Transanal endoscopic micro-surgery in elderly and very elderly patients: a safe option? Observational study with prospective data collection

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Abstract

Background Although the incidence of colorectal cancer increases with the patient's age, the elderly continue to be less likely to be scheduled for surgery. Transanal endoscopic micro-surgery (TEM) is a surgical alternative to total mesorectal excision (TME) in early stage rectal cancer and/or in selected patients that could decrease morbidity and mortality rates in this group of patients. Our main objective is to assess the safety and feasibility of TEM in elderly (75–84 years) and very elderly (≥ 85 years) patients.

Methods Observational study was conducted with prospective data collection of all consecutive patients who underwent TEM between April 2004 and January 2017. Patients were assigned to groups according to age. Descriptive and comparative analyses between groups were performed.

Results We analyzed 693 patients, 429 patients < 75 years (61.9%), 220 patients between the ages of 75 and 84 (31.7%), and 44 patients ≥ 85 years old (6.3%). The tendency in our series is to increase comorbidities with age. Palliative or consensus intent was more frequently performed in elderly (10.5%, 34/220), and very elderly (45.4%, 20/44), compared with the youngest (6.3%, 27/429), ($p < 0.001$). Global morbidity presented an increasing trend related to age from 20.3% in < 75 years, to 25.9% in elderly and 34.1% in very elderly. Surgical complications were recorded in 18.5% (128/693) of patients with no significant differences between groups. The most common one was rectal bleeding 16.1% (111/693). Significant differences were found in non-surgical complications, recorded in 7.3% (16/220) in the elderly, and 15.9% (7/44) in the group above 84 years ($p = 0.013$).

Conclusions TEM presents acceptable morbidity rates mainly due to non-surgical-related adverse effects in elderly and very elderly patients and may be a feasible and safe alternative in this population in both curative and non-curative indications.

Keywords Transanal endoscopic micro-surgery · Elderly · Rectal cancer · Transanal endoscopic operation · Minimally invasive surgery

The incidence of colorectal cancer increases in direct proportion to age [1]. The effectiveness of surgery in the elderly depends on its safety and its ability to allow the patient to return to his/her baseline state in the shortest time possible.

Surgery is also intended to extend life expectancy, or at least to maintain the quality of life that the patient presented previously [1].

In recent years, surgery has been proposed in selected elderly patients on the grounds that the results may be similar to those obtained in younger patients [2]. However, morbidity and mortality rates are higher in older surgical patients [3] and the elderly continue to be less likely to be scheduled for surgery [4], above all due to poor functional status, baseline comorbidities, and expectations of negative outcomes [4].

Several attempts have been made to establish whether baseline comorbidities and morbidity and mortality associated with surgery increase exponentially with age, and

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whether elderly patients represent a differentiated group. One of the main problems when discussing surgery in the elderly is the lack of a clear definition of this population in the literature. Generally, the cut-off points are 75 years for the elderly and 85 years for the very elderly [1]. In the literature, patients in the latter group do not present increased surgery-related morbidity, probably because they are highly selected [1]. However, a higher percentage of patients in this group will be frail and will have higher mortality [5].

Transanal endoscopic micro-surgery (TEM) is a surgical alternative to total mesorectal excision (TME) in early stage rectal cancer and/or selected patients [6]. Its major advantage is its reduced morbidity and mortality rates in relation to radical surgery or TME [7]. Postoperative morbidity has been reported to range from 7.7 to 31.4% [8, 9]. No genitourinary or sexual changes have been reported with this procedure, nor altered anal continence [10] or any surgery-related mortality [7, 11].

This study was designed to assess the safety and feasibility of TEM in elderly patients (between 75 and 84 years) and the very elderly (over 84 years). A secondary objective was to describe morbidity and mortality in the different groups.

Materials and methods

Observational descriptive study of patients who consecutively underwent TEM at a single center

Patients were enrolled from April 2004 to January 31, 2017. Initially, the TEM technique used was TEM [12]. In 2008, Storz introduced transanal endoscopic operation (TEO) [13] and since then the two systems have been used interchangeably at our center.

