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Anorectal dysfunction after radical cystectomy for bladder cancer

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ABSTRACT

Objective: To prospectively assess anorectal dysfunction using patient-reported outcomes using validated questionnaires, manovolumetry and endoanal ultrasound before and 12 months after RC.

Patients and methods: From 2014 to 2019, we prospectively included 44 patients scheduled for RC. Preoperatively and 12 months after surgery, 41 patients filled in a low anterior resection syndrome score (LARS-score) to assess fecal incontinence, increased frequency, urgency and emptying difficulties and a St Mark's score to assess fecal incontinence in conjunction with manovolumetry and endoanal ultrasound examinations. Pre- and postoperative patient-reported anorectal dysfunction were assessed by LARS-score and St Mark's score. At the same time-points, anorectal function was evaluated by measuring mean anal resting and maximal squeeze pressures, volumes and pressures at first desire, urgency to defecate and maximum toleration during manovolumetry. Wilcoxon's signed rank test was used to compare pre- and postoperative outcomes by questionnaires.

Results: Postoperatively 6/41 (15%) patients reported flatus incontinence assessed by the LARS-questionnaire, and correspondingly the St Mark's score increased postoperatively. The median anal resting pressure decreased from 57 mmHg preoperatively to 46 mmHg after RC, but without any postoperative anatomic defects detected by endoanal ultrasound. Volumes and pressures at first desire, urgency to defecate and maximum toleration during manovolumetry all increased after RC, indicating decreased postoperative rectal sensation, as rectal compliance was unaltered.

Conclusions: Postoperative flatus incontinence is reported by one out of seven patients after RC, which corresponds to decreased anal resting pressures. The finding of decreased rectal sensation might also contribute to patient-reported symptoms and anorectal dysfunction after RC.

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Introduction

Long-term bowel function and defecation disturbances after radical cystectomy (RC) for bladder cancer are only scarcely reported in the literature and with conflicting results [1–3]. One study using a validated Gastrointestinal Quality of Life Index found no relevant altered bowel function after RC and continent diversion [1]. On the contrary, an issue-tailored German Gastrointestinal Questionnaire recently detected patient-reported bowel problems in 43% of 324 individuals subjected to RC >1 year ago [2]. A similar proportion of patients (30%) with defecation disturbances after RC was identified using another study-specific questionnaire together with free-hand comments [3]. In the only prospective study assessing anorectal sphincter function before and after RC, a decreased mean resting anal sphincter pressure and maximal anal closing pressure was found in 13 investigated patients [4]. All these 13 patients received a rectal diversion after RC (Mainz pouch II), and decreased anal pressures were associated with incontinence.

Thus, based on these previous studies suggesting that bowel problems and defecation disturbances are likely to be underreported after RC the present prospective study assessed patient-reported anorectal function. To disentangle physiological and anatomical changes behind the patient-reported anorectal function after RC, we also investigated pre- and postoperative anorectal function by manovolumetry and endoanal 3 D ultrasound for anatomic assessment.

Patients and methods

Out of 392 patients subjected to radical cystectomy (RC) for urothelial carcinoma at Skåne University Hospital in Malmö and Helsingborg County Hospital in Helsingborg in Sweden between December 2014 and April 2019, 44 individuals accepted study inclusion. Previous pelvic irradiation was an exclusion criterium for study participation. No patient had prior intestinal surgery. One patient was operated before manovolumetry and ultrasound was performed and was

therefore excluded, leaving 43 patients for further analyses of which 41 completed pre- and postoperative questionnaires and 40 performed both pre- and postoperative manovolumetries (Figure 1). The surgery was performed in a cystectomy unit comprising of two hospitals (Skåne University Hospital and Helsingborg County Hospital) making treatment decisions in the same regional multidisciplinary tumor board. The intra- and postoperative cystectomy care was standardized in these two hospitals, with no particular protocol for pelvic floor training or physiotherapy applied postoperatively during the study. Two patients were subjected to systemic adjuvant treatment, one with four courses of cisplatin-based combination chemotherapy and one patient was randomized to either placebo or nivolumab for 12 months (CheckMate274). To assess if extent of lymphadenectomy, type of urinary diversion, and whether nerve-sparing surgery had an impact on anorectal dysfunction, these variables were also ascertained.

