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Is obesity a factor of surgical difficulty in transanal endoscopic surgery?



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ABSTRACT

Background: The aim of this study is to assess the feasibility of transanal endoscopic surgery (TES) in obese patients.

Methods: Observational descriptive study evaluating the feasibility of TES in obese rectal tumors between June 2004 and January 2019. Patients were assigned to two groups: body mass index $(BMI) < 30 \text{ kg/m}^2$ and $BMI > 30 \text{ kg/m}^2$, the latter defined as obese.

Results: From 775 patients, 681 were enrolled in the study, 145 (21.3%) of them obese. No statistically significant differences between groups were found with respect to overall morbidity (27, 18.6%). The obese patients presented trends towards shorter mean surgical time (65 min, IQR 48 min), less perforation in the peritoneal cavity (eight, 5.5%), and 133 (91.7%) presented a lower rate of lesion fragmentation.

Conclusion: There were no significant differences in postoperative outcomes in obese patients (BMI \geq 30 kg/m²). TES in those obese patients does not represent a factor of surgical difficulty.

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Introduction

Over the last decades, obesity has become a major public health problem all over the world. Its prevalence has more than doubled since the 1980s, with 39% of the total adult population currently classified as overweight and 13% as obese. Moreover, obesity has reached epidemic proportions in Western countries: the proportion of individuals with body mass index (BMI) > 30 kg/m² reached 36.5% in the EE. UU. in 2014 ², and the number of adults with even higher BMI has also recently increased.

Surgical procedures in obese patients are challenging due to the presence of physiological and metabolic alterations and the increased likelihood of comorbidities which must be managed perioperatively. Obese patients undergoing laparoscopic colorectal procedures have been shown to present worse perioperative outcomes and increased complication rates compared to non-obese patients ^{4,5}. The minimally invasive approach has reached new horizons with the development of transanal endoscopic surgery

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(TES) techniques. Transanal Endoscopic Micro-surgery (TEM),⁷ Transanal Endoscopic Operation (TEO)⁸ and Transanal Minimally Invasive Surgery (TAMIS)⁹ can be used to remove benign and malignant tumors from the rectum. These local approaches are surgical alternatives to total mesorectal excision (TME) in (T1) early stage rectal cancer and large rectal adenomas¹⁰ which achieve reduced morbidity and mortality rates compared with radical laparoscopic surgery.¹¹

The aim of this study is to assess the safety and feasibility of local rectal surgery in obese patients, and to compare operative and postoperative outcomes with those recorded in non-obese patients undergoing transanal endoscopic surgery. Very few data are currently available in the literature on obesity as a possible risk factor in TES.

Material and methods

Observational study with prospective data collection and retrospective analysis from June 2004 to January 2019. All patients were operated upon by five surgeons at the Coloproctology Unit.

After the preoperative study, as we have described previously, ¹⁰ patients were classified into five groups of preoperative indication:

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group I, with curative intent (biopsies of adenomas, stage u-mriT0-1 and u-mriN0-1); group II, with curative intent (biopsies of low-grade adenocarcinomas (G1-2), stage u-mriT0-1 and u-mriN0-1); group III, indication by consensus (low-grade adenocarcinomas (G1-2) with stage u-mriT2 and u-mriN0); group IV, palliative indication (adenocarcinomas of any stage with palliative indication); group V, atypical indication.¹²

All patients in groups I to IV who underwent transanal endoscopic surgery were included in the study. Patients in group V (atypical indications) and those in whom the BMI could not be calculated because of insufficient data on height or weight were excluded.

All patients are administered the Wexner sphincter function questionnaire, if there are signs of fecal incontinence, anorectal manometry is performed to obtain baseline parameters. The week prior to surgery, a preoperative anesthesiology assessment was performed in which patients' height (m) and weight (kg) were measured. In accordance with the requirements of our Institutional Review Board, all patients provided signed informed consent prior to surgery. All underwent mechanical preparation of the anterograde colon. The previous night they received antithrombotic prophylaxis. In the induction of anesthesia, antibiotic prophylaxis was administered in accordance with our hospital's institutional protocol. Surgery accordance with our hospital's institutional protocol.

