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Early results from the implementation phase of a robot-assisted laparoscopic surgery programme in rectal cancer

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Abstract

Background: *In recent years, the practice of robot-assisted laparoscopic surgery in rectal carcinoma as a development of classic laparoscopic surgery has witnessed increasingly rapid growth. Oncological outcomes appear comparable to those of classic laparoscopic procedures and it is hoped that robot-assisted laparoscopic surgery will allow improvement of functional outcomes related to faecal incontinence, disorders of bladder function and erectile dysfunction.*

As robot-assisted laparoscopic surgery programmes are being implemented in many places, the question arises if during the learning curve the demands of an oncological resection can be met and if satisfactory functional resultscan be achieved in this early phase of such a programme.

Methods: *Between March 2014 and May 2015, 17 rectal carcinomas were resectedin our clinic by means of robot-assisted laparoscopic surgery. Results regarding oncological surrogate parameters, faecal incontinence (Wexner score, LARS), bladder dysfunction (urinary function) (IPSS) and erectile dysfunction (IIEF-5) were analysed retrospectively.*

Results: *Both oncological and functional results in the early phase of ourprogramme were comparable to the results we know form classic laparoscopic or open surgery. Conclusions: A robot-assisted laparoscopic surgery programme for surgery of the rectum can achieve good oncological and functional results in anearly phase of its implementation.*

Keywords: *rectal surgery, robotics, laparoscopic surgery, functional results after rectal surgery*

Background

Conventional laparoscopic surgery (CLS) for colorectal carcinoma has been shown to be equivalent to open surgery in several randomised studies (COLOR2, CLASICC, COREAN) [1-3].

Robot-assisted laparoscopic surgery (RALS) as a further development of CLS in carcinomas of the rectum has become increasingly widespread in the last few years.

The technical advantages of RALS compared to CLS are based on a three-dimensional visualisation, tenfold magnification with a stable camera and a high degree of instrument flexibility, especially within a frequently small pelvis. On the other hand, the technique entails substantially higher costs.

First meta-analyses involving small case numbers only, have shown short-term CLS and RALSresults that are comparable with respect to oncological surrogate markers as well as perioperative parameters. There are indications that conversion rates with RALS may be lower than with CLS [4,5].An improved data base is expected with the first randomised study (ROLARR) [6].

Due to the higher resolution and more precise preparation technique it is assumed that with RALS it will be easier to spare nervous tissue. This should result in improved functional results after resection of the rectum compared to CLS or open surgery [7,8]. The outcome data available for erectile dysfunction and bladder function post CLS vs. open surgery of the rectum are uneven. The assumption that improved visualisation of the lesser pelvis leads to better outcomes was therefore not able to be confirmed [9,10] so far.

In the context of rapid dissemination with an increasing number of new RALS programmes for rectal carcinoma surgery many groups have to go through a new learning curve in robotic surgery. The question arises if patients face a higher risk concerning oncological or functional results in this early phase of a robotic programme.

We thereforecarried out closely meshedretrospective follow-up examinations in our clinic on the first 17 patients after RALS for rectal carcinoma,measuringoncological surrogate parameters such as quality of TME, number of lymph nodes and completeness of resection (R0). Functional outcomes were recorded using standardised questionnaires. To assess bladder function and erectile dysfunction, we used the International Prostate Symptom Score (IPSS) and the International Index of Erectile Function (IIEF-5) Score [11]. The evaluation of the degree of faecal continence after RALS resection of the rectum was measured pre- and postoperatively by Wexner score as well as postoperatively by the Low Anterior Resection Syndrome Score (LARSS) [12,13]. Data recorded over the patient's clinical progression were analysed retrospectively.

Methods

After approval of our study by the Ethics Committee of the Landesärztekammer Rheinland-Pfalz, retrospective data collection was carried out. This was based on patients' records as well as on

their survey scores retrieved in the context of follow-up care.

Due to the small sample size, the evaluation of data is purely descriptive.

In the period from March 2014 to May 2015, 17 patientsreceived operations to treat carcinoma of the rectum using the da Vinci Sisystem (Intuitive Surgical, Sunnyvale, California, USA). The operations were performed by the same surgeon and the same surgical team. All of the members of the team have longstanding experience of CLS and of open resection techniques but had so far no previous robotic experience. Robot-assisted resection was carried out on allpatients who would otherwise have been scheduled for a CLS resection.

Descriptive data as well as oncological surrogate parameters were analysed based on operative reports and histologic findings.

Change in faecal continence: To interpret changes in faecal continence we used the pre- and postoperative Wexner Score as well as postoperative LARSS.

Wexner Score values can range between 0 and 20, where 0 indicates consistently perfect continence and 20 indicates complete incontinence.

The LARS Score consists of a scale of 5 parameters that most impact quality of life. These parameters are categorised in 3-4 subscales. Scores can range between 0 and 42, with a score of 0-20 indicating no LARS; scores from 21-29 indicating minor LARS and scores from 30-42 indicating major LARS.

