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Endoscopic band ligation for the treatment of hemorrhoidal disease

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ABSTRACT – **Background** – There are several therapeutic options for symptomatic hemorrhoids, from hygienic and dietary measures to conventional surgery. The best technique adopted for alternative and non-surgical treatment for intermediate grade (II and III) hemorrhoidal disease is rubber band ligation. More recently, the technique has been used with the aid of a gastroscope and a kit of elastic rubber bands for esophageal varices. This technique was called Endoscopic Rubber Band Ligation of hemorrhoids (ERBL). **Objective** – The objective is Compare the results and the incidence of the immediate and late complications in patients undergoing ERBL. The satisfaction with the treatment of patients undergoing different number of rubber band ligatures were also analyzed. **Methods** – This is a cohort study included patients undergoing ERBL from 2007 to 2014 at the hospital. The incidence of early and late complications and the satisfaction with the treatment of patients undergoing until two ligatures and patients undergoing three or more ligatures in the same procedure were compared. **Results** – The study included 116 patients. The most frequently reported symptom was anal bleeding (n=72; 62.1%). The number of rubber band ligatures performed during the ERBL procedure varied from one to six; 84 (72,4%) patients had three or more rubber band ligatures performed during the procedure. No significant associations were observed between the incidence of early or late complications and satisfaction with ERBL among the group subjected until two rubber band ligatures or three or more rubber band ligatures. **Conclusion** – The endoscopic elastic ligation method proved to be a feasible, safe and efficient for the treatment of symptomatic hemorrhoidal disease grades II and III. The technique had moderate rates of immediate and late complications, but most of the complications are considered of low magnitude, easily resolved and without clinical repercussions, no matter how much ligations were performed in the same procedure.

HEADINGS – Hemorrhoids, therapy. Ligation. Colorectal surgery. Colonoscopy. Treatment outcome.

INTRODUCTION

Hemorrhoids are swollen veins of the hemorrhoidal plexus, a normal anatomical structure present in the anal canal that is involved in mechanical protection against the passage of stool, gas and fecal continence and venous drainage of the anorectal region. Whenever the connective tissue that supports the anorectal region is compromised, hemorrhoids become clinically detectable[1].

Hemorrhoidal disease (HD) is characterized by the symptomatology derived from the prolapse and consequent dilatation of these vessels. Other associated symptoms include inflammation, pruritus, hemorrhage and thrombosis of these structures. Several risk factors are described in the pathogenesis of HD such as excessive force during evacuation, chronic constipation, low fiber diet, pregnancy, heredity, age and occupation[2].

The prevalence of hemorrhoidal disease in the United States is approximately 4.4%, and HD occurs more commonly in white and economically privileged populations, without variations according to age or sex[3]. The National Institutes of Health (NIH) in the United States estimates that 10.4 million Americans seek medical attention for complaints related to the HD every year, resulting in expenditure of approximately 500 million dollars[4].

Internal hemorrhoids can be classified based on prolapse grade according to the Goligher scale[5]: grade I - bleeding only, without prolapse; grade II - prolapse that reduces spontaneously, with or without bleeding; grade III – prolapse requiring manual reduction, with or without bleeding; and grade IV - prolapse of irreducible hemorrhoidal tissue.

HD treatment varies according to the prolapse grade. Grade I and II internal hemorrhoids are suitable for clinical therapy only. Grade III and IV hemorrhoids and those refractory to the clinical approach usually require more extensive treatment. The range of techniques used varies from non-operative and minimally invasive procedures to excisional or non-excisional surgical techniques[6]. Usually, surgical treatment for HD is reserved for patients who have failed clinical treatment and have mixed and grade IV hemorrhoids.

Non-operative therapies may be a better option than surgery as a first approach due to their benign nature, the high morbidity associated with surgery, the considerable pain and duration of convalescence during the postoperative period, especially for patients with Grade III internal hemorrhoids.