Either TES equipment⁷ (Richard Wolf, Knittlingen, Germany) or TEO equipment⁸ (Karl Storz GmbH, Tüttlingen, Germany) was used, depending on availability. Full-wall excision was performed using an ultrasound scalpel (Ultracision, Ethicon Endo-Surgery, Cincinnati, OH). The defect was closed on all occasions without tension, and so either complete or partial closures were performed. At present, patients are discharged from hospital at 24 h, if there are no signs of any medical or surgical complications.

Patients were assigned to one of two groups, according to their BMI: obese (BMI \geq 30 kg/m2) or non-obese (BMI <30 kg/m2). The World Health Organization defines obesity as a BMI \geq 30 kg/m2. ¹⁴

Study variables: the main variable was the 30-day global morbidity according to the Clavien-Dindo classification (CL-D) 15 and relevant morbidity (CL-D > II). The rest of the study variables were epidemiological, preoperative, surgical, postoperative complications and pathology. all the pathological reports of transanal endoscopic surgery, have been described by the same protocol. For adenomas (size, histological type, dysplasia, resection margins, indications of the layers of rectal wall represented). For adenocarcinomas (size, histological type, grade of differentiation, presence of perineural, angiolymphatic and venous invasion, tumor budding, pT stage, resection margins, indication of the layers of rectal wall represented).

The study was approved by the local Institutional Review Board (CEIC: 2016/636) and complied with the criteria of the Declaration of Helsinki. The STROBE guidelines for observational studies were followed

The SPSS statistical package version 23 was used. Quantitative and categorical variables were described in accordance with standard statistical regulations. The univariate analysis of the quantitative variables was carried out using a simple linear regression and the Student's T-test, providing its application conditions were fulfilled; otherwise, the Mann-Whitney U test was applied. For categorical variables, Pearson's X^2 test or Fisher's exact statistical test was used. A p value < 0.05 was considered statistically significant. Statistically significant variables, or those with a trend toward significance (p < 0.2), were introduced in the multivariate analysis to avoid confounding variables in the results.

Results

Since the beginning of the study, 775 patients have undergone surgery with TES. Sixty-five patients were excluded due to an atypical indication. Despite the prospective data collection, height and weight were not a mandatory variable at the beginning of the

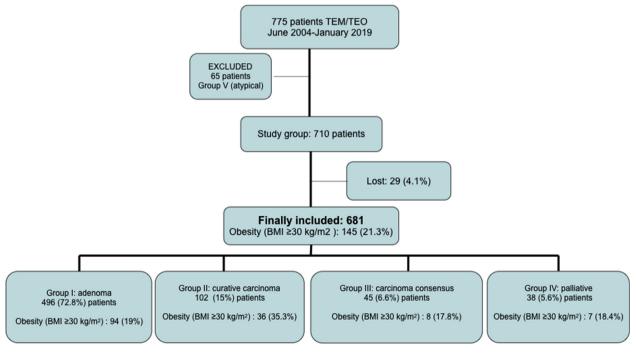


Fig. 1. Patients' flow chart. AC, adenocarcinoma. Group I: rectal lesions with biopsy revealing adenoma and staged T0-N0 by endorectal ultrasound (u) and/or pelvic magnetic resonance (mr), divided by tumor size. Group II: adenocarcinomas [either well (G1) or moderately differentiated (G2)], and staged u-mrT0-1, u-mrN0. Group III: indication by consensus, adenocarcinomas [either well (G1) or moderately differentiated (G2)], staged u-mrT0, u-mrN0. Group IV: palliative indications. Group V: atypical indications.

Table 1 Descriptive analysis of the variables of the study.

