

Transanal minimal invasive surgery for rectal lesions: should the defect be closed?

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Abstract

Aim Transanal minimal invasive surgery (TAMIS) of rectal lesions is increasingly being used, but the technique is not yet standardized. The aims of this study were to evaluate peri-operative complications and long-term functional outcome of the technique and to analyse whether or not the rectal defect needs to be closed.

Method Consecutive patients undergoing TAMIS using the SILS port (Covidien) and standard laparoscopic instruments were studied.

Results Seventy-five patients (68% male) of mean age 67 (± 15) years underwent single-port transanal surgery at three different centres for 37 benign lesions and 38 low-risk cancers located at a mean of 6.4 ± 2.3 cm from the anal verge. The median operating time was 77 (25–245) min including a median time for resection of 36 (15–75) min and for closure of the rectal defect of 38 (9–105) min. The defect was closed in 53% using interrupted (75%) or a running suture (25%). Intra-operative complications occurred in six (8%) patients and postoperative morbidity was 19% with only one

patient requiring reoperation for Grade IIIb local infection. There was no difference in the incidence of complications whether the rectal defect was closed or left open. Patients were discharged after 3.4 (1–21) days. At a median follow-up of 12.8 (2–29) months, the continence was normal (Vaizey score of 1.5; 0–16).

Conclusion Transanal rectal resection can be safely and efficiently performed by means of a SILS port and standard laparoscopic instruments. The rectal defect may be left open and at 1 year continence is not compromised.

Keywords Single-port transanal surgery, single-incision laparoscopic surgery, transanal endoscopic microsurgery, transanal minimal invasive surgery, closure

What does this paper add to the literature?

This multicentre trial demonstrates that transanal minimal invasive surgery for rectal lesions can be performed with low intra-operative and postoperative morbidity. In addition, the rectal defect can be left open without increasing complications or compromising continence.

Introduction

Transanal endoscopic microsurgery (TEM) is a well established surgical approach for benign or early malignant lesions of the rectum. Furthermore, it is increasingly used after neoadjuvant therapy for selected rectal adenocarcinoma [1,2] or more recently as a platform for transanal total mesorectal excision [3–5]. TEM is superior to conventional transanal excision with regard to completeness of excision [6–8], but the

TEM equipment is not available in many centres. The cost [9] and technical difficulties have discouraged its use.

Since the first description in 2010 [10], several case reports and small series have reported the successful use of laparoscopic single-port surgery performed via the anus [10–13]. This approach has received many labels including transanal minimal invasive surgery (TAMIS) [10,14,15], transanal single-port microsurgery [16], transanal endoscopic video-assisted excision [17], single-incision laparoscopic surgery (SILS) TEM [18] or single-port transanal surgery (SPTS). Several studies have demonstrated the feasibility of this novel technique, but all contained small numbers of patients, various ports

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were used and the technique was not standardized. In addition, there are few data on the efficacy and long-term outcome of the technique.

The aims of this study were to evaluate the safety, intra- and peri-operative complications and long-term function after TAMIS for rectal lesions in a multicentre setting and to analyse whether or not the rectal defect needs to be closed.

Method

Patients

All consecutive patients presenting to three different centres with a rectal lesion otherwise eligible for TEM were included. All underwent full colonoscopy with biopsy and endoanal ultrasound. In the case of cancer, regional staging was completed by magnetic resonance imaging. Patients were operated on using the SILS™ port (Covidien, Mansfield, MA, USA) with standard laparoscopic instruments. The preoperative work-up was according to the local standards/protocols and was identical to TEM protocols at each centre.

Data collection

Data were collected prospectively and entered in a common database. None of the authors and no centre received any financial support. The study was approved by the institutional review board of each centre. Complications were graded according to the Clavien–Dindo classification [19]. Opening the peritoneal cavity was considered an intra-operative complication. The resection specimen was pinned on a cork board and sent fresh for histopathological examination. The size of the specimen, the width of the margins and the final diagnosis were recorded. Continence was assessed using the Vaizey incontinence score [20]. The operations were performed by colorectal surgeons (DH, PD, RC) experienced in TEM surgery, each having performed more than 20 such procedures.

Statistical analysis

Summary data are presented as median \pm standard deviation for continuous variables and percentages for discrete variables. Patient subgroups were compared using analysis of variance for outcome of continuous data and the chi-squared test for discrete ordinal data. All statistical tests were two-sided and a *P* value less than 0.05 was considered significant. The analysis was performed using SPSS version 19 (IBM Switzerland Ltd., Zurich, Switzerland).