Data were collected consecutively and prospectively and stored in a Microsoft Office Access 2007 database in a protected format, in order to prevent the entry of out-of-range or anomalous values as far as was possible.

All patients undergoing TEM during the study period were analyzed. No exclusion criteria were applied. Patients were divided into three groups according to two different cut-off points: 75 and 85 years [1]. All patients who underwent TEM for rectal injury at our unit were studied and treated by the same team of experienced coloproctology surgeons as the literature suggests [14, 15].

Patients were studied with computed tomography, endorectal ultrasound, and magnetic resonance imaging and were assigned by a multidisciplinary committee to the preoperative TEM indication groups described elsewhere [7, 16]. Group I includes rectal lesions with a biopsy of adenoma classified as uT0, uN0 by endorectal ultrasound and magnetic resonance imaging. Group II includes stage uT0-1, uN0 adenocarcinomas. In the group III, the indications are

made by consensus and include stage uT2, uN0 adenocarcinomas. Group IV includes palliative indications, regardless of tumor stage. TEM surgery is also used at our center to treat lesions other than tumors, which are classed as "atypical" indications and form group V of our classification.

All patients underwent preoperative mechanical colon preparation. The position in the operating theater varied according to the quadrant in which the tumor was located. Although general anesthesia is usually recommended in TEM, some high-risk patients were operated under locoregional anesthesia [7]. Surgery involved a full wall resection (with a removal of an en block epithelium–muscularis mucosa–submucosa–muscularis propia–perirectal fat specimen and macroscopically free margins) with an ultrasonic device. Whenever possible, a continuous complete suture of the defect was performed by hand using a long-term absorbable monofilament suture. If there was excessive tension, a partial suture of the defect was performed. If, after TEM, the final pathology report revealed pT2 or pT3 and the patient was not considered for palliative care, a salvage TME was performed within the first postoperative month [17].

The demographic data recorded included age and sex, preoperative comorbidities according to American Society of Anesthesiologists (ASA) score, therapeutic indication, surgical variables, lesion characteristics, and definitive pathological anatomy. Mortality, postoperative morbidity, and adverse effects (AE) according to the Clavien–Dindo classification [18] were also recorded, as were surgery-related re-admissions at 30 days.

Data were processed and analyzed with the IBM 21 SPSS Statistics Data Editor program. In the description of the quantitative variables, means and standard deviations were given. Categorical variables were described in absolute numbers and percentages. The univariate statistical analysis of the quantitative variables with independent groups was performed using the Student's t test provided its conditions of application were met, and otherwise the Mann–Whitney U test was applied. For categorical variables, Pearson's Chi-squared test was used. For the results of the statistical tests, $p < 0.05$ was considered significant.

The study was approved by the local Institutional Ethics Committee (CEIC: 2016-36) and it complied with the criteria of the Declaration of Helsinki.

Results

We analyzed 693 patients, who were divided into a group of 429 patients < 75 years (61.9%), 220 patients between the ages of 75 and 84 years (31.7%), the "elderly" group, and 44 patients ≥ 85 years old (6.3%). These 44 patients comprised our "very elderly" group.

Table 1 displays patients by age group. The population was predominantly male (418 men, 60.3%). The tendency in our series is to increase comorbidities with age and elderly and very elderly patients presented higher rates of arterial hypertension, cardiac, renal, and respiratory diseases, and a larger number of them were receiving treatment with antiplatelet and anticoagulant agents.

Table 2 displays the distribution of these patients by ASA score and age group. As noted above, patients over 75 years presented higher percentages of ASA grade III ($p < 0.001$) compared with patients below the age of 75 who presented in most of cases ASA II.

Indications

Figure 1 shows the distribution of patients according to the surgical indication group [19]. The vast majority of patients in all groups were treated for rectal tumor with curative intent. However, almost half of the very elderly population was in the palliative or consensus indication groups ($p < 0.001$).