Erectile Dysfunction: The degree of erectile dysfunction was analysed pre- and postoperatively by means of the International Index of Erectile Function (IIEF-5-Score). The possible scores on this scale range from 0 to 25. Scores from 0 to 7 are classified as severe erectile dysfunction (ED); from 8 to 11 there is moderate ED; scores of 12-16 reflect mild functional disturbance, 17-21 indicate initial signs of ED and scores >21 are consistent with normal function.

Bladder Function: The International Prostate Symptom Score (IPSS) for urinary function is based on a five-point scale. The questionnaire is divided into seven categories of symptoms. These include incomplete bladder emptying, frequency, intermittency, urgency, weak stream, straining and nocturia. Urinary dysfunction is defined as an IPS Score of >8.

Results

AOf the 17 patients who underwent RALS resection, 8 patients were treated with neo-adjuvant radiochemotherapy, 4 were still awaiting ileostomy reversal at the time of data collection. One patient with stage UICC IV tumour died of causes unrelated to surgery (Figure 1). There were therefore a total of 12 patients available for the follow-up study of functional outcomes. Of the 12 patients, three (1 male, 2 females) underwent an abdomino-perineal rectal resection (APR). Low anterior resection (LAR) was carried out in 9 patients (5 males, 4 females). The follow-up examination was performed 10,3 (±3,3) months after the resection and 6,13 (±3) months after the ileostomy reversal. Two cases required conversion to open resection. Oncological surrogate parameters as well as length of operation are listed in Table 1 (Table 1).

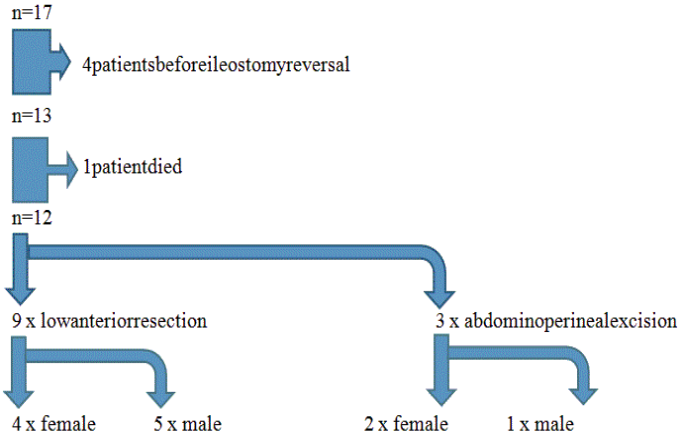

Figure 1. *Patients evaluated – flow-diagram*

Faecal Incontinence: We were able to evaluate faecal incontinence in 9 patients.

In 8 patients, postoperative Wexner Scores tended to be increased with no major worsening of faecal continence. One patient exhibited a clearly elevated score with marked worsening of symptoms.

Five out of the 9 patients displayed no postoperative signs of LARS, 3 patients showed minor LARS and 1 patientmajor LARS, while the patient with the highest LARSS also had the highest Wexner Score (Table 2).

Erectile Dysfunction: All six male patients were screened to evaluate erectile function after RALS. Since erectile function was frequently poor even before the operation in older patients, 4 patients had already suffered from severe ED previously. Of the two remaining patients, one had no preoperative dysfunction, the other only moderate symptoms. Erectile dysfunction was not worsened postoperatively in both patients.

Bladder Function: Of the 12 patients, 11were able to be evaluated. None of them experienced significant worsening of bladder function (Table 3). Good initial function remained stable postoperatively, with all scores <8, thus below the threshold for bladder dysfunction.

Discussion

The goal of our study was to determine if the beginning of our RALS programme was associated with a higher risk for our patients concerning early oncological and functional results during our early learning curve.

According to the literature the learning curve in robotic rectal surgery is calculated to be 29.7 for phase I the number of procedures needed to be classed as an expert in robotic surgery was calculated to be 39 [14].

Our patient population demonstrated that while there was a clear increase in duration of surgery initially, operative time decreased markedly over the course of the first 17 interventions.

Criteria for appropriate oncological resection as measured by surrogate parameters showed that even in the early phase of the programme results are comparable to those of CLS and open surgery, as has also been shown in larger series [4,5].