Outcome measures

The primary outcome measure was postoperative patient-reported anorectal dysfunction (LARS-score and St Marks's score) together with altered manovolumetry and ultrasound findings 12 months after RC compared to preoperative scores and findings, respectively.

Preoperatively (median 1.2 (Inter Quartile Range (IQR) 0.4–2.4) months prior to RC) and under supervision the patients filled in a LARS-score questionnaire, including one question regarding impact on quality of life, and a St Marks's score. On the same occasion, the manovolumetry and endoanal 3D ultrasound examinations were performed by the same examiner (MS). The questionnaires and anorectal examinations were filled in and repeated, respectively, at a median of 13 (IQR 12–14) months after surgery.

LARS-score

We used validated questionnaires for low anterior resection syndrome (LARS-score) after anterior resection for rectal cancer [5] to evaluate fecal incontinence, increased frequency, urgency and emptying difficulties. Previously, the LARS-score has been used to evaluate rectal function also after surgery for deep endometriosis with or without anterior resection [6]. The LARS-score was compared preoperatively and at 12 months after RC per question, and the total LARS-score excluding the question on quality of life was stratified as no LARS between 0 and 20 points, minor LARS between 21 and 29 points, and as major LARS if 30 points or more (Supplementary Appendix 1).

St Mark's score

In addition, a questionnaire for fecal incontinence (St Mark's score) was used [7], which previously has been more widely applied after different types of pelvic and anorectal surgeries. St Mark's score was compared preoperatively and at

12 months after RC per question, as well as the total score was analysed (Supplementary Appendix 2).

Manovolumetry

An enema was given before the examination and patients were examined in the left lateral position using the mcompass Anorectal Manometry System (Medspira). A catheter with a balloon (containing at most 180 ml air) was inserted into the rectum. Four sensors located proximally from the balloon on the catheter were used to measure the pressure in the anal canal, and the balloon also had a sensor located distally for measuring rectal pressure. In all patients both the mean anal resting pressure and the maximal squeeze pressure were measured at three occasions during 20 s. Furthermore, the volumes and pressures at first sensation of desire to defecate, urgency to defecate and maximum toleration were assessed [8]. As a proxy for rectal compliance measured with a computerized rectal barostat [9], we divided rectal volume (ml) with rectal pressure (mmHg) at first sensation of desire to defecate, urgency to defecate, and maximum toleration. However, in one patient no sense of urgency to defecate occurred at the maximal volume of the balloon (180 ml) postoperatively. Similarly, five patients had no sense of maximum toleration at the maximal balloon volume, and two patients' measurements were missing due to a technical balloon failure occurring at urgency to defecate preoperatively and maximum toleration postoperatively, respectively. Thus, postoperatively median rectal compliance was only possible to calculate for 34 individuals at maximum toleration, albeit these patients tolerated volumes beyond the maximal volume of the balloon.

Ultrasound

The patients were examined in lithotomy position, and a 360° rotating 13 MHz transducer (2052) with a 3D Flex Focus machine (BK Medical, Herlev, Denmark) was used for the ultrasound examinations. Pre- and postoperative 3D endoanal images from each patient were assessed by comparing images side by side. Outcome measure was anatomic defects in the sphincter complex related to previous obstetric injuries, undiagnosed fistulae or deep anal fissures contributing to anorectal symptoms.

The study was registered on a trial site (<https://doi.org/10.1186/ISRCTN42949068> ISRCTN 42949068) and approved by the Research Ethics Board of Lund University (2014/163).

Statistics

No formal power calculation was performed prior to study start given the explorative study-design, but based on the largest previous study reporting different manovolumetry-findings in 13 individuals subjected to RC and anal diversion related to incontinence or not, we aimed to include 100 patients. However, due to slow recruitment the study was closed prematurely after including 44 patients over more than four years.

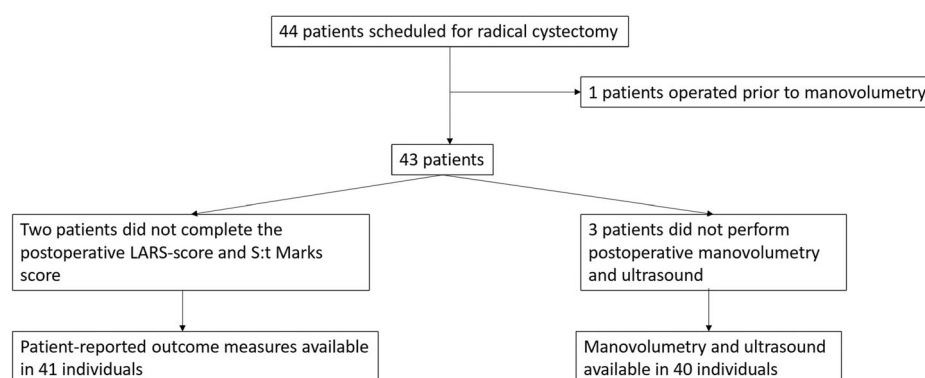


Figure 1. A CONSORT-diagram describing the study cohort.