Countless minimally invasive techniques are described in the literature, such as elastic ligation, coagulation with infrared radiation, cryotherapy, bipolar electrocoagulation, laser photocoagulation, sclerotherapy and radiofrequency ablation.

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Elastic ligation of hemorrhoidal cushions is the most commonly used non-operative technique. Initially introduced by Blaisdell[7] in 1958 and modified by Barron[8] in 1963, elastic ligation is an effective, quick, simple and low-cost technique for the treatment of symptomatic hemorrhoidal disease[9]. Recent studies have shown that elastic ligation has better resolution indexes and lower rates of recurrence in the long term compared with other approaches[10-12].

Endoscopic rubber band ligation (ERBL) combines the classical technique of elastic ligation with an endoscopic examination providing better control, the possibility of photographic recording and sedation within a hospital environment. The device used for ERBL is the same as for esophageal varices, allowing multiple hemorrhoidal ligations to be performed within a single procedure and avoiding the need for multiple sessions.

The objective of this study was to evaluate the feasibility of ERBL for the treatment of hemorrhoids and to describe the immediate and late complications of this procedure. This study also aimed to investigate the safety of multiple ligations within a single ERBL procedure.

METHODS

From January 2007 to June 2014, symptomatic patients with grade II or III hemorrhoids refractory to clinical treatment were referred to the Endoscopy Unit of Hospital Sirio-Libanês.

Patients with severe comorbidities (liver cirrhosis, HIV carriers, chronic renal failure, chronic obstructive pulmonary disease and coronary heart disease), use of heparin, warfarin, acetylsalicylic acid, clopridogrel or other systemic anticoagulants, previous operative treatment of hemorrhoidal disease, presence of hemorrhoidal thrombosis, perianal abscess, perianal fistula, anal fissure, radiation proctitis, inflammatory bowel disease, colorectal cancer, anal canal cancer, anal condylomatosis and rectal varices were excluded from this study.

Patients were admitted to the Endoscopy Department of the Hospital Sirio-Libanês, and a colonoscopy exam was performed under sedation and anesthesia after adequate colon preparation. After the complete endoscopic exam was performed, elastic ligation of the hemorrhoidal cushions was conducted using a gastroscope in retro-vision with an endoscopic elastic ligature device for esophageal varices (Cook Endoscopy, Winston-Salem, NC or Super Superview Super 7 from Boston Scientific, Marborough, MA) attached to the tip. The most prominent hemorrhoidal cushion was ligated first, followed by the other vessels, until all endoscopically visible cushions were ligated (FIGURE 1).

The ligation technique consisted of aspirating the hemorrhoidal cushion into the cap of the elastic band kit. Once the hemorrhoidal cushion was lying inside the cap, the elastic band was fired. All ligatures were performed above the dentate line to minimize post-procedure pain. The ligation kit was then removed from the gastroscope, which was reintroduced to ensure correct placement of the elastic bands (FIGURE 2).

The patients were observed for two hours after the procedure and were then discharged with a follow-up consultation scheduled 10 to 14 days after the procedure. Patients received hygienic and dietary guidelines as well as medical prescriptions for simple analgesics in case of local pain.

Complaints about ERBL, which arose from the moment of the ligation up to 48 hours after the procedure, were considered early or immediate complications. Symptoms reported after 48 hours were considered late complications. The patients were asked to quantify their degree of satisfaction with the ERBL. These data were recorded on each patient's medical chart within the physician's office.