/ariables			Patients (n = 681)	Patients (
Epidemiology	Age (years)(median-IQR-range)		71 (IQR 17) (92-31)	
	Sex	Male Female	405 276	59.5 40.5
	Weight (kg) (median-IQR-range)		71 (IQR 16) (140-38)	_
	Height (m) (median-IQR-range)		1.6 (IQR 0.13) (1.37-1.89)
	BMI (kg/m²)(median-IQR-range)		26.6 (IQR 5.7) (17-48)	_
	Obese Classification	Non-obese (BMI <30 kg/m ²)	536	78.7
		Obese (BMI 30-<40 kg/m ²)	136	20
		Morbidly obese (BMI ≥40 kg/m²)	9	1.3
Preoperative	Tumor size (cm) (median-IQR-range)		4 (IQR 2) (1-12)	_
	Tumor size (cm)	Small (0-3)	239	35.1
	,	Medium (3-5)	384	56.4
		Large (>5 cm)	58	8.5
	Distance from anal verge(cm) (median-IQR-range) Distance from proximal margin tumor to anal verge (cm) (median-IQR-range)	7 (IQR 5) (1-22) 11 (IQR 4.5) (1-26)		
	proximal margin tumor to anal verge >15 cm		126 (18.5%)	
	Location of the tumor	Anterior	170	25
		Lateral Posterior	304 207	44.6 30.4
	Morphology of the lesion	Flat	156	23.4
	worphology of the lesion	Pedunculated	142	21.3
		Sessil	316	47.4
		Ulcerated	53	7.9
	ASA	I II	22 364	3.2 53.4
		III	243	35.7
		IV	52	7.6
Surgical	Surgical equipment	TEM TEO	331 350	48.6 51.4
	Pieces of the specimen	One piece	634	93.1
		Fragmentation	47	6.9
	Surgeon experience	>150	325	47.7
		150–35 <35	279 77	41.0 11.3
	Surgical time(min) (median-IQR-range)		70 (IQR 50) (265–20)	-11.5
	Perforation into abdominal cavity	48	7	
		Committee	_	
	Suture of the defect	Complete Incomplete	592 84	87 12.3
		Absent	5	0.7
	Tumor location (quadrant)	Anterior	170	25
		Lateral Posterior	304 207	44.6 30.4
	Occasil as and district	rosterioi	_	
ostoperative	Overall morbidity		150	22
	Morbidity (Clavien-Dindo)	0 I	530 95	78 13.9
		II	22	3.2
		IIIa	11	1.6
		IIIb IVa	16 4	2.4 0.6
		IVb	1	0.1
		V (mortality)	2	0.3
	Clinically relevant morbidity (Cl—D > II)	_	34	5
Pathology	Definitive pathology	Adenoma	401	58.9
		Adenocarcinoma No pathology	226 54	33.2 7.9
	Free margins	то распоюду		_
	Free margins	_	624	91.6

TEM: Transanal Endoscopic microsurgery. BMI: Body Mass Index. TEO: Transanal Endoscopic Operation. ASA(American Society of Anesthesiology score). IQR: Interquartile range. Cl—D: Clavien-Dindo.

series, and for this reason 29 patients were lost due to the inability to calculate their BMI. Finally, 681 patients took part in the study, 145 with a BMI \geq 30 kg/m2 (21.3%). Fig. 1 shows the distribution by indication group with the number and percentage of obese patients. The highest proportion of obese patients was in group II (36/102, 35.3%).

Table 1 presents the study variables of the 681 patients in the series. Over half the patients were male (405, 59.5%) and the median BMI was 26.6 (Interquartile range (IQR) 5.7 kg/m2). One hundred and forty-five patients (21.3%) were obese, and nine (1.3%) morbidly obese. The median size of the lesion was 4 cm (IQR 2 cm). The median distance from the anal margin was 7 cm (IQR 5 cm). As for morphology, the most frequent was sessile, recorded in 316 (47.4%). TEM was used in 331 cases (48.6%) and TEO in 350 (51.4%). En bloc resection without fragmentation was achieved in 634 (93.1%). Ninety-seven lesions (14.2%) presented technical difficulty. Overall morbidity was 150 (22%), of which 95 (63.3%) were CI-D grade I, and morbidity was clinically relevant (CI-D > II) in 34 (5%).

From all pathological reports of our series, 653 (95.8%) was made by the same pathologist (AC). The others 28 (4.2%), from five others pathologist of his team. The most frequent pathology was adenoma, in 401 (58.9%), and resection with free margins was achieved in 624 patients (91.6%). Final diagnosis of adenocarcinoma was found in 226 patients (33.2%): 95 (42%) group I, 63 (27.9%)

group II, 36 (15.9%) group III, 32 (14.2%) group IV.

