

Patient-reported genitourinary dysfunction after laparoscopic and open rectal cancer surgery in a randomized trial (COLOR II)

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Background: This article reports on patient-reported sexual dysfunction and micturition symptoms following a randomized trial of laparoscopic and open surgery for rectal cancer.

Methods: Patients in the COLOR II randomized trial, comparing laparoscopic and open surgery for rectal cancer, completed the European Organization for Research and Treatment of Cancer (EORTC) QLQ-CR38 questionnaire before surgery, and after 4 weeks, 6, 12 and 24 months. Adjusted mean differences on a 100-point scale were calculated using changes from baseline value at the various time points in the domains of sexual functioning, sexual enjoyment, male and female sexual problems, and micturition symptoms.

Results: Of 617 randomized patients, 385 completed this phase of the trial. Their mean age was 67.1 years. Surgery caused an anticipated reduction in genitourinary function after 4 weeks, with no significant differences between laparoscopic and open approaches. An improvement in sexual dysfunction was seen in the first year, but some male sexual problems persisted. Before operation 64.5 per cent of men in the laparoscopic group and 55.6 per cent in the open group reported some degree of erectile dysfunction. This increased to 81.1 and 80.5 per cent respectively 4 weeks after surgery, and 76.3 versus 75.5 per cent at 12 months, with no significant differences between groups. Micturition symptoms were less affected than sexual function and gradually improved to preoperative levels by 6 months. Adjusting for confounders, including radiotherapy, did not change these results.

Conclusion: Sexual dysfunction is common in patients with rectal cancer, and treatment (including surgery) increases the proportion of patients affected. A laparoscopic approach does not change this. Registration number: NCT0029779 (<http://www.clinicaltrials.gov>).

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Introduction

Studies of laparoscopy in colonic cancer have shown less postoperative pain, faster recovery and improved health-related quality of life (HRQL), with cancer survival rates comparable to those after open surgery^{1–4}. In regard to rectal cancer, several studies describing laparoscopic total mesorectal excision (TME) have been published, with surrogate markers indicating that it is a safe procedure. No definitive long-term survival data are yet available^{3,5,6}.

Traditional primary outcome measures for evaluating laparoscopic surgery for rectal cancer were survival and local recurrence. However, secondary measures such as quality of life, including sexual and urinary dysfunction, are also important^{7–9}. Nerve pathways as well as microvasculature are damaged by radiotherapy, and this can be compounded by surgery^{10–14}. Sexual dysfunction after open rectal surgery has been reported in between 10 and 35 per cent of patients, but urinary dysfunction is present in less than 5 per cent^{15,16}. Reports^{17–19} of sexual and urinary

dysfunction after laparoscopic TME are conflicting, indicating that more research is warranted.

The aim of this study was to compare patient-reported sexual dysfunction and micturition symptoms after rectal cancer surgery in a randomized clinical trial (COlorectal cancer Laparoscopic or Open Resection, COLOR II).

Methods

COLOR II, a non-inferiority, international, randomized clinical trial, included patients in 30 hospitals. Patients with a single rectal cancer within 15 cm from the anal verge were included, in a 2:1 ratio of laparoscopic to open. Patients with tumours invading adjacent tissues or organs, T4 tumours, or T3 rectal cancers within 2 mm of the endopelvic fascia at preoperative evaluation, were excluded. Further details about inclusion and exclusion criteria, randomization and clinical short-term outcomes have been reported previously^{3,20}. The protocol of the COLOR II trial was approved by the appropriate ethics committees and registered at ClinicalTrials.gov (NCT0029779).

Quality-of-life measurements

Twelve hospitals in five countries (Canada, Denmark, Germany, The Netherlands and Sweden) participated in the optional HRQL component of the COLOR II trial²¹. Inability to understand the questionnaires was an exclusion criterion. Patients who agreed to participate were asked to fill in the preoperative questionnaire before surgery. After operation the questionnaires were sent out at 4 weeks, and 6, 12 and 24 months.

Demographic data, details of preoperative radiotherapy and chemotherapy, complications during and after surgery,

and the pathology report on the resected specimen were used from the clinical record forms (CRFs). At the follow-up visits (12 and 24 months), the surgeon recorded the presence of sexual dysfunction and stress urinary incontinence in the CRF.