Results

Patient demographics

From December 2009 to July 2012, 75 consecutive patients of mean age 67.3 ± 14.9 years underwent TAMIS. Of these 68% were male and 7% had had previous anal surgery. The median preoperative Vaizey incontinence score was 1.2 (0–10). The three centres performed 24, 24 and 27 SPTS procedures and no TEM procedure was performed during the study period.

Indication

The indications for TAMIS were low grade rectal adenoma (33%, $n = 25$), high grade rectal adenoma (23%, $n = 17$), rectal adenocarcinoma (43%, $n = 32$) and carcinoid tumour (1%, $n = 1$). The mean distance of the distal margin of the lesion from the anal verge was 6.4 ± 2.3 cm and of the proximal margin 9.2 ± 2.5 cm. The lesion was located posteriorly in 47%, laterally in 21% and anteriorly in 17%. The remaining 15% were semi-circumferential or affected more than 180° of the circumference.

Operation

Full mechanical bowel preparation was performed in 64% of patients, a rectal enema in 32% and no preparation was given in 4%. All patients received preoperative antibiotics which were continued in 84% of patients for an average of 7 ± 3.2 days. 91% of operations were performed in general anaesthesia. Seventy (93%) patients were operated in the lithotomy position, two (3%) in the lateral (3%) and three (4%) in the prone position. In 72 (96%) patients a 30° standard 5 mm laparoscopic optic was used and a flexible endoscope in three (4%). All resections were performed under 15–20 mmHg CO₂ pressure at an insufflation rate of 20 l/min using standard straight laparoscopic instruments. The following energy devices were used: 63% Ultracision (Johnson & Johnsons, Zug, Switzerland), 32% Ligasure (Covidien) or 5% monopolar cautery. For better visualization a gauze swab was placed proximal to the lesion in 12%. A full-thickness excision was performed in 68 patients.

Single-port transanal surgery was successfully completed in all 75 patients. The median operating time was 77 (25–245) min, including 36 (15–75) min for the resection and 38 (9–105) min for closure of the rectal defect. The defect was closed in 40 (53%) of the 75 patients using single stitches or a running suture of Vicryl 3-0 or V-lock 3-0 (Covidien).

Intra-operative complications

Intra-operative complications occurred in seven (9%) patients (Table 1). Bleeding noted in three patients was successfully treated by coagulation and/or the application of Flowseal® (Baxter, Volketswil, Switzerland). The peritoneal cavity was entered and the defect was closed by combined transanal and laparoscopic sutures in two patients and in one patient an open laparotomy was necessary.

Postoperative pathology

Postoperative pathology confirmed benign rectal adenoma in 35 patients (low grade $n = 12$ and high grade $n = 23$) and carcinoid and hamartoma in one patient each. In 38 patients rectal adenocarcinoma was diagnosed. In four patients, no tumour (T0) could be detected owing to a previous endoscopic resection in one patient and a complete response to radiochemotherapy in three. Tis was diagnosed in 11 cases, T1 cancer in 13, T2 cancer in nine and T3 cancer in one. On receipt of the histopathological report, a low anterior rectal resection (TME) was carried out owing to an involved margin in two cases (one T1, one T2) and the presence of a T3 tumour in one case. One patient with a Tis tumour demanded further surgery and one patient with a T1 cancer underwent extraperitoneal mesorectal excision. Two patients received postoperative radiotherapy.

The mean size of the lesions was $39 \pm 16 \times 29 \pm 13$ mm and the depth of excision was 13 ± 7 mm. Fragmentation of the specimen occurred in 8%, all for benign lesions. The margins were clear in 72/75 (96%) patients, with one low grade adenoma and two adenocarcinomas showing involvement. The mean resection margin was 7.9 ± 6.5 mm. An average of 1.6 ± 0.7 (range 1–5) lymph nodes were present in 13 (17%) of 75 specimens.

Postoperative morbidity

Patients were hospitalized for a median of 3.4 (1–21) days. The overall morbidity was 20% (Table 1). Five patients experienced postoperative bleeding, one of whom required tamponade with gauze, two were given blood transfusion (Grade II) and in two no special treatment was required (Grade I). Local infectious complications were seen in six (8%) patients. One (1.3%) patient was reoperated (TME, Grade IIb) and five were treated with antibiotics (Grade II).