All response variables were either continuous or on an ordinal. Wilcoxon's signed rank test was used to compare between the response before and one year after RC. P-values are always two-sided. All analyses were performed using R version 4.0.0 [10].

Results

A total of 43 evaluable patients with a median age of 70 (Inter Quartile Range (IQR) 64–76) years were included in the study. Postoperative questionnaires (LARS-score and St Mark's score) were missing in two individuals who developed metastatic bladder cancer prior to the postoperative assessment and therefore were not offered the postoperative follow-up visit with manovolumetry. One additional individual did not want to attend the postoperative manovolumetry and endoanal ultrasound examination, thus leaving 40 evaluable patients for pre- and postoperative anorectal volume and pressure analyses and ultrasound assessments (Figure 1). A majority of the patients received preoperative chemotherapy (27/43 (63%)), either as neoadjuvant chemotherapy ($n=13$) or as induction chemotherapy for node-positive disease ($n=14$), and the clinical stage-distribution is given in Table 1. The surgery was performed either as open radical cystectomy (RC) ($n=41$) or robotic-assisted RC ($n=2$), and the use of nerve-sparing, type of urinary diversion and extent of lymphadenectomy applied are also reported in Table 1. Eleven patients (26%) developed a highest Clavien complication grade 3 ($n=9$) or grade 4 ($n=2$) within 90 days of surgery (Table 1).

Six out of 41 patients (15%) reported postoperative flatus incontinence by the LARS-questionnaire, however no other item, proportion minor and major LARS, or the total LARS-score changed significantly after RC. Six patients reported that quality of life was affected by bowel function after RC (Table 2). The St Mark's score displayed findings in the same direction, i.e. the same six patients reported flatus incontinence, and six individuals reported that bowel function had an impact on the quality of life compared to the preoperative assessment ($p=0.07$) (Table 3). Out of the six patients reporting postoperative flatus incontinence by both scores, two claimed an impact on quality of life. The mean preoperative total St Mark's score was 0.3 (range 0–7) vs 1.1 (range 0–9) postoperatively ($p=0.02$) (Table 3). When

Table 1. Description of the study cohort ($n=43$).

	Numbers (%)
Sex	
male	33 (77)
female	10 (23)
Age	
median (IQR)	70 (64–76)
BMI	
median (IQR)	27 (25–30)
Smoker	
yes	7 (16)
previous	23 (51)
no	12 (28)
N/A	2 (5)
ASA-score	
1	3 (7)
2	27 (63)
3	13 (30)
Clinical stage distribution	
Ta/Cis	2 (5)
T1	9 (21)
T2 ^a	18 (42)
T3/T4a	14 (33)
Clinical nodal stage	
N0	29 (67)
N1	8 (19)
N2	4 (9)
N3	2 (5)
Preoperative chemotherapy	
no	16 (37)
neoadjuvant	13 (30)
induction	14 (33)
Nerve-sparing cystectomy	
no	37 (86)
unilateral	4 (9)
bilateral	2 (5)
Urinary diversion	
ileal conduit	38 (88)
continent cutaneous pouch (Lundiana)	4 (9)
neobladder (Studer)	1 (2)
Extent of lymphadenectomy	
none	2 (5)
iliac bifurcation	4 (9)
aortic bifurcation ^b	37 (86)
Primary urethrectomy in male patients	
yes	10 (30)
no	23 (70)
Perioperative blood loss (ml)	
Median (IQR)	400 (275–675)
Highest Clavien within 90 days	
0–2	32 (74)
3	9 (21)
4	2 (5)

^aOne patient with urethral carcinoma. ^bOne patient with simultaneous upper tract urothelial carcinoma subjected to simultaneous nephroureterectomy and cystectomy underwent additionally retroperitoneal lymphadenectomy including inter-aortocaval nodes. IQR: Inter Quartile Range; ASA-score: American Society of Anesthesiologists physical status classification.

