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Comparison of the efficacy of LigaSure and laser for grade 2-3 hemorrhoids

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Aim: The aim of this study is to compare the efficacy of LigaSure and LH procedures in the treatment of grade 2-3 hemorrhoids.

Material and methods: Demographic and clinical data of the patients were recorded retrospectively. A visual analogue scale (VAS) was used to evaluate the pain intensity of the patients after the procedure and a Likerttype scale was used to evaluate patient satisfaction surveys 6 months after the procedure.

Results: Of the 66 patients, (mean age: 42.12±11.92 years, %72,7 male) 34 underwent LH procedure whereas 32 underwent LigaSure procedure. Spinal anesthesia was applied for 64 patients and general anesthesia was applied for 2 patients. Procedure time and time to return to work were significantly shorter in the LH group compared to the LigaSure group (900 vs. 1200 seconds, p<0.001, and 3.64±1.29 vs. 14.46±3.73 days, p<0.001). Late complications (abscess, relapse, pruritus, and seromucous discharge) were more common in the LH group, but the difference was not statistically significant (23.5% vs. 6.3%, p=0.08). VAS pain scores were significantly lower in the LH group (p<0.001). Although there was no significant difference between the treatment groups in terms of patient satisfaction, relapse was significantly less common in the LigaSure group (p=0.045).

Conclusion: In patients with grade 2-3 hemorrhoids, LH may be preferred over LigaSure due to greater patient comfort, higher satisfaction rates, and fewer early complications. However, close follow-up of these patients is important due to the higher incidence of late complications with

Key words: hemorrhoidal disease, visual analog scale, Likert measurement system, LigaSure, laser

Introduction

Hemorrhoidal disease is the most common disease of the anorectum [1]. Its prevalence is 27.9% worldwide [2]. Hemorrhoids may become symptomatic in 50 percent of patients due to pregnancy, pushing, conditions causing increased intra-abdominal pressure, and weakening of the connective tissue, smooth muscle, and vascular structures in the anal area [3].

According to the Goligher system, grade 1 hemorrhoids do not prolapse outside the anal canal, and grade 2 hemorrhoids prolapse distally during defecation but retract spontaneously. Grade 3 hemorrhoids protrude from the anal opening during defecation and require manual reduction. Grade 4 hemorrhoids have permanent prolapse that cannot be reduced [4].

In the treatment of hemorrhoidal disease, LigaSure, an electrothermal device for cutting and sealing vessels, is now being used in addition to classical surgical procedures to reduce postoperative pain, bleeding, infection, anal stenosis, incontinence, and relapse. Moreover, minimally invasive procedures such as sclerotherapy, rubber band ligation, infrared coagulation, Doppler-guided hemorrhoidal artery ligation, cryotherapy, and laser techniques are also popular [5-7].

Laser hemorrhoidoplasty (LH), another treatment option for hemorrhoidal disease, coagulates the vascular structure in the submucosal area within the hemorrhoidal pouch with thermal energy and allows the hemorrhoidal pads to shrink and become obliterated [8,9].

LigaSure is an electrothermal and hemostatic device that causes minimal damage to surrounding tissues. It allows the complete coagulation of the vessels with radiofrequency and the closure of vessels with a combination of pressure sources. Once LigaSure has achieved coagulation of the vascular structure, the electric current is automatically interrupted. With this limited

spread of electric energy, LigaSure enables effective, bloodless hemorrhoid excision with minimal tissue damage [10,11].

There is limited evidence for the effectiveness of procedures used in the treatment of hemorrhoidal disease and patient satisfaction [12,13]. In this study, it was aimed to compare the efficacy and postoperative complications of LigaSure and LH procedures, which have recently been growing in popularity compared to the traditional Milligan-Morgan and Ferguson surgical treatment options, for patients with grade 2-3 hemorrhoids.

Material and methods

The study was retrospective in design. All the patients between the ages of 18 and 70 years who underwent LH or LigaSure treatment with a diagnosis of grade 2-3 hemorrhoids in a single center between June 2021 and April 2022 were recorded. Patients who had a the American Society of Anesthesiologists physical status classification (ASA) score above II, diabetic patients, pregnant women, patients with other anorectal diseases (fistula, abscess, rectal carcinoma, inflammatory bowel disease, etc.), and patients with a history of previous anal surgery were excluded. Finally, a total of 66 patients were included in the study.