At first follow-up at a median of 31 (7–146) days after surgery one patient presented with occasional bleeding. At last follow-up at a median of 385 (67–884) days, two patients complained of intermittent diarrhoea and one had anal pain. All patients with cancer had no evidence of persisting disease. The median postoperative Vaizey score was 1.5 (0–16). Seven (18%) of the 38 patients with a preoperative Vaizey score of 0 had mild and infrequent soiling postoperatively with a median score of 1 (1–4). There was no difference in complications whether or not the rectal defect was closed (Table 2).

Differences between centres

Preoperative bowel preparation (full bowel preparation at centre A 100%, centre B 83% and centre C 14%; $P < 0.001$), use of Ultracision (46%, 38% and 100%, $P < 0.001$) and closure of the defect (4%, 71% and 82%, $P < 0.001$) differed between the three centres. Other operative data and patient characteristics were similar. There was also no difference in the intra-operative complication rate (17%, 8% and 11%, $P = 0.6$) or postoperative morbidity (25%, 25% and 8%, $P = 0.1$). Histopathological examination showed a similar percentage of cancer patients (46%, 65% and 31%, $P = 0.2$). The size of the specimen was similar in the

Table 1 Intra-operative and postoperative complications.

	N (%)	Treatment/grade
Intra-operative complications	6 patients (8)	
Bleeding	3 (4)	Coagulation, Flowseal®
Opening abdominal cavity	3 (4)	2 laparoscopy, 1 laparotomy
Pneumoscrotum	1 (1)	None
Postoperative complications	15 patients (19)	
Bleeding	5 (7)	2 Grade I, 3 Grade II
Local Infection	6 (8)	5 Grade II, 1 Grade IIb
Urinary tract infection	2 (3)	2 Grade II
Urinary retention	2 (3)	2 Grade II

Table 2 Differences whether or not the rectal defect was closed.

	No closure, <i>n</i> = 35	Closure, <i>n</i> = 40	<i>P</i>
Peri-operative parameters (%)			
Anterior location of the lesion	2 (6)	11 (28)	0.06
Full bowel preparation	30 (86)	18 (45)	0.001
Preoperative cancer diagnosis	16 (46)	18 (45)	0.7
Distal distance from the anal verge (cm)	6.6 (± 2.2)	6.2 (± 2.5)	0.4
Proximal distance from the anal verge (cm)	9.3 (± 1.7)	9.1 (± 2.9)	0.4
Size of the specimen (surface, mm ²)	1218 (± 914)	1404 (± 1078)	0.4
Operating time (min)	62 (± 16)	90 (± 51)	0.04
Postoperative outcome (%)			
Bleeding	4 (11)	1 (3)	0.2
Infection	2 (6)	4 (10)	0.3
Use of antibiotics (days)	8.5 (± 2.9)	5.5 (± 2.7)	0.001
Hospital stay (days)	3.4 (± 3.5)	3.4 (± 1.9)	0.9

centres (A, 1208 ± 856 mm²; B, 1090 ± 687 mm²; C, 1432 ± 699 mm²; *P* = 0.09).

Discussion

To our knowledge, this is the largest multicentre series on TAMIS for rectal lesions. The procedure could be successfully completed in all patients using standard laparoscopic instruments. Intra-operative complications occurred in 8% and postoperative morbidity in 19% with only one patient requiring re-intervention. Rectal defects were left open in 47% without increasing complications or compromising continence.

The only comparative study of TAMIS with traditional TEM is on an *ex vivo* pelvitrainer model [21]. The authors compared excisions performed by 10 surgeons with no experience in transanal surgery and found that dissection and suturing were significantly faster with a better subjective appreciation of TEM. Suturing in the TAMIS group was considered not possible in 30%. Suturing remains very challenging as instruments obstruct each other, adequate tissue tension around the lesion is difficult and hence the procedure is time consuming. In the literature different methods of suturing have been described using Endo-GIA staplers [10], intracorporeal running sutures [16,17] or extracorporeal single suturing with a knot pusher [15]. In a small prospective randomized study of 44 TEMs no difference in outcome was noted if the defect was sutured or not. All defects which were not closed were found to have healed on repeated endoscopy 3 months later [22]. Wound dehiscence after TEM in patients who have had radiotherapy can be as high as 47% [23]. In the present study 47% of rectal defects were not sutured. Although this was

mainly depending on the centre, there was no difference in size and location of the defect, and most interestingly there was no increased complication rate in the non-sutured patients. This suggests that the defect can be left open without increased morbidity, although the study was not designed to answer this question.