Validated Swedish, Dutch, Danish, English and German translations of the European Organization for the Treatment of Cancer (EORTC) questionnaire QLQ-CR38 were used. This questionnaire is designed for self-administration and measures specific information about quality of life in patients with colorectal cancer. Thirty-eight questions are divided into four functional scales/single items (body image, sexual functioning, sexual enjoyment, future perspective) and eight symptom scales/items (micturition symptoms, chemotherapy side-effects, symptoms in the area of the gastrointestinal tract, male sexual problems, female sexual problems, defaecation problems, stomach-related problems and weight loss).

For this study the domains/scales/items sexual functioning, sexual enjoyment, male sexual problems, female sexual problems and micturition symptoms were used. All questions relate to the previous 4 weeks and have four alternative responses: 'not at all', 'a little', 'quite a bit' and 'very much'. The sexual functioning item comprises two questions: 'To what extent were you sexually active (with or without intercourse)?' and 'To what extent were you interested in sex?'. The answers were dichotomized into 'not at all' *versus* the rest ('a little', 'quite a bit', 'very much') to gauge sexual activity and sexual interest. The single item of sexual enjoyment is answered only if the patient has been sexually active. The symptom scale for male sexual problems has two items: 'Did you have difficulty getting or maintaining an erection?' and 'Did you have problems with ejaculation (such as so-called dry ejaculation)?'. In

Table 1 Response frequencies for functioning domains and symptom scales in EORTC QLQ-CR38 at different time points

	Preop.	4 weeks	6 months	12 months	24 months
Sexual functioning (<i>n</i> = 385)	326 (84.7)	305 (79.2)	302 (78.4)	286 (74.3)	205 (53.2)
Laparoscopic	224	207	206	197	141
Open	102	98	96	89	64
Sexual enjoyment (<i>n</i> = 385)	147 (38.2)	58 (15.1)	109 (28.3)	125 (32.5)	62 (16.1)
Laparoscopic	97	37	72	87	41
Open	50	21	37	38	21
Male sexual problems (<i>n</i> = 239)	178 (74.5)	132 (55.2)	163 (68.2)	167 (69.9)	115 (48.1)
Laparoscopic	124	91	116	117	78
Open	54	41	47	50	37
Female sexual problems (<i>n</i> = 146)	38 (26.0)	13 (8.9)	29 (19.9)	33 (22.6)	12 (8.2)
Laparoscopic	23	10	19	19	7
Open	15	3	10	14	5
Micturitional symptoms (<i>n</i> = 385)	350 (90.9)	322 (83.6)	320 (83.1)	304 (79.0)	249 (64.7)
Laparoscopic	240	219	219	209	170
Open	110	103	101	95	79

Values in parentheses are percentages. EORTC, European Organization for Research and Treatment of Cancer.

