (0.3)	<0.05
Analgesia, days	2.2 (0.3)	3.1 (0.4)	<0.05
Mobilisation, days	1.1 (0.2)	2.3 (0.3)	<0.05

*values are the median [range of values]

The median of the operation time was 210 min, and the median of the tumor size was 38 mm for the robotic surgery group, while for the open surgery group these values were 198 and 36.5 mm. On average, eleven and nine lymph nodes were resected per robotic and open surgery operation, respectively, while the average duration of hospitalisation was 7 and 8 days for robotic and open surgery operations, respectively.

Complication in the robotic group included anastomotic leakage after low anterior rectal resection. The case was managed conservatively with local drainage and secondary healing. In this case, the ileostomy was reversed after one month after he underwent adjuvant chemotherapy. Other complications included wound infection (n=1), early adhesive bowel obstruction after abdomino-perineal resection (n=1) and COVID-19 pneumonia with fatal ending (n=1). In the open surgery group, complications included perineal wound infection (n=3), one of which required wound debridement under general anesthesia, anastomotic leakage, managed conservatively (n=1), multiorgan failure and death due to concomitant chronic renal disease (n=1).

Discussion

The approach followed in the evaluation of the first short-term clinical outcomes was to compare results for patient characteristics and short-term clinical outcomes, listed in *Table 2* and *Table 3* and also to find reference data from the literature. While the BMI of a patient was not a criterion for including this patient into the study, it is of note that almost half of the patients in our study, who underwent rectal robotic surgery, had a BMI

greater than 25 kg/m^2 with a median BMI value of 25.5 kg/m^2. The corresponding values for the open surgery were slightly higher, i.e. 27.1 kg/m^2. The result of this comparison well matches the results reported in the very recent meta-analysis study of Guo et al. 2021 (19), showing the slightly higher BMI for patients undergoing open rectal surgery operations.

Further analysis shows that the mean patient's age was 65 years for patients who had robotic surgery, while the mean patient's age for the open surgery group was slightly higher: 70 years. This difference, however, is not related to the higher cost of the robot procedure as suggested by Kim et al. (8) who also reported similar observation. The data available in literature show that the average patient age for the robotic surgery group in this study compares well to the mean age of patients who were involved in laparoscopic rectal cancer surgery (9,20,21). This result validates the distribution of the parameter patient age for patients who underwent robotic surgery, since during the studied period all patients suitable for laparoscopic surgery of rectal cancer were scheduled for robot-assisted surgery.

Fifteen (71%) men and six (29%) female patients against sixteen (73%) men and six (27%) female patients had robot and open surgery of rectal cancer, respectively. Both groups, i.e., robotic and open surgery, have similar ratios, showing that much more men are operated on for rectal cancer than females. This pronounced inequality was also shown by other studies (19), which report even higher rates: 77.6% and 77.3% for robotic and open surgery, respectively and could be due to the unhealthy diet profile of the men, which includes high consumption of red meet and alcohol (22, 23). The observed ratio of operated men and women for the robotic group in this study well coincides with data from the literature for robotic surgery (21). For instance, Choi et al. (24) reported a ratio of 64% men and 36% women who underwent robotic rectal surgery. Further, the median value of the hospitalization between the two groups, i.e., the robotic and the open surgery, agrees very well and was 7 and 8 days, respectively. The median value 7 fits well in the range of length of hospital stay for robotic rectal surgery – from 4.50 to 14.2 days (21). The 22-day postoperative stay after robotic surgery was due to the exacerbations of several accompanying chronic diseases which required the prolongation of hospital treatment.

The analysis of tumor stage data shows that patients operated on with the robot system were predominantly with a tumor stage 3, which is similar to the data for the open surgery group. In addition, we compared the results for tumor stage data for robotic group to data from literature, showing similar values (10,25). This is also well explained with the COVID-19 situation, which limited many people to freely perform their regular check-ups and this resulted in delay in diagnosis which reflects the majority of tumor stage 3 in this study. However, large meta-analysis studies showed that robotic surgery is applied for all tumor stages. There is no study reported in the literature showing the surgeon preferences in the selection of patients for robotic surgery in respect to the tumor stage. Further, there was no difference in the median values reflecting the size of the tumor removed during the robotic and open surgery, which were 38 mm and 36.5 mm (p-value 0.884), respectively. This result well compares to the results from the study of Chen et al. who reported that in 81.7% of the cases, tumor size was less than or equal to 50 mm that can be compared to 76.2% of our cases, while the review paper of Lee et al. summarized the results of several studies, showing that the mean tumor size ranges from 28 to 40 mm.