Table 2 shows the univariate analysis in obese and non-obese patients with respect to epidemiological and preoperative variables. The obese group presented a significantly higher percentage of women (p=0.008), significantly smaller lesion size (p=0.045), and significantly fewer lesions located in anterior quadrant of the rectum (p=0.021).

Table 3 shows the univariate analysis for the surgical, postoperative and pathological variables.

No statistically significant differences between groups were found with respect to overall morbidity (27, 18.6%). Interestingly the obese patients presented trends towards shorter mean surgical time (65 min, IQR 48 min), less perforation in the peritoneal cavity (eight, 5.5%), lower level of surgical difficulty (16, 11%) and 133 (91.7%) presented a lower rate of lesion fragmentation. The rate of relevant morbidity (D-CL > II) was significantly lower (p = 0.045), but a higher rate of adenocarcinoma was observed (p = 0.007).

In the multivariate analysis, no predictors of recurrence were found in this group.

Discussion

Advances in surgical expertise and technology have resulted in the development of transanal surgery techniques (TEM, TEO and

Table 2Epidemiology and preoperative variable analysis in obese and non-obese patients.

Variables. Pat	ients (n = 681)		Non-obese n = 536 (78.7%)	Obese (BMI \geq 30 kg/m ²⁾ $n = 145 (21.3\%)$	p
Epidemiology Age (years)(median-IQR-range)			71 (IQR 17 (range: 31 –92)	70 (IQR 15 (range: 42-88)	0.733 ^a , Coefficient b: 0.007, p: 0.601 ^b
	Sex (%)	Male Female	332 (61.9%) 204 (38.1%)	73 (50.3%) 72 (49.7%)	0.008^
	Weight (kg) (median-IQR-range)		69 (IQR 15 (range: 38 –98)	85 (IQR 15 (range: 58-140)	<0.001 ^a
	Height (m) (median-IQR-range)		1.65 (IQR 0.12 (range: 1.4 –1.89)	1.6 (IQR 0.14 (range: 1.37 –1.85)	<0.001 ^a
	BMI (kg)/m ² (median-IQR-range)		25.7 (IQR 3.81 (range: 16.9–29.96)	32 (IQR 4.27 (range: 30–48)	<0.001 ^a
Preoperative	Tumor size (cm) (median-IQR-range)		4 (IQR 2 (range: 0.5-12)	4 (IQR 2 (range: 0.5-11)	0.045 ^a , Coefficient b: 0.204, p: 0.054 ^b
	Tumor size (cm) (%)	Small (0-3) Medium (3 -5)	302 (56.3%)	57 (39.3%) 82 (56.6%)	0.079^
		Big (>5)	52 (9.7%)	6 (4.1%)	
	Distance from anal verge(cm) (median-IQR-range) Distance from proximal margin tumor to anal verge (cm) (median-IQR-range)		7 (IQR 5 (range: 1–22) 11 (IQR 4.5 (range: 1 –25.5)	8 (IQR 5 (range: 2–22) 11 (IQR 4.3 (range: 5–26)	0.062 ^a 0.611 ^a , Coefficient b: 0.032, p: 0.49 ^b
	Proximal margin tumor to anal verge >15 cm		100 (18.7%)	26 (17.9%)	0.474^
	Location of the tumor (%)	Anterior	146 (27.2%	24 (16.6%)	0.021^
		Lateral	228 (42.5%)	76 (52.4%)	
		Posterior	162 (30.2%)	45 (31%)	
	Morphology of the lesion (%)	Flat	122 (23.2%)	24 (23.9%)	0.842^
		Pedunculated		32 (22.5%)	
		Sessil	253 (48.2%)	63 (44.4%)	
		Ulcerated	40 (7.6%)	13 (9.2%)	
	ASA (%)	I	18 (3.4%)	4 (2.8%)	0.313^
		II	295 (55.1%)	69 (47.6%)	
		III	187 (34.9%)	56 (38.6%)	
	Antinonnulouto	IV	36 (/6.7%)	16 (11%)	0.254^
	Anti-platelet medication		41 (7.6%)	14 (.7%)	0.254 [^] 0.257 [^]
	Anti-platelet medication High blood pressure		75 (14%)	24 (16.6%)	0.257 0.005 [^]
	Diabetes mellitus		211 (39.4%) 72 (13.4%)	75 (51.7%) 34 (23.4%)	0.003
	Lung disease		93 (17.4%)	39 (26.9%)	0.003
	Heart disease		91 (17%)	31 (21.4%)	0.008 0.135 [^]
	Hematological disease		7 (1.3)	1 (0.7%)	0.465 [^]
	Chronic kidney failure		24 (4.5%)	7 (4.8%)	0.502 [^]