Lesion characteristics

The median distance from the anal verge was 7.1 cm without differences between groups. The characteristics of these lesions are described in Table 3. Lesions were significantly larger in older patients [median of 3.7 cm in the group < 75 years, 4.2 cm in the group of patients 75–84 years and 4.5 cm in the "very elderly" group ($p < 0.001$)]. There were no differences in the location of the lesion (anterior, posterior or lateral, left or right) according to age group. The final pathology result in most patients was adenoma; however, in the very elderly patients group (≥ 85 years), adenocarcinoma was the most frequent result ($p = 0.013$). Surgery by TEM for other pathologies was just performed in the youngest group.

Anesthesia used

General anesthesia was administered to 625 patients (90.2%) with no differences according to age group. Loco-regional anesthesia was used in the remainder of the patients.

Table 1 Demographic data and comorbidities of patients undergoing TEM according to age group

	Total n (%)	< 75 years n (%)	75–84 years n (%)	≥ 85 years n (%)	p
Sex					0.110
Women	275 (39.7)	177 (41.3)	87 (39.5)	11 (25.0)	
Men	418 (60.3)	252 (58.7)	133 (60.5)	33 (75.0)	
High blood pressure	315 (45.5)	152 (35.4)	138 (62.7)	25 (56.8)	**< 0.001**
Diabetes Mellitus	114 (16.5)	62 (14.5)	44 (20.0)	8 (18.2)	0.186
Heart disease	133 (19.2)	50 (11.7)	67 (30.5)	16 (36.4)	**< 0.001**
Hematological disease	9 (1.3)	3 (0.7)	4 (1.8)	2 (4.5)	0.071
Respiratory diseases	147 (21.2)	76 (17.7)	57 (25.6)	14 (31.8)	**0.011**
Kidney disease	34 (4.9)	13 (3.0)	16 (7.3)	5 (11.4)	**0.007**
Antiplatelet medication	104 (15.0)	38 (8.9)	52 (23.6)	14 (31.8)	**< 0.001**
Anticoagulant medication	44 (6.3)	17 (4.0)	22 (10.0)	5 (11.4)	**0.004**

Bold values are those which are statistically significant

Table 2 ASA score according to age group

	Total n (%)	< 75 years n (%)	75–84 years n (%)	≥ 85 years n (%)	p
I: Healthy patient	27 (3.9)	25 (5.8)	2 (0.9)	0 (0.0)	
II: Mild disease without functional limitations	368 (52.8)	288 (66.7)	74 (33.6)	6 (13.6)	
III: Life-threatening systemic disease	238 (34.3)	95 (22.1)	111 (50.5)	32 (72.7)	
IV: Moribund patient	59 (8.5)	20 (4.7)	33 (15.0)	6 (13.6)	
Total	692	428	220	44	**< 0.001**

