

## Prospective Study

## Sphincter lesions observed on ultrasound after transanal endoscopic surgery

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### Abstract

**AIM:** To assess the morphological impact of transanal endoscopic surgery on the sphincter apparatus using the modified Starck classification.

**METHODS:** A prospective, observational study of 118 consecutive patients undergoing Transanal Endoscopic Operation/Transanal Endoscopic Microsurgery (TEO/TEM) from March 2013 to May 2014 was performed. All the patients underwent an endoanal ultrasound prior to surgery and one and four months postoperatively in order to measure sphincter width, identify sphincter defects and to quantify them in terms of the level, depth and size of the affected anal canal. To assess the lesions, we used the "modified" Starck classification, which incorporates the variable "sphincter fragmentation". The results were correlated with the Wexner incontinence questionnaire.

**RESULTS:** Of the 118 patients, twelve (sphincter lesions) were excluded. The results of the 106 patients were as follows after one month: 31 (29.2%) lesions found on ultrasound after one month, median overall Starck score of 4 (range 3-6); 10 (9.4%) defects in the internal anal sphincter (IAS) and 3 (2.8%) in the external anal sphincter (EAS); 17 patients (16%) had fragmentation of the sphincter apparatus with both sphincters affected in one case. At four months: 7 (6.6%) defects, all in the IAS, overall median Starck score of 4 (range 3-6). Mean IAS widths were 3.5 mm (SD 1.14) preoperatively, 4.38 mm (SD 2.1) one month postoperatively and 4.03 mm (SD 1.46) four months postoperatively. The only statistically significant difference in sphincter width in the IAS measurements was between preoperatively and one month postoperatively. No incontinence was reported, even in cases of ultrasound abnormalities.

**CONCLUSION:** TEO/TEM may produce ultrasound

abnormalities but this is not accompanied by clinical changes in continence. The modified Starck classification is useful for describing and managing these disorders.

**Key words:** Transanal endoscopic surgery; Endoscopic ultrasound; Anal continence; Starck classification; Sphincter lesions

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**Core tip:** This prospective study shows that transanal endoscopic surgery does not produce lesions in the sphincter apparatus. Alterations are described after using a 4 cm diameter rectoscope, with no alterations in continence.

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## INTRODUCTION

Transanal endoscopic surgery of rectal lesions, either by Transanal Endoscopic Microsurgery (TEM-Wolf) or by Transanal Endoscopic Operation (TEO-Storz), involves minimal surgical aggression compared to total mesorectal excision (TME)<sup>[1]</sup>. Morbidity rates of 5% and mortality rates of 0.3% have been reported in transanal endoscopic surgery (TEO-TEM)<sup>[2-5]</sup>. In contrast, morbidity rates associated with TME are estimated at between 7%-68% and mortality rates at 2%-4%. In addition, between 20% and 30% of TME patients report genitourinary disorders and impaired sexual function<sup>[6-10]</sup>.

Few studies have described morphological alterations of the sphincter after transanal endoscopic surgery. Most of those published to date have focused on functional impairment using continence questionnaires and manometry.

The performance of forced anal dilatations and the use of instruments like Parks' anal retractor may damage the sphincter apparatus, especially the internal anal sphincter (IAS)<sup>[11-13]</sup>.

During TEO/TEM, a 4 cm diameter rectoscope is used for anal canal dilatation, albeit in a controlled manner. Among the few studies published on the impact of continence caused by TEO/TEM, most agree that basal pressure (BP) and voluntary contraction pressure (VCP) both fall in comparison with the preoperative data and they tend towards normalization within six months postoperatively, although without reaching the initial rates. Our group recently described a series of 201 patients with reduced BP and VCP

after one and four months. According to the Wexner test results, however, this decrease in pressure does not lead to clinical incontinence and no risk factors for incontinence have been identified. Apparently TEO/TEM causes abnormalities in both smooth muscle (IAS) and striated muscle (external anal sphincter, EAS). While the striated muscle recovers postoperatively, the smooth muscle remains damaged<sup>[14,15]</sup>.

Little is known of TEO/TEM's morphological impact on the sphincter apparatus and its correlation with continence. In addition, these possible sphincter alterations are difficult to classify and monitor.

The aim of the present study is to describe the possible morphological lesions of EAS and IAS after TEO/TEM and their correlation with clinical symptoms. We applied a modified version of the Starck classification<sup>[15]</sup>, previously used to describe obstetric sphincter injuries and now adapted to assess abnormalities after TEO/TEM.

## MATERIALS AND METHODS

A prospective, observational study of 112 consecutive patients undergoing transanal endoscopic surgery was performed. All the patients underwent anal ultrasound prior to surgery and then one and four months postoperatively.

Ultrasound was performed using the Hawk EXL B-K medical scanner B and 1850 endosound probe with a latex sheath. The exploration was performed with the patient in the left lateral position. The presence of IAS and EAS defects was assessed using the modified Starck classification: level of anal canal affected (dividing the canal into thirds), depth (involvement of the entire sphincter or of only part) and size (involvement of up to 90° of the sphincter circumference, between 90° and 180°, or above 180°). Sphincter fragmentation was also assessed in the postoperative control scans<sup>[16]</sup> (Table 1), defined as an increase in the thickness of the sphincter affected (either the IAS or the EAS) accompanied by poorly defined margins.