^a Mann-Whitney U. ^Pearson Chi squared.

b Linear regression ASA(American Society of Anesthesiology score). IQR: Interquartile range.

Table 3Surgical, postoperative and pathological variables: comparison between obese and non-obese patients.

Variables. Pa	tients (n = 681)		Non-obese n = 536 (78.7	7%) Obese (BMI \geq 30 kg/m ²) n = 145	5 (21.3%) p
Surgical	Surgical equipment	TEM	281 (52.4%)	50 (34.5%)	0.01^
		TEO	254 (47.4%)	95 (65.5%)	
	Pieces of the specimen	One piece	501 (93.5%)	133 (91.7%)	0.284^
		Fragmentation	35 (6.5%)	12 (8.3%)	
	Surgeon's experience	>150	262 (48.9%)	63 (43.4%)	0.507^
		150-35	215 (40.1%)	64 (44.1%)	
		<35	59 (11%)	18 (12.4%)	
	Surgical time(min) (med	lian-IQR-range)	70 (IQR 50) (240-20)	65 (IQR 48) (265-25)	0.284 ^a , Coefficient b: 0.002, p: 0.698 ^b
	Surgical time	Short < 60 min	373 (69.6%)	105 (72.4%)	0.375^
		Medium 60	92 (17.2%)	27 (18.6%)	
		-120min			
		Long > 120 min	71 (13.2%)	13 (9%)	
	Perforation into abdomin	nal cavity	40 (7.5%)	8 (5.5%)	0.271^
	Suture of the defect	Complete	461 (86%)	131 (90.3%)	0.397^
		Incomplete	70 (13.3%)	14 (9.7%)	
		Absent	5 (0.9%)	0 (0%)	
Postoperative	e Overall morbidity		123 (22.9%)	27 (18.6%)	0.158^
•	Morbidity (Clavien-	0	412 (77%)	118 (81.4%)	0.546^
	Dindo)				
		I	76 (14.2%)	18 (12.4%)	
		II	16 (3%)	6 (4.1%)	
		IIIa	11 (2.1%)	0 (0%)	
		IIIb	13 (2.4%)	3 (2.1%)	
		Iva	4 (0.7%)	0 (0%)	
		Ivb	1 (0.2%)	0 (0%)	
		V (mortality)	2 (0.4%)	0 (0%)	
	Clinically relevant morbidity ($Cl-D > II$)		31 (5.8)	3 (2.1%)	0.045^
Pathology	Definitive pathology	Adenoma	332 (61.9%)	69 (47.6)	0.007
		Adenocarcinoma	166 (31%)	60 (41.4%)	
		No pathology	38 (7.1%)	16 (11%)	
	Free margins		491 (91.6%)	133 (91.7%)	0.559 [^]
	Full-thickness wall excis	ion	531 (99.1%)	144 (99.3%)	0.624^

^a Mann-Whitney U. ^Pearson Chi squared. TEM: Transanal Endoscopic microsurgery. TEO Transanal Endoscopic Operation. IQR:. IQR: Interquartile range. Cl—D: Clavien-Dindo. * Mann-Whitney U. ^Pearson Chi squared.