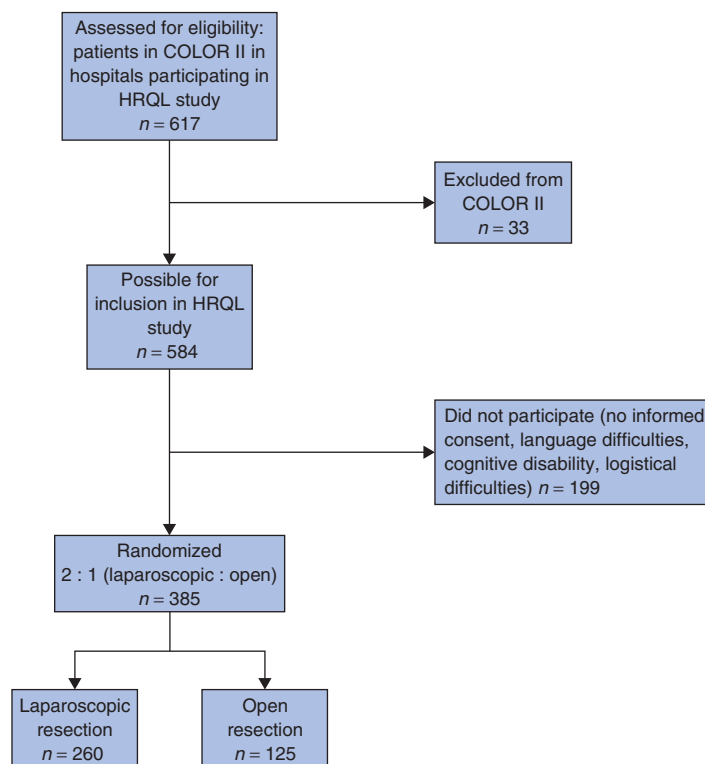


Fig. 1 Study flow chart. COLOR, COlorectal cancer Laparoscopic or Open Resection; HRQL, health-related quality of life

Table 2 Preoperative demographics for the health-related quality-of-life study group and those not included

	Not included in HRQL study (n = 199)	Included in HRQL study (n = 385)	P‡	Laparoscopic (n = 260)	Open (n = 125)	P‡
Age (years)*	67.0 (66.0, 69.4)	67.1 (66.1, 68.1)	0.696§	67.4 (66.1, 68.6)	66.6 (64.8, 68.4)	0.487§
Sex ratio (M:F)	123:76	239:146	0.949	162:98	77:48	0.893
BMI (kg/m ²)*	25.9 (25.3, 26.5)	26.0 (25.6, 26.5)	0.750§	26.0 (25.4, 26.6)	26.1 (25.3, 26.8)	0.898§
ASA grade			0.008			0.624
I	37 (18.6)	103 (26.8)		69 (26.5)	34 (27.2)	
II	101 (50.8)	224 (58.2)		149 (57.3)	75 (60.0)	
III	48 (24.1)	55 (14.3)		40 (15.4)	15 (12.0)	
IV	1 (0.5)	2 (0.5)		2 (0.8)	0 (0)	
Unknown	12 (6.0)	1 (0.3)		0 (0)	1 (0.8)	
Tumour stage†			0.262			0.552
I	8 (4.0)	22 (5.7)		18 (6.9)	4 (3.2)	
II	71 (35.7)	135 (35.1)		93 (35.8)	42 (33.6)	
III	101 (50.8)	207 (53.8)		135 (51.9)	72 (57.6)	
IV	7 (3.5)	12 (3.1)		9 (3.5)	3 (2.4)	
Unknown	12 (6.0)	9 (2.3)		5 (1.9)	4 (3.2)	

Values in parentheses are percentages unless indicated otherwise; *values are mean (95 per cent confidence interval). †Stage in the pathology report of the resected specimen. HRQL, health-related quality of life; BMI, body mass index; ASA, American Society of Anesthesiologists. ‡ χ^2 test, except §Student's *t* test.

the symptom scale for female sexual problems, answered only by women who have had sexual intercourse, the items are: 'Did you have a dry vagina during intercourse?' and 'Did you have pain during intercourse?'. The individual QLQ-CR38 scores were handled according to the EORTC

scoring manual and converted to a score ranging from 0 to 100. A high score on the symptom/item scales represents a high level of symptoms/problems, whereas a high score on the functioning scales represents a high level of functioning.

Table 3 Surgical variables for the health-related quality-of-life study group and those not included