LH was performed for 34 patients with a radial 1.470-nm diode laser and LigaSure (Aesculap Caiman, 17 cm, small jaw open sealer/divider) was applied for 32 patients. All procedures were performed by an experienced colorectal surgeon. Demographic and clinical characteristics of the patients and early / late postoperative complications were recorded from patients' data. In addition, pain levels as measured for all patients with a visual analogue scale (VAS) at the 6th, 12th, and 24th postoperative hours were also recorded (Table 1).

Table 1		Vi	Visual Analog Scale (VAS)							
0	1	2	3	4	5	6	7	8	9	10
0: No pain at all 10: Unbearable pain										
Table 2 Likert's 5-choice measurement system										
I absolutely approve		І ар	prove	I am und	ı ecided		I Disapprove		I absolutely do not approve	

The VAS was scaled from 0 to 10, with 0 representing no pain and 10 representing the most severe unbearable pain [14]. The patients of both groups were called 6 months after treatment and information was obtained about their satisfaction levels using a 5-point Likert-type scale that included questions with 5 possible answers: strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree [15] (Table 2). All patients underwent a detailed physical examination. Grade of hemorrhoids was determined by anorectal examination with the help of anoscope and flexible rectosigmoidoscopy.

General anesthesia was administered for two of the patients who underwent LigaSure treatment, and spinal anesthesia was administered for the other 30 patients in the LigaSure group. An anoscope was placed in the lithotomy position. Hemorrhoidal pockets were excised with the LigaSure device over the internal sphincter muscle, leaving the anoderm, including the submucosal vascular network structures. Bleeding was controlled by electrocautery. Spongostan was routinely inserted into the anal canal of each patient.

Spinal anesthesia was administered for all patients who underwent LH treatment. An anoscope was placed in the lithotomy position. With the help of the anoscope, a 1470-nm diode laser probe was inserted in the submucosal region from the distal of the hemorrhoidal pockets, and 3-5 shots were made in a standard crowbar pattern starting from the proximal and advancing toward the distal of the hemorrhoidal pouch (3-5 shots of 3 seconds each with 3-second pauses at 10 W). At the end of each laser treatment, ice in gloves was applied to the treated pocket for 1 minute. Spongostan was routinely inserted into the anal canal of each patient.

Two enemas (250 mL) were administered to all patients preoperatively, the evening before the procedure and early in the morning of the day of the procedure. Antibiotic prophylaxis (sephazolin 1×1, 1 gram intravenously) was routinely administered 30 minutes before the procedure. Painkillers (paracetamol, 3×1, 500 mg orally) were administered to all patients postoperatively. Laxative syrup (667 grams of lactulose 2x1 orally in 1000 ml of aqueous solution) was recommended to all patients for 7 days after discharge. In addition, routine examinations were performed in the outpatient clinic by a specialist surgeon in the 1st week and 1st, 3rd, and 6th months after the procedure. In these follow-up visits, flexible rectosigmoidoscopy was performed for patients with complaints of persistent rectal bleeding, discharge, or pain. Patients with recurrence were identified by anorectal examination and flexible rectosigmoidoscopy. Edema, urinary retention and thrombosis were considered postoperative early complications whereas abscess sero-mucous discharge, recurrence and itching were considered postoperative late complications.

Ethical approval

Ethical approval of this study was granted by the Ethics Committee of the University of Health Sciences, Bursa Yuksek Ihtisas Training and Research Hospital, with decision number 2011-KAEK-25 2022/05-26 on May 18, 2022. The study was conducted in accordance with the Declaration of Helsinki.

Statistical analysis

IBM SPSS Statistics 21.0 (IBM Corp., Armonk, NY, USA) was used for statistical evaluations in this study. Compliance with normal distribution was evaluated by Kolmogorov-Smirnov test. Measurable parametric data were given as mean±standard deviation, and distributions were defined as median (minimum-maximum) for measurable data that did not satisfy parametric conditions. Categorical variables were given as numbers and percentages. In comparisons of data between two groups, independent samples t-tests were used for data that satisfied parametric conditions and Mann-Whitney U tests were used for non-parametric data. Chi-square tests were used for the comparison of categorical variables. Values of p<0.05 were considered significant in all statistical evaluations.