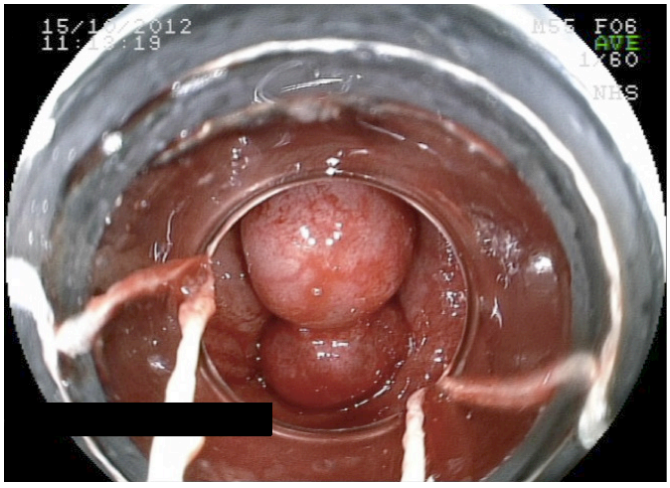

FIGURE 1. Hemorrhoidal band ligation. Immediately after application.

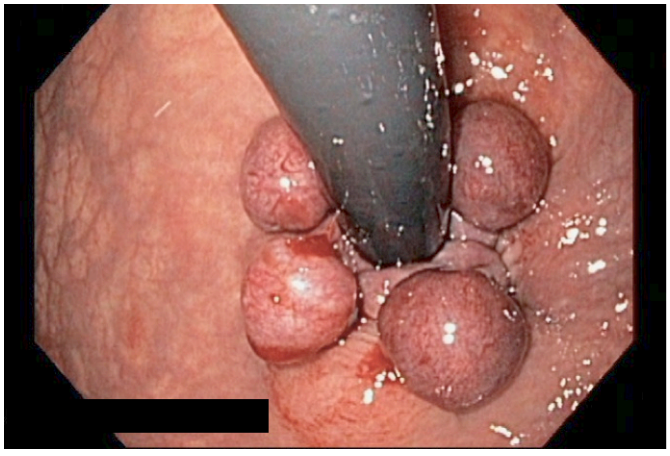

FIGURE 2. Status after ligations of the hemorrhoidal nipples. Gastroscopy in retrovision without the cap device.

To analyze the correlation between adverse effects and the number of elastic bands placed, the patients were divided into two groups: one or two and three or more elastic bands.

The data collected was then entered into a worksheet using Microsoft Excel. After the data were checked for consistency, a descriptive analysis was conducted with absolute frequencies and percentages for qualitative variables and measures of central tendency (mean or median) and dispersion (standard deviation or first [p25] and third [P75] quartiles) for the quantitative variables. To test the association between the number of ligatures performed and the frequency of immediate complications after ERBL, the Kruskal-Wallis test was used (since the number of ligatures was not normal). The Wilcoxon test was used to test the association between the occurrence of bleeding or pain and the number of ligatures performed. The correlation between the number of ligatures and the score given for the pain intensity was evaluated using Spearman's correlation coefficient (ϱ [rô]). The Chi-square test was used to determine the association between the incidence of early or late complications and patient groups. This test was also used

to compare satisfaction rates between groups. A comparison of pain intensity according to the groups was performed using the Wilcoxon test (since the pain intensity variable did not present a normal distribution). The statistical significance level was set at $P<0.05$. Statistical analyses were performed using the statistical program Stata® (version 13.1).

This project was submitted and approved by the Ethics Committee on Research in Human Beings of the Institute of Education and Research of the Hospital Sirio-Libanês.

RESULTS

Of a total of 127 patients, 11 were excluded from the study. Two elderly patients were excluded because of cognitive deficits, and five patients had heart disease and were using multiple oral anticoagulants and antiplatelet drugs. Four patients had undergone previous surgical treatment of hemorrhoidal disease.

The study included 116 patients, of whom 76 (65.5%) were men. The patients' age ranged from 30 to 88 years (mean =53.9 years, standard deviation ±11.6 years). Seventy-two (62.1%) patients had only one previous symptom of hemorrhoidal disease, and the most frequently reported symptom was anal bleeding (n=72; 62.1%) (TABLE 1). The number of bandages applied during the ERBL ranged from one to six; 84 (72.4%) patients had three or more ligatures performed during the same procedure.

