Laser hemorrhoidoplasty combined with blind hemorrhoidal artery ligation compared to Milligan–Morgan hemorrhoidectomy in patients with second and third degree piles; a prospective randomized study

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Background
Laser hemorrhoidoplasty is a relatively new management option for symptomatic hemorrhoids. Although its advantages over the Milligan–Morgan approach were highlighted in previous trials, the combination of laser and mucopexy (hemorrhoidal artery ligation) is scarcely discussed in the literature. Herein, the author compared the outcomes of the previous combination with the traditional Milligan–Morgan procedure in cases with second and third-degree piles.

Methods
The 66 included patients were randomly divided into two groups; group A underwent the combined approach, while group B underwent the Milligan–Morgan procedure. Postoperative pain, satisfaction, and complications were assessed.

Results
Preoperative data, including patient presentation and the degree of piles, were comparable between the two groups. Nonetheless, operative time and hospitalization period showed a significant increase in group B ($P = 0.004$ and < 0.001). Group A patients expressed significantly lower pain scores during rest and defection, as well as a better satisfaction level, compared with group B patients. The incidence of postoperative complication did not differ between the two interventions, except for urine retention, which was more frequently encountered in group B cases. An earlier return to normal daily activities was noted in group A. 1-month Wexner scores did not differ between the two groups, and no cases developed recurrence during the 1-year follow-up.

Conclusion
The combination of laser with hemorrhoidal artery ligation is associated with multiple advantages over surgical hemorroidectomy manifested in a better analgesic profile, better satisfaction, and an early restoration to daily activities.

Keywords:
hemorrhoids, laser, surgical hemorrhoidectomy, mucopexy

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Introduction

Hemorrhoids are a common surgical problem that is commonly encountered in daily anorectal practice [1]. It is the most common anorectal disorder with a high prevalence, reaching up to 28% [2,3]. The main presentation of that disease is bleeding and prolapse, and it often leads to a significant impairment of the quality of life [4].

Although multiple management options are available to alleviate patient symptoms, surgical intervention remains the gold standard approach, especially for patients who are refractory to conservative management [5,6]. However, the surgical excision of hemorrhoids is usually associated with severe and intolerable postoperative pain [7], especially because the anal area is rich in sensory nerve supply [8].

Laser hemorrhoidoplasty is a relatively novel management technique for symptomatic hemorrhoids that was initially published in 2009 [9]. Since then, multiple trials have described its feasibility, safety, and efficacy in the management of that pathology with comparable outcomes to surgical excision. However, the laser technique was associated with a better postoperative analgesic profile and better patient satisfaction, making it more advantageous compared with surgery [5,7,10].

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Hemorrhoidal artery ligation (sutures mucopexy), either blindly or doppler-guided, has also been described as an effective minimally invasive option for hemorrhoids, with no significant difference regarding the outcomes between blind and radiology-guided procedures [11–13].

Numerous studies have compared laser hemorrhoidoplasty with surgical excision in symptomatic hemorrhoid patients [3,5,7]. However, little has been described regarding the combination of laser and mucopexy in such patients. Herein, we compared perioperative and 1-year outcomes of patients undergoing combined laser and sutured mucopexy with patients undergoing Milligan–Morgan hemorroidectomy.

Patients and methods

This randomized prospective trial was conducted at Tanta University General Surgery Department after gaining scientific and ethical approval from the Institutional Review Board (IRB) of our faculty of medicine. The trial was conducted over an 18-month period, from June 2021 to December 2022. We included adult patients, whatever their age, who visited to our outpatient surgical clinic during the previous period and presented with symptomatic second or third-degree piles. Patients with previous intervention for hemorrhoidal surgery, bleeding diathesis, thrombosed piles, or inflammatory bowel disease were excluded from the analysis.