The number of lymph nodes resected in patients differed between the two groups (p-value 0.0069), and this number corresponded to 11 and 9, respectively. Both numbers are lower than those shown in rectal cancer studies (9,19,21), with resected lymph nodes ranging between 10 and 22 for the robotic groups and 16 to 23 for the open surgery groups. The lower number of resected lymph

nodes is due to the fact that most of the patients for both robotic and open surgery underwent preoperative radiochemotherapy (26).

There was no significant difference between the robotic and open surgery groups in respect to the operative time, while this is not the case for the parameter blood loss during operations, where the median value for blood loss for open surgery was 100 ml vs 40 ml for the robotic group. Robotic surgery has led to significant less blood loss compared to open surgery. These results compare well to the results in Huang et al. (10) who reported an average operation time of 274 min. and 41.9 ml blood loss, respectively for the case of rectal robotic surgery. Further, the immediate postoperative outcomes in case of robotic surgery demonstrate to be better in comparison to open surgery. Time to first flatus and stool, as well as analgesia and mobilisation were significantly reduced, which is also supported by data found in a few publications (27).

Conversion from robot-assisted to open surgery was done to only one patient during robotic surgery due to intraoperative hemorrhage, which is 4.8% and can be compared to 4.8% reported by Debakey et al. (28), 5.7% reported by Feroci et a.l (20), and 8.1% reported by Corrigan et al. (29), while Huang et al. showed no conversion at all.

The median value of the distance from the anal verge for the robotic group was 12 cm, which shows to be significantly different from the corresponding value of 17 cm in case of open surgery group. This difference will be further investigated; however, the first suggestion is that this is due to the patient cases for this period. The data for robotic surgery was also compared to data in literature to investigate the distribution of the tumor location in patients who had robotic surgery of rectal cancer. The distribution of the tumor location in respect to the anal verge is 52.4% upper rectum, 38.1 % middle rectum, and 9.5% lower rectum and these results well compare to the results reported in the study of Debakey et al. Furthermore, the distal resection margins between the two groups were not statistically different, similarly to other published results from studies between two groups (19, 30).

The effects of the COVID-19 on the patient's group were observed in one case. Unfortunately, one patient died during the study period. The cause of death was COVID-19 pneumonia. A 75-year-old male patient with metastatic cT3N1M1(hep) rectal cancer had been infected 2 weeks preoperatively. On admission, his polymerase chain-reaction (PCR) test for COVID-19 was negative and the patient was scheduled for surgery. On the 3rd postoperative day fever up to 38.1° was registered with consequent positive PCR-test and computer-tomography confirmation of pneumonia. He was transferred to a specialized unit where treatment continued for another 2 days until the fatal ending.

Although the limited patient sample size, the compared patient characteristics and short-term clinical outputs for patients who had robot-assisted surgery of rectal cancer, showed the successful introduction of the new technology in the clinical work of our surgery department. Moreover, this happened during drastic decrease in surgical activity for general and colorectal surgeons due to pandemic situation. The COVID-19 pandemic created great challenges to regular worked and planned surgery at our Department. For the period of March-May 2020, the planned operations were postponed or cancelled. In addition, the training of one of the console surgeon assistants was postponed for a period of 6 months due to the limitations in the work of the training centers. Despite these obstacles, the robot-assisted surgery for rectal cancers was successfully implemented in the workflow of the department. Initial results are promising, well coinciding with the results of other studies, which is an indicator for the successful establishment of the Robotic Surgery Center of Competence in Bulgaria. The advantages provided by da Vinci for rectal surgery are considerable in terms of flexibility and safety for both for patients and surgeons. Among the advantages of the robotic surgery, according to the surgeons' feedback is enhanced and safety access to the lower

rectum as well as the possibility to perform operations, while in a sitting position. The lower number of medical staff in the room for the robot-assisted operation is also a great advantage resulting in a reduced risk for the medical staff of the surgery department. The availability of a 3D surgical view is an excellent tool for surgeons during operations, which greatly facilitates the pelvic autonomic nerves preservation.