TABLE 1. Preoperative symptoms and number of bands performed in patients undergoing endoscopic band ligation of hemorrhoids. (n=116).

	n	%
Number of symptoms		
One	72	62.1
Two	44	37.9
Symptoms*		
Bleeding	97	83.6
Prolapse	49	42.2
Pain	13	11.2
Pruritus	1	0.9
Numbers of bands placed		
One	9	7.8
Two	23	19.8
Three	35	30.2
Four	27	23.3
Five	15	12.9
Six	7	6.0

*The sum of symptoms exceeds the total number of patients, as 44 patients had more than one symptom. For the symptoms prevalence estimation, the total number of patients (n=116) was used as the denominator.

Twenty-four (20.7%) patients did not present any immediate complications after the ERBL procedure (TABLE 2). The two most frequent immediate complications were pain (n=64, 55.2%) and anal bleeding (n=34, 29.3%). The pain intensity score after the ERBL procedure ranged from zero to 10 (median = 4, p25=2, p75=6).

TABLE 2. Early complications of patients undergoing endoscopic band ligation of hemorrhoids. (n=116).

	n	%
Number of immediate post-procedure complications		
None	24	20.7
One	80	69.0
Two	12	10.3
Immediate post-procedure complications *		
Pain	64	55.2
Bleeding	34	29.3
Bacteremia	4	3.4
Tenesmus	2	1.7

*The sum of the number of patients with each immediate complication in particular exceeds the total of patients since 12 patients had more than one complication. To calculate the incidence of complications immediate total patients (n=116) was used as denominator.

Fifty-seven (49.1%) patients did not present late complications after the LEE procedure (TABLE 3). The two most frequent late complications were pain (n=30, 25.9%) and anal bleeding (n=12, 10.3%). Thirty-nine (33.6%) patients reported feeling cured after ERBL, and 61 (52.6%) reported feeling better.

TABLE 3. Late complications and satisfaction after endoscopic elastic hemorrhoid ligation. (n=116).

	n	%
Number of late post-procedure complications		
None	57	49.1
One	54	46.6
Two	5	4.3
Late post-procedure complications*		
Pain	30	25.9
Bleeding	12	10.3
Thrombosis	7	6.0
Prolapse	5	4.3
Mucorrhea	4	3.4
Pruritis	2	1.7
Constipation	2	1.7
Bacteremia	1	0.9
Exteriorization of the elastic band	1	0.9
Satisfaction with ERBL		
Cured	39	33.6
Better	61	52.6
No difference	15	12.9
Worse	1	0.9

*The sum of the number of patients with each particular late complication exceeds the total number of patients, since five patients had more than one complication. For the incidence of late complications calculation, the total number of patients (n=116) was used as the denominator.

There was no significant correlation between the number of ligatures performed and the pain intensity score (FIGURE 3) (*P*=-0.02, *P*=0.866).

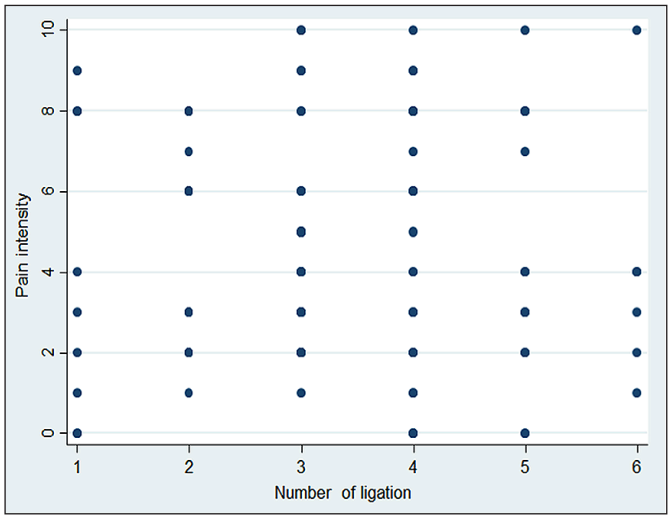

FIGURE 3. Number of ligatures and pain intensity score after endoscopic hemorrhoid elastic ligation (n=116).