Bold values are those which are statistically significant

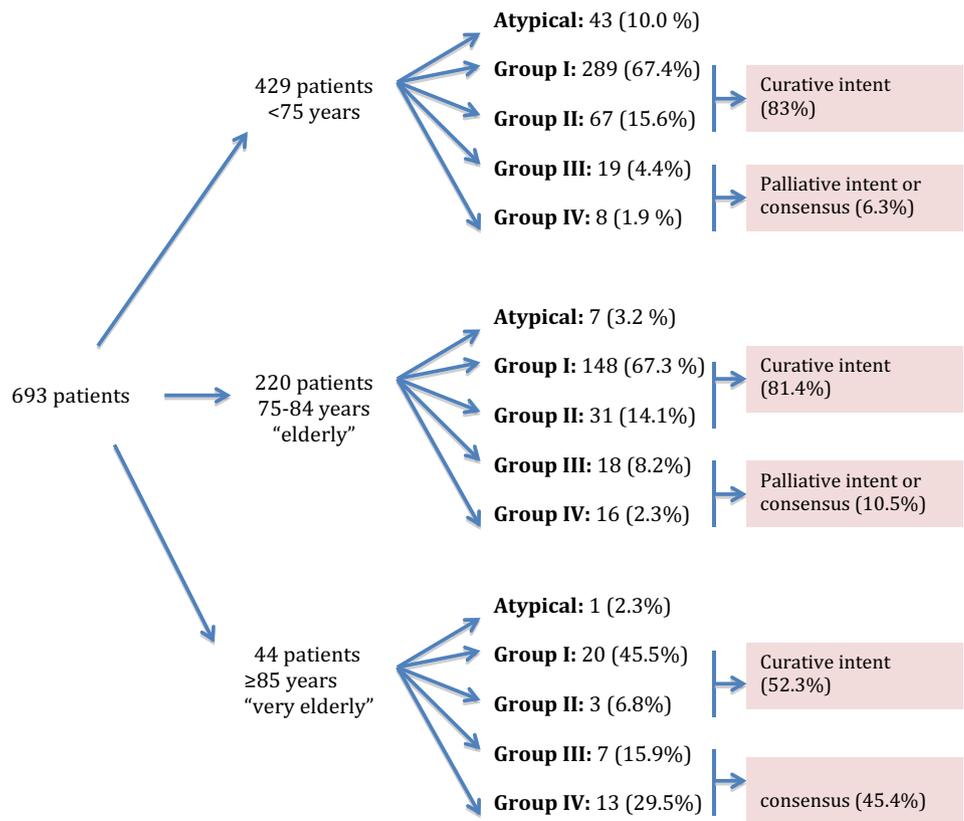**Fig. 1** Flow diagram of the population according to surgical indication group and age

Table 3 Characteristics of the lesion and surgical characteristics according to age group

	Total n (%)	<75 years n (%)	75–84 years n (%)	≥85 years n (%)	p
Distance from verge[a] (cm)	7.1 (3.4)	6.9 (3.5)	7.5 (3.9)	6.3 (3.8)	0.066
Tumor size[a] (cm)	3.9 (1.8)	3.7 (1.8)	4.2 (1.9)	4.5 (2.2)	**<0.001**
Quadrant					0.305
Anterior	179 (25.8)	113 (26.3)	57 (25.9)	9 (20.5)	
Posterior	188 (27.1)	107 (24.9)	65 (29.5)	16 (36.4)	
Left lateral	167 (24.1)	104 (24.2)	50 (22.7)	13 (29.5)	
Right lateral	132 (19.0)	83 (19.3)	43 (19.5)	6 (13.6)	
Pathology					**0.013**
Adenoma	385 (55.6)	241 (56.2)	129 (58.6)	15 (34.1)	
Adenocarcinoma	212 (30.6)	107 (24.9)	80 (36.4)	25 (56.8)	
No pathology	76 (11.0)	61 (14.2)	11 (5.0)	4 (9.1)	
Other pathology	20 (2.9)	20 (4.7)	0 (0.00)	0 (0.00)	
General anesthetic	625 (90.2)	392 (91.4)	192 (87.3)	41 (93.2)	0.385
Surgical technique					
TEM	361(52.3)	217(50.9)	123 (55.9)	21 (47.7)	0.389
TEO	328 (47.5)	209 (49.1)	96 (43.6)	23 (52.3)	
Full wall section	656 (94.8)	401(93.5)	213 (96.8)	43(97.7)	0.577
Perforation	45(6.5)	24 (5.6)	15 (6.8)	6 (13.6)	0.116
Full wall suture	590 (85.1)	368 (85.8)	190 (86.4)	32 (72.7)	0.300
Surgical time[a] (min)	81.29 (40.3)	77.74 (38.4)	85.22 (40.7)	96.32 (50.0)	**0.003**
Total	693	429	220	44	

Bold values are those which are statistically significant

[a]Median (standard deviation). ANOVA test

Surgical technique

No differences were found in the type of equipment used (i.e., TEM 52.3 vs. TEO 47.5%).