Based on the reported data, we are planning to expand the applications of da Vinci Xi platform in the field of colorectal operations. In parallel, the COVID-19 pandemic stimulated the development of modern curricula for training and educating medical students in Medical University - Varna with the assistance of da Vinci Xi simulator. A recent example is the elective course named "Introduction to robotic surgery", available to the medical students of our university.

Conclusions

This paper reports the initial experience using the Vinci Xi surgical system for operations of rectal cancer. Twenty-one patients underwent rectal surgery during the period January 2020 – October 2020. The summarized patient characteristics as well as short-term clinical outputs were compared to those of patients who underwent open surgery of rectal cancer for the same period, showing advantage of the robot-assisted surgery considerably less blood loss, while the other parameters were close. In addition, results for robot-assisted surgery are consistent with those from the patients who had rectal open surgery as well as with the reported data from other similar studies. Current results are encouraging for both surgeons and patients with rectal cancer, and with a potential to overcome the limitations of the laparoscopic surgery applied for advanced lower rectum cancers. An extensive study is currently undergoing aiming at cost analysis of robotic surgery for rectal cancer as well as evaluation of long-term clinical outcomes by comparing to open surgery.

Disclosure Statement

The authors report no conflict of interest.

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References

1. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6): 394-424.
2. Ferlay J, Colombet M, Soerjomataram I, Dyba T, Randi G, Bettio M, et al. Cancer incidence and mortality patterns in Europe: Estimates for 40 countries and 25 major cancers in 2018. Eur J Cancer. 2018;103:356-87.
3. Cote A, Graur F, Lebovici A, Mois E, Al Hajjar N, Mare C, et al. The accuracy of endorectal ultrasonography in rectal cancer staging. Clujul Med. 2015;88(3):348-56.
4. Ding Z, Wang Z, Huang S, Zhong S, Lin J. Comparison of laparoscopic vs. open surgery for rectal cancer. Mol Clin Oncol. 2017;6(2):170-6.
5. Bonjer HJ, Deijen CL, Abis GA, Cuesta MA, van der Pas MH, de Lange-de Klerk ES, et al. A randomized trial of laparoscopic versus open surgery for rectal cancer. N Engl J Med. 2015;372(14):1324-32.
6. Ngu JC, Kim SH. Robotic surgery in colorectal cancer: the way forward or a passing fad. J Gastrointest Oncol. 2019;10(6):1222-8.
7. Kim MJ, Park SC, Park JW, Chang HJ, Kim DY, Nam BH, et al. Robot-assisted Versus Laparoscopic Surgery for Rectal Cancer: A Phase II Open Label Prospective Randomized Controlled Trial. Ann Surg. 2018;267(2): 243-51.
8. Kim JC, Lee JL, Kim CW. Comparative analysis of robot-assisted vs. open abdominoperineal resection in terms of operative and initial oncological outcomes. Annals of surgical treatment and research. 2018;95(1):37-44.
9. Han C, Yan P, Jing W, Li M, Du B, Si M, et al. Clinical, pathological, and oncologic outcomes of robotic-assisted versus laparoscopic proctectomy for rectal cancer: A meta-analysis of randomized controlled studies. Asian J Surg. 2020;43(9):880-90.
10. Huang YM, Huang YJ, Wei PL. Outcomes of robotic versus laparoscopic surgery for mid and low rectal cancer after neoadjuvant chemoradiation therapy and the effect of learning curve. Medicine (Baltimore). 2017;96(40): e8171.
11. Park SY, Choi GS, Park JS, Kim HJ, Ryuk JP. Short-term clinical outcome of robot-assisted intersphincteric resection for low rectal cancer: a retrospective comparison with conventional laparoscopy. Surg Endosc. 2013; 27(1):48-55.
12. Crolla R, Mulder PG, van der Schelling GP. Does robotic rectal cancer surgery improve the results of experienced laparoscopic surgeons? An observational single institution study comparing 168 robotic assisted with 184 laparoscopic rectal resections. Surg Endosc. 2018;32(11):4562-70.
13. Quijano Y, Nunez-Alfonsel J, Ielpo B, Ferri V, Caruso R, Duran H, et al. Robotic versus laparoscopic surgery for rectal cancer: a comparative cost-effectiveness study. Tech Coloproctol. 2020;24(3):247-54.
14. Park EJ, Cho MS, Baek SJ, Hur H, Min BS, Baik SH, et al. Long-term oncologic outcomes of robotic low anterior resection for rectal cancer: a comparative study with laparoscopic surgery. Ann Surg. 2015;261(1):