	Not included in HRQL study (n = 199)	Included in HRQL study (n = 385)	P§	Laparoscopic (n = 260)	Open (n = 125)	P§
Type of resection			0.632			0.956
PME	15 (7.5)	42 (10.9)		27 (10.4)	15 (12.0)	
TME	112 (56.3)	219 (56.9)		147 (56.5)	72 (57.6)	
APE	64 (32.2)	116 (30.1)		80 (30.8)	36 (28.8)	
Other	3 (1.5)	6 (1.6)		4 (1.5)	2 (1.6)	
Unknown	5 (2.5)	2 (0.5)		2 (0.8)	0 (0)	
Preoperative radiation			0.001			0.409
Yes	139 (69.8)	216 (56.1)		150 (57.7)	66 (52.8)	
Short†	110 (55.3)	157 (40.8)		110 (42.3)	47 (37.6)	
Long‡	23 (11.6)	40 (10.4)		27 (10.4)	13 (10.4)	
Dose not specified	6 (3.0)	19 (4.9)		13 (0.5)	6 (4.8)	
No	60 (30.2)	168 (43.6)		110 (42.3)	58 (46.4)	
Unknown	0 (0)	1 (0.3)		0 (0)	1 (0.8)	
Preoperative chemotherapy			0.895			0.816
Yes	31 (15.6)	64 (16.6)		44 (16.9)	20 (16.0)	
No	145 (72.9)	290 (75.3)		195 (75.0)	95 (76.0)	
Unknown	23 (11.6)	31 (8.1)		21 (8.1)	10 (8.0)	
Stoma						
Permanent colostomy	71 (35.7)	139 (36.1)	0.980	96 (36.9)	43 (34.4)	0.490
Loop ileostomy	49 (24.6)	123 (31.9)	0.098	84 (32.3)	39 (31.2)	0.808
Reversed by 1 year	29 (59)	45 (36.6)	0.275	29 (35)	16 (41)	0.975
Perioperative nerve preservation			0.195			0.610
Total preservation	187 (94.0)	371 (96.4)		248 (95.4)	123 (98.4)	
Bilateral	0 (0)	2 (0.5)		2 (0.8)	0 (0)	
Unilateral	4 (2.0)	3 (0.8)		2 (0.8)	1 (0.8)	
Other	1 (0.5)	0 (0)		0 (0)	0 (0)	
Unknown	7 (3.5)	9 (2.3)		8 (3.1)	1 (0.8)	
Blood loss (ml)*	408 (384, 551)	463 (404, 522)	0.924¶	358 (292, 424)	676 (566, 786)	< 0.001¶
Anastomotic leakage	22 (11.1)	17 (4.4)	0.002	13 (5.0)	4 (3.2)	0.421
Skin-to-skin time (min)*	213 (203, 223)	253 (244, 262)	< 0.001¶	272 (261, 283)	213 (201, 226)	< 0.001¶
Conversion				65 (25.0)		

Values in parentheses are percentages unless indicated otherwise; *values are mean (95 per cent confidence interval). HRQL, health-related quality of life; PME, partial mesorectal excision; TME, total mesorectal excision; APR, abdominoperineal excision using TME dissection. †5 × 5 Gy or less; ‡all programmes more than 5 days. § χ^2 test, except ¶Student's *t* test.

Statistical analysis

The COLOR II study was powered for the primary endpoint of local recurrence at 3 years after index surgery. For this substudy a *post hoc* analysis was performed. The sample size achieved (Table 1) corresponds to a power of 80 per cent to detect a difference in change between the two surgical procedures of around 7 points, using Student's independent-samples *t* test (5 per cent significance level) and assuming a standard deviation of 20 points in both samples. Applying the same principle to male sexual problems enabled detection of a difference of 10 points (Table 1). The domain sexual enjoyment and the symptom scale female sexual function were not analysed because response rates were low.

In the EORTC questionnaires, several studies have examined the minimal important difference (MID), which represents the difference in scores corresponding to a clinically meaningful difference. Osoba²² suggested that the MID is in the range of 5–10 points on the 100-point scale and that a difference of more than 20 points suggests

a substantial change. Missing data were handled according to instructions in the EORTC score manual.

Results were calculated for the individual patient and expressed as a change from baseline before being presented as means on a group level. Comparisons of groups at baseline were made using Student's *t* test, χ^2 test and, where appropriate, Fisher's exact test. Function and symptom scales in the QLQ-CR38 were analysed using ANCOVA with the baseline (preoperative) score as a co-variable and surgical procedure as a factor. The results are presented as mean changes adjusted for baseline with *P* values and 95 per cent confidence intervals. The perspective of all statistical analyses was intention to treat. The level of significance was set at *P* < 0.050. All baseline factors and preoperative scores on functioning domains and symptom scales were considered possible confounders. To check for confounders (age, sex, body mass index, American Society of Anesthesiologists (ASA) grade, tumour stage, type of resection, preoperative radiotherapy, preoperative chemotherapy, stoma, blood loss, anastomotic