A full wall resection was performed in 656/693 patients (94.8%), with no differences according to age group. In 45 patients (6.5%), the abdominal cavity was perforated during the resection. The incidence of perforation was higher in the ≥ 85 years group: 13.6% (6/44 patients), although these differences were no statistically significant ($p = 0.116$).

In the vast majority of patients (590/693, 85.1%), a complete suture of the defect was performed. There were no differences according to age group.

Surgical time

The median surgical time in our series was 81.29 min. Median surgical time increased with age being longer in the very elderly patients (96.32 min) ($p = 0.003$).

Associated morbidity

Table 4 shows the morbidity according to age group and the type of AE according to the Clavien–Dindo classification [18].

Our population presented a global morbidity of 22.9% and presented an increasing trend related to age going from 20.3% in patients < 75 years, to 25.9% in elderly and 34.1% in very elderly. Moreover, older patients presented higher postoperative morbidity over I according to the Clavien–Dindo classification and required more frequently pharmaceutical or surgical treatment when an AE occurs: 7.5% (32/429) in the < 75 years group, 7.7% (17/220) in the 75–84 years group and 22.7% (10/44) in the ≥ 85 years group ($p = 0.002$).

This same table shows a breakdown of the postoperative morbidity. Surgical complications were recorded in 18.5% (128/693), the most common being rectal bleeding 16.1% (111/693). From these 111 patients with rectal bleeding, 89 were self-limited without clinical repercussion (80.2%), endoscopic or radiological treatment was performed in 18 patients (16.2%) and 4 patients required a re-intervention to control it (3.6%). As for patients with anticoagulant treatment (44 patients), 8 of them presented rectal bleeding (18.2%). Thirty-one patients from the group with antiplatelet treatment (104 patients) presented this complication (29.8%). Four patients were treated with both anticoagulant and antiplatelet treatment, one of which presented a rectal bleeding (25%). Other surgical complications were perirectal abscesses, recto-vaginal fistulas, and difficult to control pain, none of them requiring re-interventions.

Finally, non-surgical complications, understood as decompensations of baseline comorbidities (heart failure, arrhythmias, etc.) were recorded in 5.9% of the patients in our series (41/693), with an age-related growing trend: 7.3% (16/220) in the group aged 75–84 years, 15.9% (7/44) in the group above 84 years ($p = 0.013$).

Re-admissions: The overall readmission rate was 7.3% (50/693); no differences were found according to age.

Table 4 Morbidity according to Clavien–Dindo grade and age group

	Total n (%)	< 75 years n (%)	75–84 years n (%)	≥ 85 years n (%)	p
No comorbidity	534 (77.1)	342 (79.7)	163 (74.1)	29 (65.9)	
I: deviation from normal postoperative course without need for treatment	98 (14.1)	54 (12.6)	39 (17.7)	5 (11.4)	
II: need for pharmaceutical treatment	25 (3.6)	15 (3.5)	5 (2.3)	5 (11.4)	
IIIa: need for surgical, endoscopic or radiological treatment without general anesthetic	11 (1.6)	6 (1.4)	3 (1.4)	2 (4.5)	
IIIb: need for surgical, endoscopic or radiological treatment with general anesthetic	16 (2.3)	9 (2.1)	5 (2.3)	2 (4.5)	
IVa: single organ dysfunction	6 (0.9)	2 (0.5)	4 (1.8)	0 (0.0)	
IVb: multiple organ dysfunction	1 (0.1)	0 (0.0)	0 (0.0)	1 (2.3)	
V: exitus	2 (0.3)	1 (0.2)	1 (0.5)	0 (0.0)	**0.001**
Surgical complication	128 (18.5)	67 (15.6)	50 (22.7)	11 (25.0)	0.097
Rectal bleeding	111 (16.1)	56 (13.1)	47 (21.4)	8 (18.2)	**0.025**
Nosocomial infection	24 (3.5)	12 (2.8)	7 (3.2)	5 (11.4)	**0.031**
Non-surgical complications	41 (5.9)	18 (4.2)	16 (7.3)	7 (15.9)	**0.013**
Re-admissions	50 (7.3)	31 (7.3)	14 (6.4)	5 (11.4)	0.506
Total	693	429	220	44	