There was no significant association between the number of early complications of ERBL and the number of bands performed (*P*=0.670) (TABLE 4). The incidences of bleeding, pain, tenesmus and bacteremia were similar between both groups (TABLE 4).

TABLE 4. Effect of early complications after endoscopic band ligation of hemorrhoids according to number of bands performed. (n=116).

	Number of ligatures performed				*P**
	One to two (n=32)		Three to six (n=84)		
	n	%	n	%	
Number of early complications					0.670
None	7	21.9	17	20.2	
One	23	71.9	57	67.9	
Two	2	6.2	10	11.9	
Bleeding					0.123
No	26	81.2	56	66.7	
Yes	6	18.8	28	33.3	
Pain					0.327
No	12	37.5	40	47.6	
Yes	20	62.5	44	52.4	
Bacteremia					0.906
No	31	96.9	81	96.4	
Yes	1	3.1	3	3.6	
Tenesmus					0.379
No	32	100.0	82	97.6	
Yes	–	–	2	2.4	

*P corresponding to the chi-square test.

There were also no significant differences between the groups in the assessment of pain intensity (FIGURE 4) (*P*=0.837).

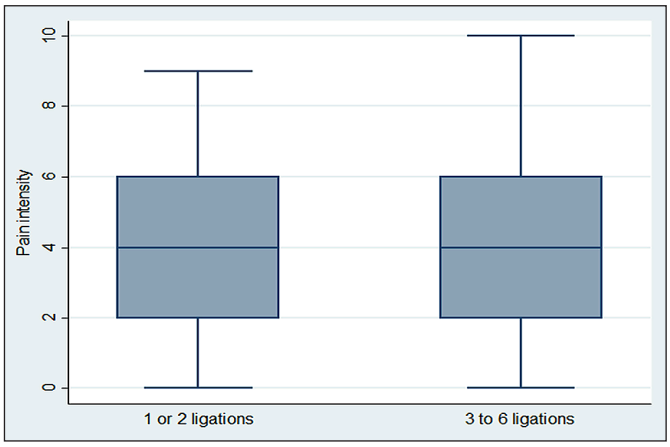

FIGURE 4. Pain intensity after endoscopic band ligation of hemorrhoids according to the number of bands placed (n=116).

No significant differences were observed between the two groups regarding the number of late complications (*P*=0.394) (TABLE 5). For both groups, the most common late complication was pain followed by bleeding. The effects of other late complications were similar between groups (TABLE 5).

TABLE 5. Late complications after endoscopic band ligation of hemorrhoids according to the number of bands placed. (n=116).

	Number of ligatures performed *P**				*P**
	One to two (n=32)		Three to six (n=84)		
	n	%	n	%	
Number of late complications					0.394
None	19	59.4	38	45.2	
One	12	37.5	42	50.0	
Two	1	3.1	4	4.8	
Pain					0.545
No	25	78.1	61	72.6	
Yes	7	21.9	23	27.4	
Bleeding					0.115
No	31	96.9	73	86.9	
Yes	1	3.1	11	13.1	
Thrombosis					0.351
No	29	90.6	80	95.2	
Yes	3	9.4	4	4.8	
Prolapse					0.698
No	31	96.9	80	95.2	
Yes	1	3.1	4	4.8	
Mucorrhea					0.209
No	32	100.0	80	95.2	
Yes	–	–	4	4.8	

*P corresponding to the chi-square test.

The satisfaction with the outcome of ERBL was similar for both groups: 27 (84.4%) patients with one or two ligatures and 73 (86.9%) patients with three to six bandages felt cured or improved (*P*=0.724) (FIGURE 5).