Table 4 Changes in functional domains and symptom scale scores in EORTC QLQ-CR38

	Mean preop. score	4 weeks		6 months		12 months		24 months	
		Mean change from preop.	Adjusted mean difference*	Mean change from preop.	Adjusted mean difference*	Mean change from preop.	Adjusted mean difference*	Mean change from preop.	Adjusted mean difference*
Sexual functioning†									
Laparoscopic	19.9 (16.9, 22.8)	-11.2		-4.2		-1.2		2.0	
Open	24.3 (19.5, 29.2)	-17.2	2.5 (-0.3, 6.3)	-5.8	-0.8 (-5.5, 3.9)	-6.7	3.1 (-1.7, 7.9)	-4.7	4.6 (-1.7, 10.9)
Sexual enjoyment†									
Laparoscopic	49.1 (42.5, 55.8)	-8.0		-12.9		-3.1		-7.3	
Open	61.3 (52.1, 70.6)	-11.1	-0.7 (-0.4, 18.9)	-24.6	0.7 (-13.6, 15.0)	-16.7	8.0 (-5.0, 21.0)	-11.1	-2.1 (-17.2, 13.0)
Male sexual problems‡									
Laparoscopic	36.2 (29.9, 42.4)	27.2		22.4		21.6		24.1	
Open	27.8 (19.7, 35.8)	38.9	-6.5 (-19.9, 6.8)	34.2	-6.9 (-20.5, 6.7)	36.6	-9.8 (-22.3, 2.6)	27.5	1.1 (-12.2, 14.4)
Female sexual problems‡									
Laparoscopic	10.9 (4.1, 17.6)	11.1		16.7		14.8		11.9	
Open	12.2 (1.5, 23.0)	16.7	-7.3 (-6.3, 11.7)	7.4	5.1 (-16.5, 26.8)	13.6	0.9 (-20.8, 22.7)	0.0	11.8 (-18.9, 42.5)
Micturition symptoms‡									
Laparoscopic	24.0 (21.7, 26.3)	9.6		0.5		-1.2		-1.8	
Open	23.3 (20.0, 26.7)	9.4	0.9 (-4.4, 6.2)	1.6	-1.0 (-5.0, 3.0)	-3.3	2.2 (-2.0, 6.4)	-3.0	2.4 (-2.4, 7.2)

Values in parentheses are 95 per cent confidence intervals. *Laparoscopic minus open. †A high value indicates a high grade of functioning/enjoyment. ‡A high value means a high grade of symptoms/problems. EORTC, European Organization for Research and Treatment of Cancer.

leakage, duration of operation and conversion), Student's *t* test, ANOVA or correlation, where appropriate, were used. Confounders with $P < 0.200$ in the bivariable analysis were included in a multiple regression model together with surgical technique. This analysis applied to 12-month data.

All statistical analyses were performed using SPSS® 20 software (IBM, Armonk, New York, USA). Owing to the explorative nature of this study, significant *P* values should be interpreted with care, as interesting findings rather than conclusive evidence.

Results

Between 2004 and 2010, 1103 patients were included in the COLOR II trial; 385 patients (260 laparoscopic and 125 open) were included in this study (*Fig. 1*). The patients included in the HRQL study had a lower ASA grade, a longer operating time, a smaller proportion had received preoperative radiation, and fewer had postoperative anastomotic leakage compared with the eligible patients who were not included (*Tables 2 and 3*)²¹. Demographic characteristics did not differ between the laparoscopic and open groups.

At 1-year follow-up, sexual dysfunction was registered in the CRFs for 29 of 326 patients (16 laparoscopic and 13 open; data missing for 59). The corresponding proportion at 2-year follow-up was 19 of 263 (11 laparoscopic

and 8 open; data missing for 114 and 8 dead). There were no significant differences between the laparoscopic and open groups regarding sexual dysfunction or micturition problems at any time point (*Table 4*). Adjusting