Results

Of the 66 patients included in the study (mean age: 42.12 ± 11.92 years, % 72.7 male), LH was applied for 34 patients (%51.5) and the LigaSure procedure was applied for 32 patients (%48.5).In terms of age , gender and body mass index , there was no statically difference between the groups. Fifteen patients (%22.7) had edema, 2 patients (%3) had urinary retention, and 1 patient (%1.5) had thrombosis. The patient who experienced thrombosis underwent surgical thrombectomy in another clinic. No postoperative bleeding or hematoma was observed in any

Variables	Ligasure group (n: 32)	Laser group (n: 34)	p
Early postoperative complication, n (%)	(n. 32)	(11. 54)	
Edema	13 (41)	2 (6)	0,001
Urinary retention	2 (6)	0 (0)	0.141
Trombosis	0 (0)	1 (3)	0.332
Late postoperative complication, n (%)			
Abscess	0 (0)	1 (3)	0.334
Sero-mucous discharge	2 (6)	1 (3)	0.526
Recurrence	0 (0)	4 (12)	0.045
Itching	0 (0)	1 (3)	0.331
Likert scale answers, n (%)			
Very unsatifsfied	0 (0)	0 (0)	0.002
Unsatisfied	0 (0)	5 (15)	
Neutral	0(0)	1 (3)	
Satisfied	13 (41)	22 (65)	
Very satisfied	19 (59)	6 (18)	

Table 4

Comparison of the demographic and clinic characteristics of the patients based on the group

Variables	Ligasure group (n: 32)	Laser group (n: 34)	р
Age, mean ± SD	40±10	44±14	0.201
Gender, Male, n (%)	24 (75)	28 (71)	0.683
BMI (kg/m²), mean ± SD	26,00 ± 4,97	25,73 ± 5,28	0,835
Smoking, n(%)	15 (47)	15 (44)	0.822
Hemorrhoids grade, n (%)			
Grade 2	6 (19)	10 (29)	0.313
Grade 3	26 (81)	24 (71)	
Mean operating time, second* Hospitalisation, day mean + SD Return to work, day mean + SD	1200 (900-6000) 1,31 + 0,47 14,46 + 3,73	900 (540-1800) 1,14 + 0,35 3,64 + 1,29	< 0.001 0,116 < 0.001
İntroperatif hemorrhage, n (%)	25 (78)	11 (32)	< 0.001
Postoperatif VAS score*			
6. hour	6 (2-10)	3 (0-6)	< 0.001
12.hour	6 (1-9)	2 (0-7)	<0.001
24. hour	2 (0-7)	0.5 (0-3)	0.001

BMI: body mass index, SD:standard deviation, *: Median (minimum-maximum), VAS:Visual Analog Scale

case. Early complications (edema, thrombosis, urinary retention) were significantly more common in the LigaSure group (%46.9 vs. %8.8, p=0.001). This difference between the groups was due to significantly more edema complications in the LigaSure group (%40.6 vs. %5.9, p=0.001). When late complications were evaluated at the 6-month follow-up period, the following were determined: abscess in 1 case (%1.5), discharge in 3 cases (%4.5), relapse in 4 cases (%6.1), and pruritus in 1 case (%1.5). The patient with abscess developed a perianal fistula after drainage. Anal incontinence or stenosis was not observed in any of the patients during the six-month follow-up. No relapse was observed in any patient in the group treated by LigaSure, while relapse was seen in 4 patients (%11.8) in the group treated by LH (p=0.045). Other late complication rates (abscess, pruritus, seromucous discharge) did not differ significantly between the groups. When all late complications were compared, it was observed that late complications were more common in the LH group, but the difference was not statistically significant (%23.5 vs. %6.3, p=0.08) (Table 3). When the clinical and demographic data of the patients were compared, operation time was significantly shorter in the LH group (p<0.001). Pain levels as evaluated by VAS at 6, 12, and 24 hours postoperatively were significantly lower in the LH group (p<0.001 for all). The time to return to work was significantly shorter in the LH group than the LigaSure group (p<0.001). Comparisons of the demographic, clinical, and procedural results of the patients according to type of procedure are shown in Table 4.