Sixty-six patients were eligible for the study, and they were all included after signing an informed consent explaining the benefits and possible complications of each intervention. All patients received the standard preoperative evaluation, including history taking, clinical examination (including perrectal examination), and routine preoperative laboratory investigations. A colonoscopy or sigmoidoscopy was ordered for patients with suspected rectal cancer (old age, presence of tenesmus, or family history of colorectal cancer). No bowel preparation was done for the participants prior to the operation.

All patients were performed under a saddle block when the patient was in a lithotomy position. All patients received antibiotic prophylaxis 30 min before the incision (IV ceftriaxone, 2 gm and metronidazole, 500 mg). The procedures were performed by the same surgical team, which had at least 10-year experience in anorectal surgical procedures.

In group A, we used a 1470-n diode laser generator for the laser hemorroidopexy procedure (GBOX, Wuhan Gigaa Optronics Technology Co, China) with a disposable 1.85 mm probe (Fig. 1a). Direct skin puncture was performed using the sharp pointed edge of the laser probe, and the puncture was made about 0.5-1 cm distal to the anal verge, followed by the introduction of the probe through the subcutaneous plane till reaching the hemorrhoidal plexus. We delivered 8–12 pulses for each hemorrhoidal column, and each pulse had an 8 watt power and lasted for 3 s, with 1 s in between the pulses. About 200–250 Joules were delivered to each hemorrhoid (150 for the pedicle and 100 for the cushion). Half of the pulses were delivered to the submucosal tissue, while the remaining pulses were delivered to the intranodal compartment. We took care not to injure the rectal mucosa or the underlying anal sphincter. The shrinkage of the hemorrhoidal tissue was noted with the application of pulses. The procedure was repeated for each hemorrhoidal column (Fig. 1b & c).

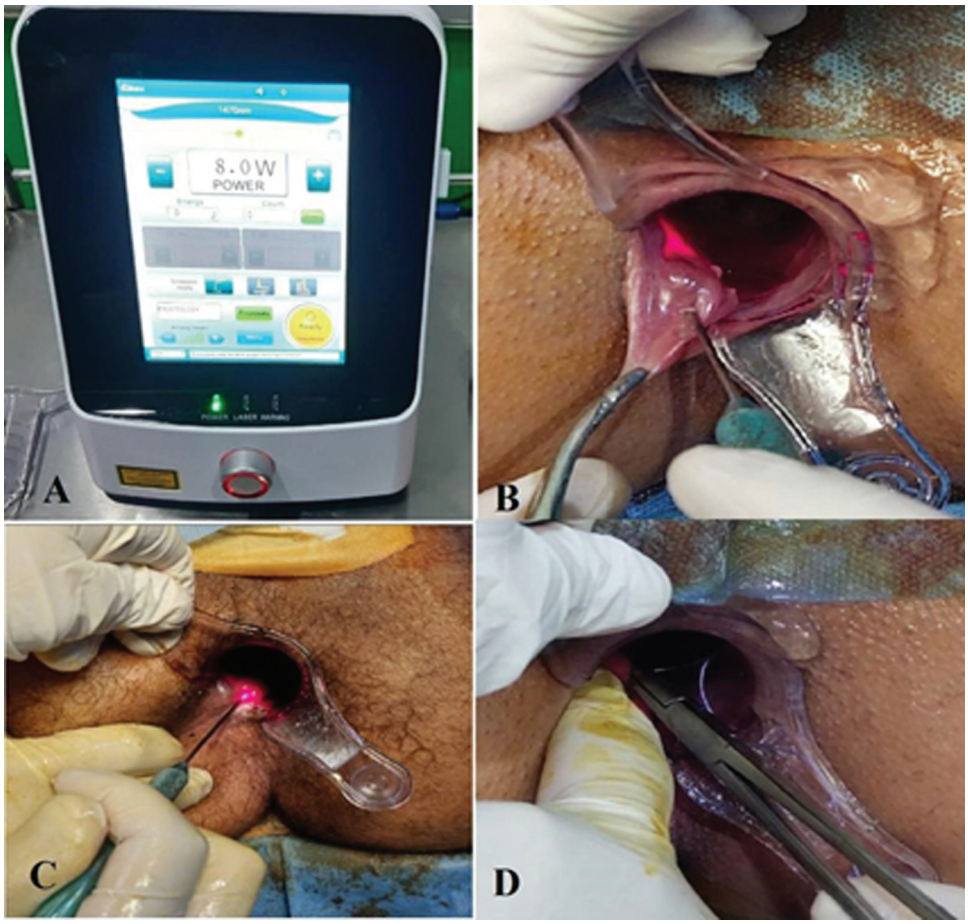
After the laser procedure, hemorrhoidal artery ligation was done by taking a suture (vicryl 2/0) at the level of the pedicle to include the feeding vessel inside the suture (Fig. 1d). The sutures were continued downwards till reaching the dentate line. The continuous suture was then tied, leading to more lifting up of the hemorrhoidal tissue, if was still prolapsed.