TAMIS). In selected patients, this minimally invasive approach for the treatment of rectal lesions has established itself as an alternative to total mesorectal excision. These techniques are becoming increasingly popular among colorectal surgeons due to their reduced morbidity and mortality rates compared to radical laparoscopic surgery. ¹⁰

Despite the high prevalence of obese patients in clinical practice, the evidence regarding the impact of obesity on perioperative outcomes in patients undergoing transanal surgery is very scarce. Fenig et al. ¹⁶ retrospectively analysed outcomes after TEM in 158 patients, and found similar complication rates in obese and nonobese populations. An earlier case-control study published by Kumar et al. ¹⁷ reported similar findings, with no differences between obese and non-obese subjects, but the small size of the case group (only nine patients) meant that the study was not sufficiently powered to detect any significant differences.

The present study is one of the largest comparisons of perioperative outcomes in obese and non-obese patients undergoing transanal surgery. In previous work, our group identified tumor size >6 cm, anti-platelet treatment and surgeon's experience as risk factors for complications after TES in the general population. ¹¹ The present study shows that transanal surgery is safe in the obese population for the resection of both benign and malignant lesions regardless of the height of the lesion, and that the results are similar to those achieved in non-obese patients. Overall morbidity in our series was 22.0%, which is consistent with the post-TES morbidity rates reported previously in the literature (range 7.7%—31.4%). ^{11,18} Furthermore, we found no differences in overall morbidity between the non-obese (22.9%) and the obese groups (18.6%), and the latter group even demonstrated a trend towards fewer

complications. The majority of complications in both groups were mild and did not require specific treatment (Cl-D I and II). Interestingly, there was a difference in clinically relevant morbidity (Cl-D > II), which was significantly higher in the non-obese group (5.8% vs 2.1%). In fact, the only seven patients with life-threatening complications were non-obese. There were two deaths in the non-obese group (0.4%) and none in the obese group. The trend towards more complications and the higher rate of severe complications in the non-obese group could have been influenced by certain factors such as the presence of larger lesions in these patients.

In this study, carried out in a transanal surgery setting, our obese patients did not present greater morbidity, even though these patients usually present associated morbid conditions. This finding is interesting, as it contrasts notably with the evidence with regard to laparoscopic surgery and obesity. Furthermore, our series did not present differences in surgical time between groups (70 min in the non-obese group vs 65 min in obese group; IQR 240–20 vs 265–25), in contrast to the longer operative time that is regularly reported in obese patients undergoing laparoscopic colorectal procedures. ^{19,20} Nor did we observe any differences with respect to intraoperative outcomes such as the rate of perforation into the abdominal cavity (non-obese: 7.5% vs obese: 5.5%) or in the ability to suture the defect after excision of the lesion.

The technical feasibility of the transanal approach in the obese is also supported by our pathological results, which did not find any differences in the quality of surgical specimens in terms of free margins, full thickness wall excision, or fragmentation of the specimen, even though the obese group presented a higher proportion of malignancy.

^b Linear regression.





В

Fig. 2. 2-A: Morbid obesity. 2-B: Perineal area.

For morbid obese (Fig. 2-A) it is important the decision to use rigid (TEM/TEO) or soft platforms (TAMIS) for transanal surgery. We consider that the rigid platform facilitate the surgery in terms of introduction the platform, avoid leak air and placement of the assistant in the perineal area (Fig. 2-B), The same circumstances occur in the local resection of anal canal tumors.²¹

Our study has certain limitations. First of all, it is an observational study with prospective data collection and retrospective analysis, carried out at a single institution. The follow-up of patients with adenomas and adenocarcinomas neither the absence of objective sphincter function and incontinence scores within the study has not been described, due that it has not been the aim of the study. In addition, only nine of the 145 obese patients in our study had morbid or severe obesity (BMI > 40 kg/m2). Future explorations should evaluate the association between the severity of the obesity and surgical outcomes after transanal surgery.

Conclusions

There were no significant differences in the postoperative outcomes in the obese and the non-obese populations undergoing transanal excision of rectal lesions. In our experience, TES in those obese patients (BMI $\geq\!30~kg/m^2)$ does not represent a factor of surgical difficulty and the rigid platform facilitate the surgical technique.

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Declaration of competing interest

The authors have no competing interests to declare.

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