Bold values are those which are statistically significant

Discussion

Because of the association of age and morbidity/mortality [3], elderly patients are less likely to undergo surgery than their younger peers [4]. TEM, a minimally invasive surgical approach that is associated with lower morbidity and mortality than TME in colorectal cancer, may be a valid option in this group of patients. To date, the results with the TEM technique in elderly and very elderly patients have not been published and this is one of the objectives of this study. There are other alternative approaches for transanal excision of local rectal cancer just as Transanal Minimally Invasive Surgery (TAMIS) with similar results [20] but they are outside the scope of this study since they are not routinely used in our center.

One of the main problems when discussing surgery in the elderly is the lack of a clear definition of this age group, as different authors have used different cut-off points to define age. In general, the cut-off points tend to be set at 75 years for the elderly and 85 years for very elderly patients [1]. In our series of 693 patients, we applied two different cut-off points, including patients aged 75 years or over (38.1%) in the elderly population and those aged 85 years or over (6.3%) in the very elderly population. This allowed us to detect an age-related growing trend in comorbidities and to distinguish a group of over-85s with more baseline comorbidities than their peers below this age and a higher use of anticoagulant and antiplatelet treatment. This distinctive group presented larger tumors and a definitive pathological anatomy more likely to be adenocarcinoma, which leaded to larger surgical times and a higher risk of perforation to abdominal cavity. Another one of the most important age-related differences in our series was found in the consensus and palliative groups, much more frequent in very elderly group. Moreover, very elderly patients are more prone to suffer from non-surgical complications and when they occur, they present a higher-grade morbidity according to the Clavien–Dindo classification.

As revealed above, comorbidities increase with age and while the majority of younger patients are part of group II according to ASA score, most of elderly and very elderly patients present a life-threatening systemic disease (ASA III).

Unlike the very elderly group, the vast majority of patients were operated upon with curative intent (surgical indication groups I and II). Anyway, an age-related growing trend was found in the use of non-curative indication. The percentage of patients undergoing TEM with non-curative intent was 10.5% in patients with ages comprised between 75 and 84 years, and 45.5% in patients aged 85 and older. In this group, in which TME may well cause elevated morbidity but will not achieve a satisfactory cancer outcome, less aggressive surgery that is able to obtain partial disease control appears to be a reasonable choice; it will reduce the local symptoms of rectal cancer and restore the patient's quality of life to pre-surgery levels. We would like to highlight that all patients treated with non-curative intent were carefully selected in a multidisciplinary committee. Moreover, in these patients, curative intention surgery was dismissed due to frailty or high basal comorbidities, which conferred a too high-risk surgery.

The final pathology result in most patients was adenoma. In 2014, our group published an observational study showing that a high proportion of rectal adenomas are, in fact, invasive adenocarcinomas [21]. Since then, we perform full-thickness excision in all the adenomas, either by endoscopy or by TEM when lesions are too big to be removed endoscopically.

General anesthesia is usually recommended in TEM, since it achieves complete relaxation of the patient and facilitates the pneumorectum. However, loco-regional anesthesia can be used in selected patients [7], especially in those with baseline comorbidities that involve a high surgical risk. Most TEM patients in our series underwent general anesthesia, with no statistically significant differences according to age group. This suggests that the use of loco-regional anesthesia is independent of the patient's age and that elderly and very elderly patients can be administered either anesthetic technique, depending on the specific needs of the individual.

Approximately half of the series underwent surgery with TEM equipment, and the other half with TEO. Since these two techniques have shown elsewhere to present with similar results [22], both techniques were used indistinctively.

In the vast majority of patients, a full wall resection was performed. Again, there were no differences according to age group. When full wall resection was not possible, a mucosectomy or partial wall resection was chosen. All defects are systematically closed in our center, with a complete suture whenever is possible, since there appears to be fewer postoperative complications when the defect is sutured [23]. A complete suture of the defect was performed in most cases of this series, with no differences between groups.