In the Likert-type satisfaction survey administered in the 6th month of follow-up, all 32 patients (%100) in the LigaSure group stated that they were satisfied or very satisfied with the operation, while in the LH group, 28 patients (%83) were satisfied or very satisfied (p=0.002). Comparisons of complication and satisfaction rates of the patient groups are shown in Table 3.

Discussion

In the last 50 years, new procedures have been developed to replace traditional surgical approaches for hemorrhoidal disease in order to improve patient satisfaction and minimize complications [16-18]. However, there has been no study to date comparing the outcomes of LH and LigaSure procedures in the treatment of hemorrhoidal disease. In this respect, our study can be considered the first of its kind in the literature.

In some previous studies, it was found that the operation time, postoperative pain levels, and postoperative length of hospital stay were significantly lower with the LigaSure procedure compared to the Milligan-Morgan procedure [19,20]. Upon comparing the LigaSure procedure with the Ferguson

procedure, intraoperative bleeding and postoperative pain were found to be significantly lower [21,6]. These procedures did not yield significant differences in terms of early and late postoperative complications in comparison to the LigaSure approach [22,6].

While LH has been found to provide statistically significantly lower operation times, hospitalization times, and rates of urinary retention, anal stenosis, postoperative pain, and intraoperative bleeding compared to the Milligan-Morgan procedure, no difference in relapse rate was observed [23,24]. There are no studies in the literature comparing the results of LH and Ferguson procedures. However, according to an evaluation of the results of the Milligan-Morgan and Ferguson procedures, there was no statistically significant difference in terms of hospitalization time, operation time, postoperative pain level, or urinary retention [25].

In previous studies, it was observed that male patients significantly predominated among cases of both LH and LigaSure treatment for hemorrhoidal disease compared to female patients [26,27]. In the present study, it was similarly found that more male patients were treated by both LigaSure and LH compared to female patients.

In previous studies, the mean duration of surgery was 900 seconds for the LigaSure procedure and 600 seconds for LH [27,19]. In our study, the mean duration of surgery was 1200 seconds for LigaSure and 900 seconds for LH. For these patients with grade 2-3 hemorrhoids, the mean duration of surgery was thus significantly shorter with LH compared to LigaSure.

In our study, none of the patients in either group had early postoperative bleeding. In the literature, this rate was reported to be % 0-3 for LH and 0.4% for LigaSure [28,29]. Mean postoperative VAS pain levels on the 1st day were previously reported as 3.7 after LigaSure treatment and 2 after LH [29,30]. In our study, VAS scores on the 1st day after surgery were 2 in the LigaSure group and 0.5 in the LH group. In previous studies, the mean time to return to work was 11.1 days after LigaSure and 2.8 days after LH [31,32]. In our study, mean time to return to work was 14.46 days after LigaSure and 3.64 days after LH.

In previous studies, the postoperative relapse rate at 6

months was % 0 after LigaSure and 0-% 8.8 after LH [33,34]. In those studies, % 80-90 of the patients had grade 3 hemorrhoids. However, no information was provided in those studies about whether the patients who experienced recurrence had grade 2 or grade 3 hemorrhoids [8,30,34]. In our study, the recurrence rate was % 0 after LigaSure and % 12 after LH. Thus, the recurrence rate after LigaSure was statistically significantly lower than that for LH among our patients, and % 75.7 of our total patients had grade 3 hemorrhoids. All of our patients who experienced postoperative recurrence were patients with grade 3 hemorrhoids. None of our patients with grade 2 hemorrhoids had recurrence at 6 months postoperatively.

We administered a satisfaction survey to our patients in the 6th postoperative month, and % 100 of patients treated by LigaSure and % 83 of those treated by LH reported being satisfied or very satisfied. In previous studies, % 98.9 of patients treated by LigaSure and % 98 treated by LH reported being satisfied or very satisfied [27,35].

Limitations

The limitations of this study include its retrospective nature, the small number of patients, and the relatively short follow-up period.

Conclusion

For patients with grade 2-3 hemorrhoids, LH could be the preferred treatment choice compared to LigaSure due to higher levels of patient comfort, better satisfaction rates, and fewer early complications. However, close follow-up of these patients is important due to the higher incidence of late complications following LH.

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