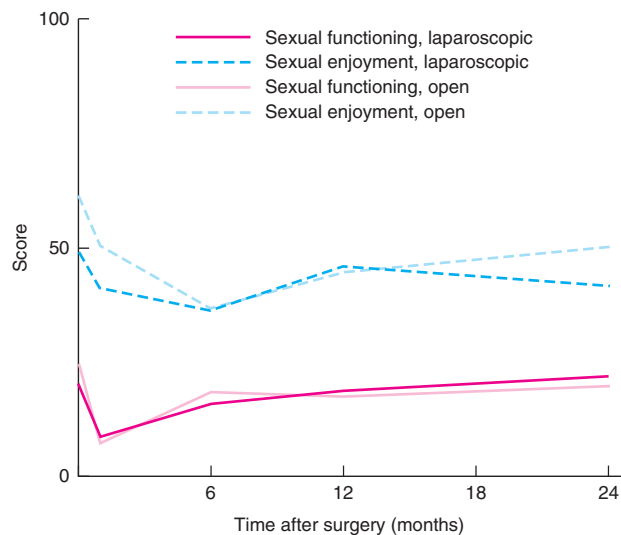


Fig. 2 Mean scores on European Organization for Research and Treatment of Cancer QLQ-CR38 domains for sexual functioning and sexual enjoyment over time and by surgical technique. A high value on the 100-point scale suggests a high level of functioning

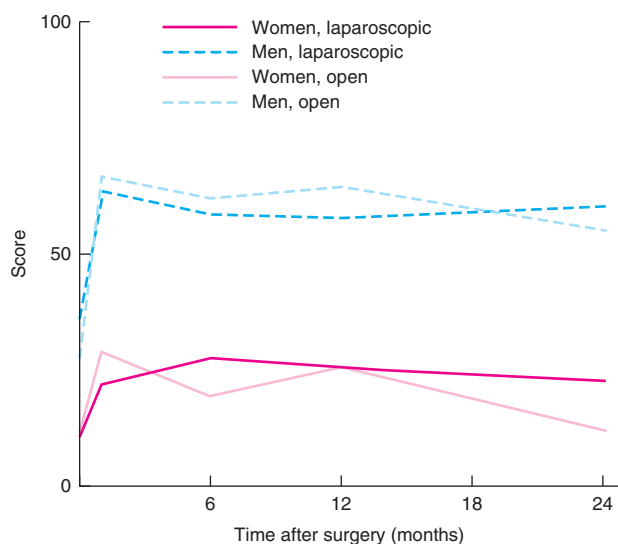


Fig. 3 Mean scores on European Organization for Research and Treatment of Cancer QLQ-CR38 symptom scales for male and female sexual problems over time and by surgical technique. A high value on the 100-point scale suggests a high level of symptoms

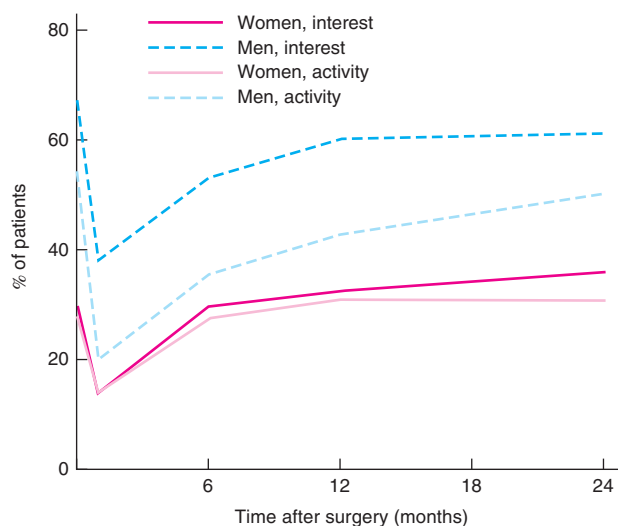


Fig. 4 Proportion of patients reporting sexual interest and sexual activity by sex

for confounders, including radiotherapy, did not change these results. Regarding radiation, none of the functioning domains and symptom scales showed a significant correlation in bivariable analysis ($P > 0.200$), except male sexual problems, but this was not significant in the multivariable analysis (mean score difference 12.4 between patients who received short preoperative radiation and those who did not receive radiation; $P = 0.164$).