In group B, a V-shaped skin incision was made by electrocautery in the skin covering the hemorrhoidal base after proper field exposure using the Ferguson retractor. Dissection was continued proximally through the submucosal plane to separate the hemorrhoidal tissue from the underlying structures. When the pedicle was reached, it was ligated with a 2/0 vicryl suture. Followed by complete excision of the hemorrhoidal tissue. The same steps were repeated for each hemorrhoidal column.

In both groups, a wet gauze was left at the anal verge for compression. The operative time was calculated in minutes in both groups. Analgesia was achieved with IV acetaminophen (1 gm/8 h) in addition to ketorolac (30 mg/12 h).

The patients were asked to express their pain on an 11° scale (numerical rating scale, or NRS), ranging from 0 to 10, with 0 for no pain and 10 for the most severe pain ever felt [14]. The NRS was measured during rest every 2 h till patient discharge. The patients were asked to express the same score during defecation. The means of

Figure 1



(A) The GBOX device used in the current study. (B and C) Laser coagulation of haemorrhoid cushion at 7 o'clock position piles. (D) Blind haemorrhoidal artery ligation using 2/0 vicryl stitches.

these scores were calculated and recorded. All patients were discharged on the same day of the operation, after adequate mobilization, adequate oral intake, and removal of the anal pack. The duration of hospitalization was calculated in hours in both groups. The patients were commenced on oral antibiotics (a combination of ciprofloxacin 500 mg and metronidazole 500 mg/12 h for 10 days), analgesics (acetaminophen 1 gm/8 h) and oral laxatives (single dose once daily in the evening following the procedure, and if diarrhoea happened, it was commenced every other day). The patients were also recommended to receive fiber-rich diet to avoid postoperative constipation. Before discharge, the patients were asked to express their satisfaction with the surgical intervention on a five-point Likert scale (from very satisfied to very unsatisfied) [15].

Follow-up visits were arranged for all patients at 1 week intervals during the first month after surgery. Any complications (infection, bleeding, urine retention, stenosis, or perianal fistula) were noted and recorded. The Wexner score [16] was also calculated for all patients one month after the procedure to assess the degree of postoperative incontinence. The patients were asked about the time interval they took to return to their normal daily activities. After that, the patients were ordered to visit our outpatient clinic every 3 months for 1 year after the procedure. Our main outcome in this trial was postoperative pain scores, while other outcomes included the duration of the procedure, patient satisfaction, and the incidence of complications.

Sample size calculation

The IBM SPSS Sample Power software was used to estimate the proper sample size. According to the previously published results of Naderan and his associates, who reported mean values of 1.6 (±1.5) and 2.7 (±1.5) for postoperative pain scores in the laser and surgical hemorrhoidectomy groups, respectively [5]. A minimal sample size of 30 patients was needed in each group to achieve 80% power and 95% significance level. With an expected

10% nonresponse or drop-out rate, we increased the participants to 33 in each group.