129-37.
15. Baek SJ, Kim SH, Cho JS, Shin JW, Kim J. Robotic versus conventional laparoscopic surgery for rectal cancer: a cost analysis from a single institute in Korea. World J Surg. 2012;36(11):2722-9.
16. Blanc T, Pinar U, Anract J, Assouad J, Audenet F, Borghese B, et al. Impact of the COVID-19 pandemic on oncological and functional robotic-assisted surgical procedures. J Robot Surg. 2021;15(6):937-944.
17. Hoeffel C, Mule S, Laurent V, Bouche O, Volet J, Soyer P. Primary rectal cancer local staging. Diagn Interv Imaging. 2014;95(5):485-94.
18. Morgan CJ. Use of proper statistical techniques for research studies with small samples. Am J Physiol-Lung C. 2017;313(5):L873-L7.
19. Guo Y, Luo Y, Song X, Zhao H, Li L. Comparison of pathologic outcomes of robotic and open resections for rectal cancer: A systematic review and meta-analysis. PLoS ONE. 2021;16(1):e0245154.
20. Feroci F, Vannucchi A, Bianchi PP, Cantafio S, Garzi A, Formisano G, et al. Total mesorectal excision for mid and low rectal cancer: Laparoscopic vs robotic surgery. World J Gastroenterol. 2016;22(13):3602-10.
21. Staderini F, Foppa C, Minuzzo A, Badii B, Qirici E, Trallori G, et al. Robotic rectal surgery: State of the art. World J Gastrointest Oncol. 2016;8(11): 757-71.
22. Aykan NF. Red Meat and Colorectal Cancer. Oncol Rev. 2015;9(1):288.
23. Alves ISS, Coser PHP, Loureiro GJZ, Nogueira da Gama LP, Ribeiro FSS, Bautz WG, et al. Fibrosis and Mast Cells in Colorectal Lesions: Significance in Adenoma-Colorectal Cancer Sequence and Association with Diet. J Gastrointest Cancer. 2016 Sep;47(3):278-86.
24. Choi DJ, Kim SH, Lee PJ, Kim J, Woo SU. Single-stage totally robotic dissection for rectal cancer surgery: technique and short-term outcome in 50 consecutive patients. Dis Colon Rectum. 2009;52(11):1824-30.
25. Chen YT, Huang CW, Ma CJ, Tsai HL, Yeh YS, Su WC, et al. An observational study of patho-oncological outcomes of various surgical methods in total mesorectal excision for rectal cancer: a single center analysis. BMC Surg. 2020;20(1):23.
26. Yin TC, Su WC, Chen PJ, Chang TK, Chen YC, Li CC, et al. Oncological Outcomes of Robotic-Assisted Surgery With High Dissection and Selective Ligation Technique for Sigmoid Colon and Rectal Cancer. Front Oncol. 2020;10:570376.
27. Liao GX, Li YB, Zhao ZH, Li XM, Deng HJ, Li G. Robotic-assisted surgery versus open surgery in the treatment of rectal cancer: the current evidence. Sci Rep. 2016;6:26981.
28. Debakey Y, Zaghloul A, Farag A, Mahmoud A, Elattar I. Robotic-Assisted versus Conventional Laparoscopic Approach for Rectal Cancer Surgery, First Egyptian Academic Center Experience, RCT. Minim Invasive Surg. 2018;2018:5836562.
29. Corrigan N, Marshall H, Croft J, Copeland J, Jayne D, Brown J. Exploring and adjusting for potential learning effects in ROLARR: a randomised controlled trial comparing robotic-assisted vs. standard laparoscopic surgery for rectal cancer resection. Trials. 2018;19(1):339.
30. Ghezzi TL, Luca F, Valvo M, Corleta OC, Zuccaro M, Cenciarelli S, et al. Robotic versus open total mesorectal excision for rectal cancer: comparative study of short and long-term outcomes. Eur J Surg Oncol. 2014;40(9): 1072-9.