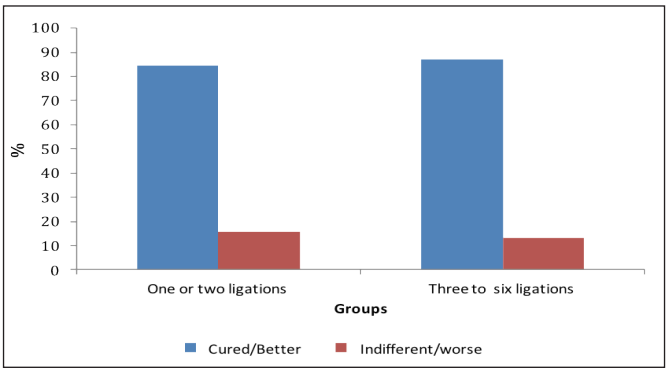

FIGURE 5. Satisfaction with endoscopic variceal ligation after endoscopic band ligation of hemorrhoids according to the number of bands performed (n=116).

DISCUSSION

The largest study about ERBL available was published by Su et al.[13] and included 759 patients. These authors observed a satisfaction rate of 95% with a follow-up time of 55 months. The main complication was rectal bleeding, which was controlled in 98% of patients after a single session of elastic ligation, with a mean of 2.35 ligatures per patient. The recurrence rate was 3.7% at 1 year, 6.6% at two years and 13% at 5 years. Reduction of prolapse by at least one degree according to the Goligher scale was possible in 82.5% of cases. A total of 93 patients (12.3%) had moderate rectal bleeding and tenesmus for up to three days after treatment. Mortality was not reported in the ERBL group. In the present study, 79.3% of the patients presented some immediate complication after the ERBL procedure: 64 patients (55.2%) had anal pain and 34 (29.3%) had anal bleeding. The patients rated their pain as mild to moderate in more than 75% of cases using an analogic pain scale[14].

Several uncontrolled studies have demonstrated the safety and efficacy of ERBL. In a prospective study involving 83 patients with hemorrhoidal rectal prolapse or bleeding, endoscopic elastic ligation was performed with the endoscopic tube in retrovision with 90% of patients having their symptoms controlled within a single session[15].

In the present study, late-onset morbidity was higher. Fifty-four (46.6%) patients presented at least one clinical complaint at 14 days after the ERBL procedure; 30 patients presented with persistent anal pain, 12 patients presented with persistent anal bleeding complaints and five (4.3%) reported more than one associated complaint. Among the associated complaints were seven cases of hemorrhoidal thrombosis, two cases of anal pruritus, one case of transient bacteremia and one case of complete exteriorization of the elastic band.

The technique of endoscopic elastic ligation in this study demonstrated superior rates of complications compared with the literature, especially regarding early anal pain after the procedure. It is important to highlight that postoperative anal discomfort has also been classified as anal pain, and because patients are encouraged to score their pain on a numerical pain scale, the rate of this complication may be overestimated.

Anal pruritus can be attributed to the presence of soiling due to transient alteration of resting pressure after the elastic ligation procedure[16]. Patients who presented with this complaint were treated with corticoid topical ointments and hygienic and behavioral measures were intensified. The rare cases of transient bacteremia can be explained as a systemic response of the organism to the translocation of bacteria from the intestinal lumen to blood circulation[17]. These episodes are invariably self-limiting and supported by the medical literature as a benign course[17].

Differently from the traditional approach, where a maximum of two conventional elastic bandages are applied per session, the number of elastic bandages varied from one to six, and 84 patients (72.4%) experienced three or more elastic bandages per procedure. Because of this, we performed a detailed analysis and divided the series into two groups: patients who were submitted to one or two ligatures and patients who were submitted to three or more ligatures. No significant associations were observed between the number of elastic bandages performed in the two groups and the presence of immediate or late complications, nor the intensity of the pain measured on the numerical scoring scale. ERBL promotes the treatment of grade II and III hemorrhoidal disease most of the time in a single session, regardless of the number of elastic bandages required, without increasing morbidity after the procedure.