Few abdominal cavity perforations during the resection of the specimen occurred in any of the groups, though the likelihood of this event increased with age. Anyway, we would like to highlight that none of this patients required anything else but a closure of the perforation without any other AE associated.

Median surgical time also increased with age. Larger lesions and non-curative intention surgery in the very elderly group exposed above could explain this increment.

To analyze safety, we recorded morbidity in the form of AE associated with the surgery at 30 days. Morbidity in our series increased with age, rising from 20.3% in patients

aged < 75 to 34.1% in the ≥ 85 group. These morbidity rates may seem high. Anyway, we would like to stress that are the result of a systematic, prospective and exhaustive recording of AE [24] in operation at our service in all patients undergoing surgery. Clavien–Dindo classification was used to analyze postoperative adverse effects. We used Clavien–Dindo since it has been used in several studies analyzing adverse effects and gives the chance to compare to other results [25].

In addition to a higher morbidity related to age, very elderly patients presented higher-grade morbidity according to Clavien–Dindo classification, which required added treatment and implied multiorgan dysfunction in more cases, probably because of their vulnerability and their less effective physiological responses to possible complications [26]. However, we would like to highlight that differences in surgery-related AE between groups are not statistically significant and main differences are found according to more medical complications such as decompensation of underlying pathologies which have also been described in the literature [3] and to more nosocomial infections just as respiratory or urinary infections.

Breaking down surgical complications, the most frequent AE was rectal bleeding, self-limited in the majority of cases. Although we do not find statistically significant differences in surgical complications between groups, there is a growing trend of rectal bleeding in elderly and very elderly patients, probably associated to the increasing tendency of treatment with anticoagulant and antiplatelet in this groups, associated to a higher risk of bleeding (25% of patients with both treatment presented with this complication).

Finally, we saw that age was not a risk factor for readmission after TEM surgery, a finding that supports the safety of this technique in older patients.

Recently, the concept of "frailty" has been introduced in the literature. Frailty is understood as a clinical syndrome which involves a progressive loss of physical and mental functions [27] and makes an individual more likely to develop postoperative complications or to die [28]. Some of the studies published on the frailty of patients undergoing surgery conclude that although this condition is highly prevalent in the elderly, age is not a good predictor of complications after an acute stress such as surgery [27]. This suggests that, perhaps, chronological age alone is not a valid reason for ruling out surgery, especially in the case of minimally invasive surgeries such as TEM.

The main limitation of the study is that it is an observational, non-randomized study. This impedes drawing solid conclusions or performing analysis that could also be interesting just as seeing if age is an independent factor for complications (although results obtained in this series suggest it is not). Moreover, it could be scientifically interesting to compare TEM to radical surgery in elderly and very elderly patients to draw safety and feasibility conclusions but it would be ethically unacceptable as radical surgery is a too aggressive treatment in some elderly and very elderly patients. Nonetheless, it presents one of the largest series of patients undergoing TEM, and so, we consider that the results obtained may be relevant. In addition, the study's external validity is borne out by the fact that the data were collected prospectively and consecutively and also by the fact that it included all patients operated upon via TEM during the study period. Moreover, thorough collection of AE performed systematically in our service applies a greater weight based on results achieved. Another possible limitation is the lack of oncological results. We stress that the assessment of oncological outcomes was not the aim of this paper and we are fully convinced that curative intent is not our main goal in some populations with high risk of mortality at 30 days [29]. In these patients, maintaining quality of life must be the main objective [1, 28].

In conclusion, TEM is a type of minimally invasive surgery that presents acceptable morbidity rates in elderly (over-75) and very elderly (over-85) patients. Albeit higher than in the general population, main differences in morbidity between groups are mainly related to non-surgical complications such as decompensation of baseline comorbidities. These findings show that TEM may be a feasible and safe alternative in elderly and very elderly in curative intention and a reasonable choice in palliative surgery. They also suggest that a surgical approach should not be ruled out on the grounds of age alone.

Compliance with ethical standards

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