Table 2. LARS-score questions including a question on impact on quality of life (the latter was not included when LARS-score was calculated) prior to and 12 months after cystectomy ($n = 41$).

	Preoperatively numbers (%)	At 12 months numbers (%)
Incontinence for flatus ($p = 0.046$)		
Never	40 (98)	35 (85)
<once a week	0	1 (2)
≥once a week	1 (2)	5 (12)
Incontinence for liquid stools		
Never	41 (98)	39 (95)
<once a week	1 (2)	2 (5)
≥once a week	0	0
Frequency of bowel movements		
>7 times a day	0	1 (2)
4–7 times a day	0	0
1–3 times a day	35 (83)	29 (71)
<once a day	7 (17)	11 (27)
Clustering of stools		
Never	31 (78)	32 (78)
<once a week	2 (5)	5 (12)
≥once a week	7 (18)	4 (10)
Urgency		
Never	38 (93)	37 (90)
<once a week	3 (7)	1 (2)
≥once a week	0	3 (7)
Impact on quality of life		
Never	37 (90)	35 (85)
Rarely	3 (7)	4 (10)
Sometimes	1 (2)	1 (2)
Often	0	1 (2)
LARS-score category		
No LARS	38 (97)	38 (93)
Minor LARS	1 (3)	0
Major LARS	0	3 (8)
LARS-score		
Mean (Range)	4.4 (0–22)	6.2 (0–37)
Median (IQR)	0 (0–8)	0 (0–9)

The total LARS-scores were also categorized as; No LARS 0–20 points/Minor LARS 21–29 points/Major LARS 30–42 points (weighted points per question is given in [Supplementary Appendix 1](#)). IQR: Inter Quartile Range.

Table 3. St Mark's score questions and total St Mark's score before and after cystectomy ($n = 41$).

	Preoperatively numbers (%)	At 12 months numbers (%)
Incontinence for solid stool*		
Never	42 (100)	40 (100)
Incontinence for liquid stool		
Never	41 (98)	38 (93)
Rarely	1 (2)	1 (2)
Sometimes	0	2 (5)
Incontinence for flatus ($p = 0.052$)		
Never	42 (98)	35 (85)
Rarely	0	1 (2)
Often	1 (2)	4 (10)
Always	0	1 (2)
Impact on quality of life ($p = 0.07$)		
Never	41 (95)	35 (85)
Rarely	2 (5)	4 (10)
Sometimes	0	1 (2)
Often	0	1 (2)
Need to wear a pad		
No	42 (98)	41 (100)
Yes	1 (2)	0
Medication for fecal incontinence		
No	42 (98)	41 (100)
Yes	1 (2)	0
Unable to defer defecation for 15 min		
No	42 (98)	38 (93)
Yes	1 (2)	3 (7)
St Mark's score ($p = 0.02$)		
Mean (Range)	0.3 (0–7)	1.1 (0–9)
Median (IQR)	0 (0–0)	0 (0–1)

IQR: Inter Quartile Range; *: one missing observation postoperatively.

Table 4. Manovolumetry before and after cystectomy ($n = 40$).

	Preoperatively Median (IQR) (numbers)	At 12 months Median (IQR) (numbers)	<i>p</i> Value
Volume at first desire to defecate (ml)	60.0 (50–70) (41)	76.0 (58–90) (40)	0.002
Resting pressure (mmHg)	57.0 (40–68) (39)	46.0 (37–59) (39)	0.007
Maximal squeeze pressure (mmHg)	144.0 (112–179) (39)	148.0 (102–178) (38)	0.7
Pressure at first desire to defecate (mmHg)	70.0 (60–80) (42)	80.0 (70–80) (40)	0.09
Rectal compliance at first desire to defecate (ml/mmHg)	0.8 (0.7–1) (41)	1.0 (0.8–1.1) (40)	0.07
Volume at urgency to defecate (ml)	110.0 (90–130) (41)	120.0 (100–140) (39)	0.02
Pressure at urgency to defecate (mmHg)	90.0 (80–100) (40)	100.0 (88–108) (39)	0.01
Rectal compliance at urgency to defecate (ml/mmHg)	1.2 (1.1–1.4) (40)	1.3 (1.1–1.4) (39)	0.7
Volume at maximum toleration (ml)	160.0 (120–180) (39)	180.0 (150–180) (34)	0.01
Pressure at maximum toleration (mmHg)	110.0 (100–123) (35)	120.0 (110–130) (34)	0.03
Rectal compliance at maximum toleration (ml/mmHg)	1.4 (1.2–1.6) (35)	1.4 (1.3–1.5) (34)	0.8