Statistical analysis

The SPSS software (version 26 for MacOS) was used to collect and analyze the previously mentioned data. We expressed our categorical variables as numbers and percentages and compared using the χ^2 test. Numerical data were expressed as means and standard deviations (and compared using the student-*t* test) or medians and ranges (and compared using the Mann–Whitney test). Any *P* value less than 0.05 was considered statistically significant, and was marked by the symbol (*) in the next tables.

Results

Patients in group A had a mean age of 37.36 years compared with 37.27 years in group B. Most patients were men, who formed 69.7% and 75.76% of participants in groups A and B, respectively, whereas the remaining patients were women. Their BMI had mean values of 29.62 and 28.46 kg/m^2 in the same groups, respectively. The prevalence of medical comorbidities, including diabetes and hypertension, was statistically comparable between the two groups. Also, smokers represented 9.09% and 12.12% of patients in the same groups, respectively.

Regarding the clinical presentation of our patients, bleeding per rectum was the most common complaint in both groups, followed by prolapse. Other complaints included itching and perianal pain. Most participants had third-degree piles (84.85% and 81.82% of cases in the two groups, respectively), while the remaining patients had second-degree piles. The previous data are presented in Table 1, and all of these data did not form any statistical difference between the two groups ($P > 0.05$).

Table 1 Baseline criteria of the patients in the two groups

	Group A (*n*=33)	Group B (*n*=33)	*P* value
Age (years)	37.36±9.55	37.27±9.34	0.969
Sex			
Male	23 (69.7%)	25 (75.76%)	0.580
Female	10 (30.3%)	8 (24.24%)	
BMI (Kg/m^2)	29.62±3.12	28.46±2.89	0.122
Comorbidities			
Diabetes	4 (12.12%)	5 (15.15%)	0.720
Hypertension	4 (12.12%)	3 (9.09%)	0.689
Smoking	3 (9.09%)	4 (12.12%)	0.689
Clinical presentation			
Bleeding	29 (87.88%)	30 (90.91%)	0.689
Prolapse	28 (84.85%)	27 (81.82%)	0.741
Itching	11 (33.33%)	11 (33.33%)	1
Pain	10 (30.3%)	8 (24.24%)	0.580
Degree of piles			
2nd	5 (15.15%)	6 (18.18%)	0.741
3rd	28 (84.85%)	27 (81.82%)	

BMI, Body mass index.

In group A, the surgical operation took an average of 29.58 min, whereas in group B, it took 33.52 min despite being clinically insignificant, the difference was significant according to the statistical analysis ($P=0.004$) (Table 2).

Patients in group A showed a significant reduction in the duration of hospitalization, pain scores during rest, and pain scores during defecation compared with patients in group B. The duration of hospitalization had mean values of 9.91 and 12.18 h in groups A and B, respectively. Pain scores during rest had median values of 3 and 6, while the same scores during defecation had median values of 4 and 6 in groups A and B, respectively. Subsequently, patients in group A had better satisfaction than those in group B.

The incidence of postoperative complications, including infection and bleeding, did not significantly differ between the two groups. However, there was a significant rise in the incidence of urine retention in group B patients (18.18% vs. no patients in group A–$P=0.01$). No patients developed anal stenosis, perianal fistula, or recurrence during the 1-year follow-up period.

Patients in group A showed a significantly earlier return to normal daily activities (range, 4–7) compared with group B (range, 15–23) ($P < 0.001$). However, the 1-month Wexner score was comparable between the two groups ($P=0.102$). Table 3 illustrates the previous data.

Discussion

Postoperative pain is one of the main concerns of patients scheduled for anorectal procedures, including hemorrhoidectomy. That has led to the recent popularity of nonexcisional procedures for hemorrhoid patients like mucopexy and laser hemorrhoidoplasty Longchampand colleagues, Trenti and colleagues [17–19].