During the examinations prior to surgery and at one and four months postoperatively, patients completed the Wexner incontinence questionnaire. Patients with Wexner scores of 6 or higher were considered to be incontinent<sup>[17]</sup>. The width of both sphincters was recorded in each of the three ultrasound sessions in the middle anal canal.

To calculate the number of subjects required, we started from an estimated proportion of 25% with an alpha value of 0.05. Assuming a maximum error of 10%, we obtained the figure of 73 patients. Assuming a possible loss of 25% (19 patients), the minimum number of patients was 92.

Quantitative variables are described taking the mean and standard deviation when the distribution was normal, otherwise the values of median and

**Table 1 Modified Starck classification**

Score	0	1	2	3
Eas defect				
Length	No	≤ 50%	> 50%	Total
Depth	No	Partial	Total	-
Size	No	≤ 90°	90°-180°	>180°
EAS fragmentation : Yes/no				
IAS defect				
Length	No	≤ 50%	> 50%	Total
Depth	No	Partial	Total	-
Size	No	≤ 90°	90°-180°	> 180°
IAS fragmentation: Yes /no				
No defect: Score = 0; Maximum defect: Score =16				
Considered as defect: score > 8				

EAS: External anal sphincter; IAS: Internal anal sphincter.

range. Categorical variables are described in absolute numbers and percentages. The statistical analysis of the quantitative variables was performed using the Student "t" parametric test for paired data; if a nonparametric test was necessary, the Wilcoxon T test was used. The variable "Wexner test" was analyzed as a categorical variable since Wexner scores  $\geq 6$  indicate incontinence and scores  $< 6$  indicate continence. The data were analyzed using the McNemar test of symmetry. *P* values of  $< 0.05$  were considered statistically significant. All data were analyzed using SPSS version 18.0.

## RESULTS

From March 2013 to May 2014, 118 patients were evaluated. Twelve were excluded from the study: six who presented sphincter abnormalities on preoperative ultrasound, three with fragmentation of the IAS, two with a left posterolateral defect due to prior internal lateral sphincterotomy and one who had previously undergone rectovaginal fistula repair. The 106 remaining patients comprised 59 men and 47 women with a mean age of 68 years (SD 11; range: 33-86 years). Table 2 displays all the patient characteristics.

Table 3 shows these abnormalities using the Starck classification. Ultrasound at one month identified 31 abnormalities (29.2%) with a median overall Stark score of 4 (range 3-6). Ten defects were in the IAS (9.4%), with a median Stark score of 4 (range 3-5), and 3 in the EAS (2.8%), with a median Stark score of 4 (range 4-6). Seventeen patients (16%) presented with fragmentation of the sphincter apparatus (one case with both EAS and IAS involvement, the others with only IAS involvement). The ultrasound performed at four months revealed only seven abnormalities in the IAS (6.6%), with a median Stark score of 4 (range 3-6).

Focusing on the length of the IAS abnormalities at one month, the middle anal canal was involved in all cases but one. Only two cases also presented with

**Table 2 Patient characteristics**

Lesion characteristics	
Lesion size	4.3 ± 2.17 cm (1-12 cm)
Lesion height	10.2 ± 14.02 cm (1-15 cm)
Quadrants affected by lesion	1 quadrant: 40 patients 2 quadrants: 52 patients 3 quadrants: 10 patients 4 quadrants: 1 patient
Surgical characteristics	
Surgical time	98.0 ± 45.4 min (25-265 min)
Surgical position	Lithotomy: 29 patients Prone: 24 patients Left lateral: 29 patients Right lateral: 21 patients
Hospital stay	4.2 ± 3.38 d (2-34 d)

upper anal canal involvement and only one presented with involvement of the upper anal canal alone. In most cases the defect was partial and in only three cases was it complete. The median degree of the circumference of the IAS affected at one month was 67.5° (range 27°-141°), that is, below half in all cases. As for abnormalities in the EAS, the middle anal canal was affected in all cases and one case presented with lower anal canal involvement. All the defects were complete and the median degree of involvement of the circumference was between 55° and 105°.

In the scan at four months, only the IAS continued to present with defects. In three of the ten cases which presented with IAS defects at one month the defect had disappeared. The seven remaining cases were patients with persistent abnormalities affecting the middle anal canal and two also presented with a defect in the upper anal canal. Most of the defects were complete, three were partial, and the degrees of circumference affected ranged between 45° and 180°. All patients had Wexner scores between 1 and 2 at both one and four months.

As regards sphincter width in the 106 patients, the mean IAS width was 3.5 mm (SD 1.14) preoperatively, 4.38 mm (SD: 2.1) one month postoperatively and 4.03 mm (SD 1.46) after four months. Mean EAS width was 7.33 mm (SD 2.01) preoperatively, 7.47 mm (SD 1.92) one month postoperatively and 7.14 mm (SD 2.36) at four months (Table 4).