In one patient no sense of urgency to defecate occurred at the maximal volume of the balloon (180 ml) postoperatively. Similarly in five patients no sense of maximum toleration was reached at the maximal volume of the balloon postoperatively, and two patients' measurements were missing due to a technical balloon failure occurring at urgency to defecate preoperatively and maximum toleration postoperatively, respectively. IQR: Inter Quartile Range.

analysing the free text commentaries in the LARS-questionnaire, four patients used prescriptions to improve bowel function before RC, which increased to seven individuals postoperatively. The main prescriptions used for bowel function used after cystectomy were osmotic and bulk-forming laxatives.

The median anal resting pressure declined from 57 (IQR 40–68) mmHg before RC to 46 (IQR 37–59) mmHg postoperatively, whereas the median maximal anal squeeze pressure was similar pre- and postoperatively (Table 4). When comparing the six individuals reporting postoperative flatus incontinence with those 37 without, no differences between absolute decrease in anal resting pressure was found between the two groups (data not shown). There were no anatomic changes between preoperative and postoperative endoanal 3D ultrasound imaging. In one female, a similar partial anterior external and internal sphincter defect was identified pre- and postoperatively. This particular patient had the largest absolute decrease in mean anal resting pressure from 73 mmHg preoperatively to 24 mmHg after surgery.

Rectal sensation changed postoperatively, and the rectal volume, rectal diameter and rectal pressure at first desire, urgency to defecate and maximum toleration all increased after RC (Table 4). On the other hand, median rectal compliance (rectal volume (ml) divided by rectal pressure (mmHg)) at first desire to defecate, urgency to defecate and maximum toleration did not change after RC (Table 4).

Discussion

After RC, 6/41 (15%) patients reported flatus incontinence and St. Marks score assessing faecal incontinence increased. Anorectal manovolumetry revealed a decreased median anal

resting pressure from 57 mmHg before RC to 46 mmHg postoperatively as one physiologic explanation for postoperative flatus incontinence reported in the questionnaires. Furthermore, the increased volumes and pressures measured at first desire, urgency to defecate and maximum toleration together with an unaltered rectal compliance after RC, suggest involvement of neurogenic mechanisms behind the anorectal hyposensitivity and corresponding patient-reported symptoms.

In the only previously published study investigating manovolumetry findings prior to and after RC ($n = 13$), the authors also reported a decreased mean postoperative anal resting pressure [4]. Furthermore, a decreased maximal anal squeeze pressure was detected in that study comprising of patients selected for rectal diversion (Mainz pouch II) [4], which is different from the similar pre- and postoperative median maximal squeeze pressures found in the present study (144 vs 148 mmHg). However, comparisons of anorectal dysfunction between these two cohorts are difficult since other factors such as type of urinary diversion and length and type of intestinal segment used for reconstruction (colonic segment for continent cutaneous pouch vs ileum for ileal conduit) also has been reported to affect postoperative bowel function and consequently also influence anorectal function [11].

It is largely unknown if or how the extent of lymphadenectomy and nerve-sparing surgery during RC affect postoperative anorectal function related to possible injury of the superior and/or inferior hypogastric plexus [12], albeit nerve-sparing radical hysterectomy has been suggested to maintain anorectal function postoperatively [13]. On the other hand, a recent prospective assessment with Patient Assessment of Constipation Symptoms and Patient Assessment of Constipation Quality of Life questionnaires in patients

subjected to RC, although reporting few constipation symptoms postoperatively, extended lymphadenectomy did not increase postoperative constipation symptoms compared to a more limited template [14].