Table 2 Operative time in the two groups

	Group A (*n*=33)	Group B (*n*=33)	*P* value
Operative time (min)	29.58±2.76	33.52±5.48	0.004*

Table 3 Hospital stay, postoperative, and follow-up data in the two groups

	Group A (*n*=33)	Group B (*n*=33)	*P* value
Hospital stay (hours)	9.91±1.10	12.18±2.57	<**0.001***
Postoperative pain score during rest	3 (2–5)	6 (4–8)	<**0.001***
Postoperative pain score during defecation	4 (2–6)	6 (5–9)	<**0.001***
Patient satisfaction			
Very satisfied	11 (33.33%)	1 (3.03%)	**0.002***
Satisfied	10 (30.3%)	7 (21.21%)	
Neutral	8 (24.24%)	10 (30.3%)	
Dissatisfied	4 (12.12%)	8 (24.24%)	
Very dissatisfied	0	7 (21.21%)	
Complications			
Infection	0	1 (3.03%)	0.314
Bleeding	0	1 (3.03%)	0.314
Urine retention	0	6 (18.18%)	**0.010***
Stenosis	0	0	___
Fistula	0	0	_____
Return to daily activity (days)	5 (4–7)	18 (15–23)	<**0.001***
1-month Wexner score	0 (0–3)	0 (0–5)	0.102
1-year recurrence	0	0	_____

Laser therapy induces denaturation of the submucosal plane contents, leading to a marked and controllable shrinkage of the hemorrhoidal columns Brusciano and colleagues [10]. The diode laser is preferred for such procedures as it is selectively absorbed by hemoglobin, leading to minimal surrounding tissue damage and better sphincter preservation Plapler and colleagues [9].

The mucopexy technique is also effective in the management of hemorrhoids, as the sutures induce fixation of the prolapsed mucosa to the underlying muscle layer. Also, it closes the vascular elements of the hemorrhoidal cushions, leading to a marked decline in its engorgement Chivate and colleagues [20].

Herein, we combined the previous two minimally invasive nonexcisional techniques and compared their outcomes to the Milligan–Morgan approach. There is a paucity of data in the current literature handling the same comparison, which poses a great advantage in favor of our research.

The reader cannot detect a substantial difference between our two groups when looking at the preoperative data. That proves that our randomization was correct. Thus, any bias skewing our results in favour of one group over the other should be lessened as a result.

In our study, operative time had mean values of 29.58 and 33.52 min in groups A and B, respectively. Although the time difference could be clinically irrelevant (about a 5 min difference), the difference was significant in the statistical analysis ($P < 0.05$).

Naderan and colleagues [5] also reported a significant prolongation in the operative time in the surgical excision group compared with the laser group (52.6 vs. 33.1 min, respectively – $P < 0.001$). The previous study showed about a 20 min time difference between the two approaches, which is far higher than ours. The reader should notice that the previous authors performed the laser procedure without mucopexy, which could explain the previous difference.

We noted a significant reduction in pain scores during rest and defection in group A compared with group B. That could be secondary to the smaller wounds performed in the laser approach compared with the surgical one Plapler and colleagues [9]. Our findings regarding postoperative pain are in accordance with Brusciano and colleagues who reported that pain scores after laser hemorrhoidoplasty were extremely low, as they did not exceed 3 in the initial three days following the intervention. Even painkillers were not administered routinely. Instead, it was given only on patient request Brusciano and colleagues [10].

Moreover, Poskus and colleagues [7] reported that both laser and mucopexy were associated with lower postoperative pain scores compared with the excisional hemorrhoidectomy. During rest, the pain score had mean values of 3.1, 2.7, and 5 in the previous three groups, respectively. During defecation, the same three groups had mean scores of 3.8, 4.0, and 6.4,

respectively Poskus and colleagues [7]. Other authors also reported similar findings that were in favor of the laser technique Naderan and colleagues [5].