Of note, antibiotics were continued for a median of 7 days in most patients in this study. Whether this is necessary, especially in the non-sutured group, is unclear. Another unanswered question is whether full bowel preparation is mandatory if the defect is not closed. There was a trend to lower complication rates in centre C, where the Ultracision was used in all patients without bowel preparation and closure of the defect was carried out in 80% of patients. Unfortunately, we do not know whether one or all of these factors was responsible for this observation. For all these reasons, further study in the form of randomized trials using the SPTS technique is necessary. Suturing is technically difficult and can double the operation time.

A possible advantage of TAMIS using a SILS trocar may be its smaller diameter (30 mm) and pliability in contrast to the rigid proctoscope used in the TEM or transanal endoscopic operation technique (40 mm). The larger instrument may cause a degree of anal dilatation which might cause disturbance of anorectal function. Faecal soiling may persist in 21% of patients even at 6 months after TEM [24]. In the present study, only 18% of patients with a preoperative Vaizey score of 0 had a postoperative continence disturbance which in any event was only occasional. Another advantage of TAMIS is the use of conventional laparoscopic instruments and the set-up, which is familiar

Table 3 Case series with more than 10 patients.

First author	N	Distance from anal verge (cm)	Cancer (%)	Bowel preparation	Postoperative antibiotics	Closure (%)	Overall morbidity (%)	Reoperation (%)	Hospital stay (days)
Lorenz (2011) [25]	13	6.5	100	NA	NA	NA	NA	NA	NA
van den Boezem (2011) [26]	12	7 (3–20)	25	Enema	NA	100	8.3	NA	1
Ragupathi (2011) [17]	20	10.6 ± 2.4	30	NA	NA	100	5	5	1.1 ± 1.7
Barendse (2012) [11]	15	NA	38	Enema	NA	92	7.7	0%	2.5 (0–10)
Lim (2012) [15]	16	7.5	69	MBP	NA	100	NA	NA	3
Albert (2013) [14]	50	8.2 (3–14)	46	MBP	NA	100	6	0	0.6
Gorgun (2014) [27]	12	9 (5–10)	8	MBP	NA	100	25	0	1 (0–38)
Hompes (2014) [28]	16	8 (3–10)	31	MBP	NA	81	13	0	1.3 (0–4)
Bridoux (2014) [29]	14	10 (5–17)	71	Enema	All 5 days	NA	21	0	4 (1–13)
McLemore (2014) [30]	32	4 ± 3	50	MBP	NA	100	25	0	2.5 ± 2
This study	75	6.4 ± 2.3	51	64% MBP, 36% enema	84% 7 days	53	20	1.3	3.4 (1–21)

NA, not available; MBP, mechanical bowel preparation (polyethylene glycol).

and already available in any unit performing minimally invasive surgery.

Most lesions in series reporting TAMIS have been located at 6–10 cm from the anal verge (Table 3) and, as with TEM, lesions should not be lower than 4 cm. In higher lesions there is an increased danger of entering the peritoneal cavity, which occurred in three patients in the present study. Others have managed to suture the defect transanally without the need of an additional approach [11]. On the other hand, entering the peritoneal cavity in the case of a high lesion placed on the anterior rectal wall is inevitable when a full-thickness resection is performed since it is part of the procedure and in this circumstance cannot be regarded as a complication. Reports in the literature indicate that resection margins are negative in 94–100% and fragmentation occurs in 0–4% with TAMIS, similar to the rates obtained in the present study, although fragmentation at 8% was seen only in benign disease and in polyps > 5 cm, which is similar to TEM (6%) [8].

The indications for SPTS are identical to those of TEM but they should not be widened without careful

consideration just because TAMIS is more easily accessible and regular laparoscopic instruments can be used. Patient selection especially for rectal cancer remains crucial. In conclusion, transanal rectal resection for low-risk tumours can be safely and efficiently performed via a SILS port using standard laparoscopic instruments. The rectal defect may be left open and at 1 year continence seems not to be compromised.

Author contributions

DH, RC, PD, DD: conception and design. DH, RC, PD, DD, GS, DR: acquisition, analysis and interpretation of data. DH, RC, PD, DD: drafting the manuscript. DH, RC, PD, DD, GS, DR: critical revision. DH, RC, PD, DD, GS, DR: final approval.

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