In order to further explain and understand the physiologic findings with decreased anal resting pressure and anorectal hyposensitivity identified in our study, anorectal neurophysiologic assessment with anal electromyography and to measure pudendal nerve terminal motor latencies might be beneficial [7]. In addition, a proper barostat setup with multiple measurements of anorectal volumes and pressures instead of the three measure points used in the present study, could also have been informative to more properly assess rectal compliance [15]. On the other hand, it is unlikely that anorectal sensation in the anal canal is of importance in preserving continence based on findings from a study applying topical anaesthesia in the anal canal [16]. Nonetheless, the contribution from the physical absence of the urinary bladder and prostate/uterus and consequently increased space in the pelvis in itself after cystectomy to the finding of rectal hyposensitivity in the present study would not be possible to completely understand, despite applying electromyography and measuring pudendal nerve terminal motor latencies in conjunction with proper rectal compliance assessment by a barostat. Furthermore, interaction between the two study findings with postoperatively decreased anal resting pressures and postoperative anorectal hyposensitivity is possible. Thus, anorectal hyposensitivity resulting in incomplete or decreased rectal emptying which generates accumulation of faeces has been well documented in individuals with functional fecal incontinence [17], and might cooperate together with simultaneously decreased anal resting pressures in individuals with postoperative flatus incontinence.

The proportion of patients reporting incontinence for flatus in the present study (15%) is in line with a threefold increase in bowel symptom distress after cystectomy when comparing with a matched control population [18], supporting the previous observation that bowel symptoms after RC is an underestimated issue [19]. The significantly increased St Mark's score after RC in the current study also substantiates such statement, albeit impacting quality of life only in six individuals according to the quality of life-question included in the score.

The current study limitations are mainly related to the limited number of patients included in the study due to trial closure before the initially planned 100 patients were recruited and to the design of the questionnaires used, as the LARS-questionnaire was developed in patients subjected to anterior resection for rectal cancer to assess symptoms related to the low anterior resection syndrome, and neither the LARS-score nor the St Mark's score are validated for use in a population subjected to RC. Still, both questionnaires are the most frequently and broadly used instruments to assess anorectal function irrespective of diagnosis, furthermore the St Mark's score correlates with patients' subjective perception and is reliable regardless of type of anal incontinence [7] as well as the LARS-score has been subjected to international assessment of validity and reliability also in a

Swedish context [5]. Also, the slightly different timing for filling out the questionnaires preoperatively (median 1.2 (IQR 0.4–2.4) months) before RC and not at a fixed interval prior to surgery is suboptimal, although it was pointed out to each patient that the timepoint of interest at baseline was prior to any preoperative chemotherapy-associated bowel-disturbances. Furthermore, although patients included in the study were recruited in a population-based cystectomy unit comprising of two hospitals, selection of younger and healthier individuals for study participation might have resulted in a study cohort with less postoperative bowel complaints compared to a cross-sectional population subjected to RC, i.e. inclusion bias precludes generalization of the study outcomes to the average patient subjected to RC. The fact that an increased number of patients were prescribed osmotic and bulk-forming laxatives when the postoperative evaluations were performed might also have affected the study outcome, i.e. those prescriptions reduced symptoms that would otherwise have been reported in the questionnaires. Difficulties to assess undiagnosed irritable bowel syndrome (IBS), is another study limitation, as IBS is a heterogenous and symptom-based diagnosis necessitating exclusion of organic bowel disease. For example, four patients used prescriptions to improve bowel function already before RC, and without using additional questionnaires assessing also abdominal pain, undiagnosed IBS affecting study outcomes cannot be ruled out even if each patient was his/her own control. Furthermore, despite that the current prospective study to the authors knowledge is the largest prospective trial investigating anorectal dysfunction after RC, the size is not large enough to adjust for other factors known to affect bowel dysfunction and defecation disturbances such as for example gender [20] and age [21]. Lack of power also precluded any further comparisons of manovolumetry outcomes between patients with and without patient-reported postoperative anorectal dysfunction and to perform associations with quality of life questions.

In the future large prospective intervention studies are needed to investigate the use of medications and other interventions to treat anorectal dysfunction after RC. Additionally, a matched control group with for example individuals with non-muscle invasive bladder cancer treated with bladder preservation would be a relevant reference cohort to compare anorectal function with.

Conclusions

Flatus incontinence is the dominating patient-reported anorectal dysfunction after RC, which corresponds to decreased anal resting pressures postoperatively. The anorectal hyposensitivity noted after RC requires further neurophysiological studies to elucidate the underlying neurogenic mechanisms, as well as prospective intervention studies are needed to define useful measures for patients with anorectal dysfunction after RC.

Disclosure statement

None of the authors have any conflicts of interest.

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