Patient	TNM stage, distance from the anal verge (cm)	Operation	LK	R0	MERCURY	Conversion	Operation time (min)	Anastomotic insufficiency, treatment	DaVinci-related complication
1	pT1,N0, 10	r.a.l.TAR	0/14	Yes	1	No	300	No	No
2	ypT3,N1, 10	r.a.l.TAR	2/18	Yes	1	No	390	Yes, conservative	No
3	ypT1,N0, 9	r.a.l.TAR	0/13	Yes	1	No	285	No	No
4	ypT3,N0, 13	K-r.a.l.TAR	0/15	Yes	1	Yes	600	No	No
5	ypT3,N0, 10	r.a.l.TAR	0/18	Yes	1	No	395	No	No
6	ypT0,N0, 8	r.a.l.TAR	0/24	Yes	1	No	380	No	No
7	pT3,N0, 12	r.a.l.TAR	0/32	Yes	1	No	247	No	No
8	pT2,N0, 10	r.a.l.TAR	1/19	Yes	1	No	272	Yes, conservative	No
9	pT1,N0, 15	r.a.l.TAR	0/15	Yes	1	No	205	No	No
10	pT1,N0, 15	K-r.a.l.TAR	1/16	Yes	1	Yes	330	No	No
I	ypT3,N0, 4	r.a.l.APR	0/12	Yes	1	No	264	-	No
II	ypT2,N0, 1	r.a.l.APR	0/19	Yes	1	No	360	-	No
III	pT3,N2, 1	r.a.l.APR	5/13	Yes	1	No	240	-	No

+:deceased; r.a.l.TAR: robot-assisted lap. low anterior rectal resection (K-: conversion-); r.a.l.APR: robot-assisted lap. abdomino-perineal rectal resection

Table 1: *Patient data*

Patient	Wexner Score		LARSS
	pre op	post op	
1	0	0	0
3	0	0	24
4	0	15	41
5	3	4	26
6	4	8	20
7	0	3	29
8	2	5	9
9	0	5	0
10	0	2	20
Wexner Score: 0=perfect continence; 20=complete incontinence LARS: 0-20=no LARS; 21-29=minor LARS; 30-42=major LARS			

Table 2. *Fecal incontinence after ileostomy reversal in RAL anterior rectal resection*

Patient	Wexner Score		LARSS
	pre op	post op	
1	0	0	0
3	0	0	24
4	0	15	41
5	3	4	26
6	4	8	20
7	0	3	29
8	2	5	9
9	0	5	0
10	0	2	20
IPSS: 0-7 mild symptoms; 8-19 moderate symptoms; 20-35severe impairment due to lower urinary tractsymptoms			

Table 3: *IPSS International Prostate Syndrome Score*

Two cases had to be converted. In one case an anterior rectal carcinoma after neo-adjuvant therapy adhered to the urinary bladder and was suspected to infiltrate it. In this case, conversion followed successful robot-assisted mobilisation of the left flexure and nearly fully robot-assisted TME. Subsequent open partial resection of the posterior wall of the urinary bladder in the region of the vesical trigone was carried out together with internal splinting of the ureter. The complexity of the intervention means that this was by far the longest operation. The length of procedure is therefore not exclusively attributable to robot-assisted resection. The postoperative progression was normal and the reversal of the ileostomy took place as scheduled. In the interim period the patient developed major LARS, which was, however, successfully treated with Interstim therapy. Currently the patient has achieved a LARS score of 24 with a good quality of life and therefore only has residual minor LARS.

The second patient was converted because of anatomic uncertainty during TME. The reason for conversion in the early phase of the programme would appear to be attributable to a lack of experience. Conversion would no longer be carried out in such a case.

The conversion rate in this small early series is comparable to that of laparoscopic surgery [1].

There was evidence of two anastomotic insufficiencies, both of which were treated conservatively and demonstrated good functional results after reversal of the ileostomy.

With regard to anorectal dysfunction, the literature reveals uneven outcomes in both open and laparoscopic rectal surgery, with development of LARS in up to 60-90% of patients. [13].

Two of our patients' developed minor and 1 patient developed major LARS. At least in this very small series there is no increased rate of anorectal dysfunction after surgery of the rectum compared to the literature.

In terms of functional outcomes regarding urinary function and erectile dysfunction, CLS has not, until now, been shown to have any advantage compared to conventional surgery [10]. There are early indications that RALS may be preferable to CLS for preservation of urinary and sexual function [7,15].

Regarding urinary function, none of the patients we studied exhibited significant worsening of postoperative symptoms compared to their preoperative status.

Erectile function was already restricted in several patients. We saw no further postoperative deterioration in those patients with good erectile function preoperatively.

Conclusions

In summary, we demonstrate that in our early phase of the implementation of a RALS programme for rectal cancer surgery we had no difference in the oncological as well as functional results compared to CLS or open surgery results described in the literature.

Compliance with ethical standards

Conflicts of interest

The corresponding author as well as Dr. Rolf Schneider and Dr. Valero-Fernandez received free system training by Intuitive surgical before the programme started. The first two operations were supervised by a proctor from Intuitive surgical.

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with wthical standards of the institutional/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Ethics approval was obtained by the Ethics Committee of the Landesärztekammer Rheinland-Pfalz.

“ For this type of study formal consent is not required.

Availability of Data and Materials

All data available in this retrospective study is included in the article.

Authors’ contributions:

Markus Hirschburger: Drafting of manuscript, Analysis and interpretation of data.

Ines Metzger: Acquistion of data, critical revision of the manuscript

Jose Valero-Fernandez: Acquisition of data, involved in drafting the manuscript

Rolf Schneider: Study conception and design, critical revision of manuscript

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