Our findings showed a significant increase in the incidence of urine retention in the surgical excision group. That could be secondary to higher pain scores in the excision group, which induce a reflex originating from the rich sensory supply of the anal region Jeong and colleagues [21]. Naderan and colleagues reported similar findings, as the same complication was relatively higher in the surgical excision group (10% vs. 3.3% in the laser group). Nonetheless, no significant difference was detected in the statistical analysis ($P=0.612$) Naderan and colleagues [5].

We encountered only one patient with bleeding in the surgical excision group. Another patient developed a surgical site infection. Neither of the previous two complications was encountered in the minimally invasive group. The bleeding patient was managed by compression and IV hemostatic agents (tranexamic acid 1 gm), while the infectious complication was managed by IV antibiotics, and local wound irrigation with hydrogen peroxide and warm saline. Although the difference between the two groups was not significant ($P > 0.05$), one could attribute the incidence of these two complications to the wider raw areas in the surgical excision group, compared with the laser group, making it more susceptible to infection, friction, and bleeding.

The hospital stay in our study was significantly shortened in group A, and that could be explained by the better pain scores and lower incidence of complications compared with the other group. Contrarily, Shabahang and colleagues reported a mean hospitalization period of 1.7 days in the surgical group versus 1.5 days in the laser group ($P=0.142$) [22]. Differences in treatment protocols and complication rates between studies could explain the previous heterogenicity.

In our study, patients who had the minimally invasive procedures reported earlier return to their normal daily activities. Likewise, Brusciano and colleagues [10] also noted that laser hemorrhoidoplasty was associated with an early return to daily activities, as 40% of their patients were able to do so after one day, while the remaining 60% achieved the same objective two days after the procedure. Additionally, Poskus and colleagues reported that both laser and mucopexy were associated with an earlier return to work (15 and 24 days, respectively) compared with the surgical excision approach (30 days), which turned out to be significant between the three approaches (in favor of the less invasive ones) [7].

We noted no significant difference between our two groups regarding the 1-month Wexner score. In the same context, another study reported that the same score had a median value of 3 and ranged between 0 and 5 in both laser and surgical excision groups, which was comparable in statistical analysis ($P=0.125$) Poskus and colleagues [7].

In the current study, no patients developed recurrence one year after the operation. Jahanshahi and colleagues also reported a 0% recurrence rate at 1-year follow-up following laser hemorrhoidoplasty [23]. Additionally, Shabahang and colleagues reported that no patients developed recurrence 6 months after surgery or laser [22], which is similar to our findings.

On the other hand, Poskus and colleagues [7] noted a significant rise in the incidence of the same complication with the mucopexy technique (22%), compared with 10% and 0% in the laser and surgical excision groups, respectively ($P=0.004$). These findings should confirm our concept regarding the combination of the two minimally invasive techniques to reach a recurrence rate similar to the excisional procedure, which is the gold standard management option.

Based on the previous data regarding lower pain scores, an earlier return to daily activities, and a lower complication rate, one could expect better patient satisfaction in group A, which was evident in our results.

In spite of the advantages of laser therapy, it has some disadvantages. The main one is the excessively high financial cost compared with surgical excision Giamundo and colleagues [24]. That should be considered, especially in a very poor country living on external foreign aid, like Egypt, although it was not estimated in the current trial.

Our trial has some limitations to be mentioned. The relatively small patient sample and lack of long-term follow-up are the main drawbacks. That would be a good reason to conduct more studies to cover the previous drawbacks.

Conclusion

The combination of laser with hemorrhoidal artery ligation is associated with multiple advantages over

surgical hemorroidectomy, manifested in a better analgesic profile, better satisfaction, and an earlier return to daily activities. Junior surgeons should be encouraged to use the previous combination to obtain excellent patient outcomes.

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Conflicts of interest
There are no conflicts of interest.

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