The differences of the means were calculated by paired data analysis and were correlated with the variation in continence. Sphincter width differed between the preoperative scan and the scans at one and four months, although the only significant difference was in IAS width between the preoperative and one month postoperative measurements. No clinical incontinence was recorded at any of the time points. The difference on the Wexner questionnaire comparing preoperative data and data at one and four months was 0.4; it was not statistically significant in either case and all patients had scores well below 6.



Table 4 Description of sphincter width

	EAI			EAE			WEXNER
	Average difference	DE	P value	Average difference	DE	P value	McNemar (Sig)
Preop-1m	-0.70	1.58	0.0008	-0.310	2.34	0.13	1.0
Preop- 4m	-0.38	1.81	0.0590	0.081	2.51	0.59	0.4

In a series of 112 patients studied by our group<sup>[14]</sup>, abnormalities were observed in the IAS in 10 (9.4%) cases and in the EAS in 3 (2.8%). At four months, only 7 patients (6.6%) had ultrasound abnormalities, all in the IAS. These abnormalities were detected on the ultrasound at one month and persisted over time. Only one case presented with a deterioration since the scan at one month; however, the variation was slight and may in fact have been due to inaccuracies in the measurement since this exploration is observer-dependent.

Our findings of sphincter fragmentation and the increase in IAS width have rarely been reported by other groups. In the few previous descriptions published to date they were considered as sphincter injuries<sup>[12]</sup> but in our study we did not see any functional impact. In our group, we saw sphincter fragmentation in 17 (16%) patients in the ultrasound scan after a month, mainly in the IAS; we only found one case affecting the EAS, which also presented as IAS fragmentation, but this abnormality was no longer observed at four months. Both these variations may be immediate consequences of the surgery.

As far as continence was concerned, no differences were observed at either postoperative assessment between patients with ultrasound abnormalities and those without. No patients presented with clinical symptoms of incontinence. All patients (both those with and without ultrasound abnormalities) had Wexner scores below 2 - that is, well below 6, which is considered the cut-off point for incontinence.

Comparing the width of both sphincters in the scans preoperatively and at one and four months postoperatively, we found statistically significant differences in the measurement of the IAS prior to surgery and at one month. This is probably related to the appearance of sphincter fragmentation, which was observed in 17 (16%) cases after one month. It may be that the IAS is affected in all cases, although not enough to cause fragmentation. In our patients, IAS width had returned to normal four months after surgery and, in our view, the variations were not associated with any clinical abnormality.

In conclusion, endoscopic transanal surgery may produce ultrasound abnormalities in the sphincter apparatus, especially in the IAS. However, these abnormalities have little clinical impact on continence. The modified Starck classification appears to be a good tool for diagnosing and monitoring the sphincter defects identified by ultrasound since it demonstrates

the low impact of the impairment.

## COMMENTS

### Background

Performing transanal surgery using a rigid rectoscope (TEO/TEM) is increasing as it allows the excision of benign rectal lesions and initial malignant rectal lesions. This may be expanded to the removal of foreign bodies, pelvic abscess debridement or excision of presacral tumors, part of NOTES surgery. A rigid 4 cm diameter rectoscope is used to produce a forced and maintained anal dilatation throughout the process, which can be 1 to 4 h. Little is known about the impact of this anal dilatation on anal continence. The authors have already done a study showing that at a functional level this procedure does not produce clinical changes but as they do not know what the morphological alterations that may result could be, this study has been carried out. In addition, the authors have shown that the Starck classification is useful for defining possible alterations that can be generated from the rigid rectoscope.

### Research frontiers

In this study, the authors demonstrated that the use of a rigid rectoscope for performing transanal surgery produces little morphological alterations on the sphincter apparatus and no changes in clinical continence. The modified Starck classification appears to be a good tool for diagnosing and monitoring the sphincter defects identified by ultrasound.

### Innovations and breakthroughs

There are very few studies that analyze the ultrasound effects on the sphincter that transanal surgery by TEO/TEM may cause. There are only two studies that have described sphincter lesions on the internal anal sphincter in 6/40 (Garcia-Solanas) or 5/37 (Jin) patients studied. Both refer to alterations in clinical continence which subsequently recovered. The authors show that the sphincter alterations do not become injuries and have no impact on clinical continence.

### Applications

The absence of sphincter lesions and the lack of clinical impact on continence after TEO/TEM means that this procedure can be used without fear of causing incontinence in patients and that it can be indicated for procedures already mentioned at the beginning: NOTES and presacral tumor resection.

### Terminology

Transanal surgery (TEO/TEM): specific surgery that allows approach by transanal excision of rectal lesions. This requires a specific instrument, a 4 cm diameter rigid rectoscope, has a learning curve before it can be used and allows a better view of the injury. The Starck classification of anal lesions was initially used to describe obstetric injury.

### Peer-review

A descriptive study that can prove that the use of a rigid 4 cm diameter sigmoidoscope does not produce ultrasound abnormalities in the sphincter apparatus and has no clinical impact on continence. It shows that using the Starck classification to diagnose and follow the sphincter ultrasound changes is a good tool.

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