The endoscopic elastic ligature provides a high degree of symptom control, comfort for the application and the possibility of photographic registration. ERBL with the patient sedated minimizes the involuntary contraction of the anal sphincter, the psychological embarrassment and the need to assist in performing the procedure. The possibility of a combination of the classical and effective elastic ligation technique and an endoscopic examination allowed a new therapeutic modality and an option in the treatment of the degree II and III HD.

CONCLUSION

The endoscopic elastic ligation method proved to be feasible, safe and efficient for the treatment of grade II and III symptomatic hemorrhoidal disease.

The technique had moderate rates of immediate and late complications, but most of the complications were considered of low magnitude, easily resolved and without clinical repercussions. The vast majority was satisfied at the end of the treatment with the ERBL procedure.

There was no significant difference among complications such as pain or bleeding between patients who had one or two compared with three or more rubber band ligations in the same procedure.

Authors' contribution

Schleinstein HP acquisition of data, interpretation of data; drafting and writing of the manuscript. Averbach M conceptualized this coorte study and approved the final version of the manuscript. Averbach P performed the data collection. Correa PAFP, Popoutchi P and Rossini LGB reviewed the manuscript critically for important intellectual content.

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RESUMO – **Contexto** – Existem diversas opções terapêuticas para o tratamento da doença hemorroidária sintomática, desde medidas higienodietéticas até cirurgia. A técnica mais consagrada para o tratamento alternativo e não operatório da doença hemorroidária em graus intermediários (graus II e III) é a ligadura elástica. Mais recentemente, tem se utilizado a técnica com o auxílio de um gastroscópio e um kit de ligadura elástica de varizes esofágicas. Esta técnica recebeu o nome de ligadura elástica endoscópica (LEE) de mamilos hemorroidários. **Objetivo** – Avaliar a exequibilidade do método de LEE. Descrever os resultados e as complicações imediatas e tardias de pacientes submetidos a LEE. Comparar a incidência de complicações precoces e tardias e a satisfação com o tratamento de pacientes submetidos de uma a duas LEE e de pacientes submetidos a três ou mais LEE no mesmo procedimento. **Métodos** – Estudo de coorte retrospectivo, em que foram incluídos pacientes submetidos à LEE no período de janeiro de 2007 a junho de 2014, no setor de Endoscopia da Sociedade Beneficente de Senhoras Hospital Sírio-Libanês. As informações foram obtidas a partir dos prontuários médicos do hospital e dos prontuários dos consultórios privados dos médicos que realizaram os procedimentos e registrados em uma ficha padronizada de coleta de dados. As incidências de complicações precoces e tardias e a satisfação com o tratamento de pacientes submetidos a uma ou duas ligaduras e dos submetidos a três ou mais ligaduras no mesmo procedimento foram comparadas com uso do teste de qui-quadrado. **Resultados** – Foram incluídos no estudo 116 pacientes, dos quais 76 (65,5%) eram homens. A idade dos mesmos variou de 30 a 88 anos (média =53,9 anos; desvio padrão =11,6 anos). O sintoma mais frequentemente relatado foi sangramento anal (n=72; 62,1%). O número de ligaduras realizadas, durante o procedimento de LEE, variou de um a seis; 49 (42,2%) pacientes tiveram quatro ou mais ligaduras realizadas durante o procedimento. Não foram observadas associações significativas entre a incidência de complicações precoces ou tardias e a satisfação com a LEE, entre os grupos submetidos a uma a duas ligaduras ou a três a seis ligaduras. **Conclusão** – A incidência de complicações precoces e tardias foi baixa, entre os pacientes submetidos à LEE, o que sugere que o método é seguro e exequível. A realização de mais de duas ligaduras, durante o mesmo procedimento, não esteve associada, significativamente, a aumento da incidência de complicações, o que reforça a opção da LEE como método para o tratamento não operatório da doença hemorroidária não complicada em graus II e III.

DESCRITORES – Hemorroidas, terapia. Ligadura. Cirurgia colorretal. Colonoscopia. Resultado do tratamento.

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