All aspects of sexual dysfunction and micturition symptoms had deteriorated by 4 weeks after surgery. Sexual functioning showed a pronounced deterioration, but returned to baseline. Sexual enjoyment decreased by 6 months and stayed at a lower level throughout the study (Fig. 2). Male sexual problems increased by 4 weeks after surgery and were relatively stable thereafter (Fig. 3). Changes over time in sexual activity and sexual interest are shown in Fig. 4. Sexual activity was decreased at 4 weeks after surgery, but recovered partially. There were differences between men and women regarding both sexual interest and activity.

Before surgery 64.5 per cent of the men in the laparoscopic group reported some degree of erectile dysfunction compared with 55.6 per cent in the open group ($P = 0.253$). Corresponding values were 81.1 and 80.5 per cent 4 weeks after surgery ($P = 0.933$), and 76.3 and 75.5 per cent respectively at 12 months ($P = 0.912$).

Discussion

There were no differences in sexual dysfunction and micturition symptoms after laparoscopic *versus* open surgery for rectal cancer. Sexual dysfunction was more pronounced than micturition symptoms, regardless of technique. As in previous studies^{16,23}, it was found that women showed less interest and had lower sexual activity than men. In the setting of the randomized Conventional *versus* Laparoscopic-Assisted Surgery In Colorectal Cancer (CLASICC) trial¹⁸, in which EORTC QLQ-CR38 questionnaires were collected prospectively and the International Index of Erectile Function (IIEF) was added retrospectively, there were no significant differences in sexual function between laparoscopic and open surgery for rectal cancer¹⁸. Quah and colleagues¹⁷ reported a significant difference in male sexual dysfunction between patients undergoing laparoscopic and open rectal cancer surgery, in favour of open surgery. That study was based on retrospective interviews and questionnaires (IIEF) 3 years after surgery for about 50 per cent of the patients in a randomized trial¹⁷, and the results should be evaluated in view of these methodological shortcomings. In a retrospective study²⁴ of 173 patients treated in a single centre by an expert laparoscopic surgeon, there was a significant difference in sexual function in favour of laparoscopic compared with open surgery. As previously indicated by Stephens and colleagues¹², radiotherapy has less effect on sexual dysfunction than surgery.

The main strengths of the present study are the prospective and randomized design, population size, collection of baseline data, reporting of HRQL at several time points,

and the use of validated and established instruments. The weaknesses include that the HRQL part of the COLOR II study was optional for participating centres and had a relatively low inclusion rate (62.4 per cent of those eligible), with a small but significant selection bias regarding ASA grade, preoperative radiation, rate of anastomotic leakage and duration of operation between eligible patients who did not participate and included patients. There were differences between the laparoscopic and open surgery groups in operating time and blood loss, concordant with findings in the total COLOR II trial cohort³.

The same group of patients had a response rate of approximately 90 per cent²¹ for other parts of the QLQ-CR38 questionnaire, whereas for the scales or symptoms reported in this study the response rates varied between 8.2 and 90.9 per cent. In the EORTC instrument there is a structural problem regarding the symptom scale female sexual problems as the questions are tied to the condition of sexual intercourse during the past 4 weeks. This may in part explain the low response to this symptom scale. Owing to its international design, this study was restricted to using instruments validated in many languages. The instrument has a heteronormative approach with sexual penetration as the norm. On the other hand, it is possible that some patients may be offended by sexual questions insinuating homosexual behaviour or masturbation, which could influence the response rates²⁵.

The low frequency of CRF-reported complications regarding sexual dysfunction contrasted with the higher frequency of problems reported by patients in the questionnaires. This emphasizes the need for patient-reported outcomes as a complement to the surgeon's records when evaluating postoperative morbidity.

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Snapshot quiz

Snapshot quiz 14/13

Answer: This patient was admitted because of a tender irreducible perineal mass. He had an abdominoperineal resection for rectal cancer 9 years previously. The pelvic floor was reconstructed with a gluteal muscle flap. CT shows herniation of small bowel below and behind the sacral bone. At laparotomy, 150 cm of gangrenous small bowel was resected with primary anastomosis. The perineal defect was closed with a biological mesh (porcine collagen). Posterior perineal hernias are only seen as a surgical complication.