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Research Article

Comparison of Intrahemorrhoidal Coagulation with 980 Nanometer Diode Laser and Milligan Morgan hemorrhoidectomy: A Randomized Clinical Trial

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Abstract

Purpose: Numerous surgical methods are applied as the gold standard for the operative treatment of severe hemorrhoids; however patients often experience notable postoperative pain and complications which can impact on their function for weeks following surgery. Nowadays, using laser-based techniques are now considered to minimize these events. In the present study, we compared the efficacy and complications of intrahemorrhoidal coagulation with 980 nanometer diode laser and Milligan Morgan hemorrhoidectomy.

Methods: Fifty nine consecutive adult patients more than 18 years with symptomatic internal hemorrhoid disease scheduled for hemorrhoidectomy surgery between January 2010 and 2011 were included in this randomized double-blind placebo controlled trial. The patients were randomly allocated by drawing blocked randomization to undergo either Milligan-Morgan hemorrhoidectomy (n=30) or intrahemorrhoidal coagulation with 980 nanometer diode laser (n=30).

Results: With respect to the postoperative pain severity based on VAS score within 24 hours after the operation, although pain severity during first 6 hours was nonsignificantly higher in the diode laser group, but pain severity was significantly more decrease in this group compared with the surgical hemorrhoidectomy group. Both intraoperative and postoperative bleeding was more severe in the Milligan-Morgan hemorrhoidectomy group. Also, hospital stay was longer in Milligan-Morgan hemorrhoidectomy group as well as the dose of consumed morphine after the procedure was significantly lower in those who treated with coagulation with 980 nanometer diode laser. The two groups were not different in terms of the prevalence of postoperative urinary retention, the number of regressed hemorrhoidal pockets, and also improvement of clinical signs within six months follow-up time. According to the multivariable linear regression analysis, postoperative pain severity and bleeding were significantly lower in the patients treated with intrahemorrhoidal coagulation with 980 nanometer diode laser than another technique

Conclusion: Intrahemorrhoidal coagulation with 980 nanometer diode laser is associated with reduced postoperative pain, intraoperative and postoperative bleeding, hospital stay, and dose of consumed morphine, and therefore it has more efficiency compared with the Milligan-Morgan hemorrhoidectomy.

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Introduction

Numerous methods have been examined and applied to treat internal hemorrhoids including rubber band ligation, sclerotherapy injection, infrared photocoagulation, laser ablation, carbon dioxide freezing,stapled hemorrhoidectomy, and surgical resection [1-3]. Most of the recommended methods are considered non-operative and should be the first-line treatment of all first- and second-degree internal hemorrhoids that do not respond to conservative therapy [4]. However, operative resection is generally reserved for patients with third- and fourth-degree hemorrhoids, those who fail non-operative therapy, and patients who also have significant symptoms from external hemorrhoids or skin tags [5-7]. Hemorrhoidectomy as the excision of hemorrhoids) is the procedure of standard for high grade symptomatic hemorrhoids. One of the standard techniques is open Milligan-Morgan surgery

that excises the hemorrhoids spinal or local anesthesia leaving raw areas in anal canal [8]. Although this would be considered as the gold standard for the operative treatment of hemorrhoids, patients often experience notable postoperative pain which can impact on patient function for weeks following surgery. Due to the difficult postoperative recovery of this procedure, alternative techniques for performing hemorrhoidectomy have been explored [9]. Unlike specialized surgical devices, lasers are widely available in the operating theatre and are used in many operations to cauterise tissue. Consequently, lasers have been used to treat hemorrhoids with the expectation of reducing post operative pain [10]. Although the laser appears to offer some advantages in open hemorrhoidal surgical procedures, some randomized trials comparing the use of lasers versus open hemorrhoidectomy have shown no significant differences in post operative pain and other complications [11]. In the present study, we compared the efficacy and complications between intrahemorrhoidal coagulation with 980 nanometer diode laser versus Milligan Morgan hemorrhoidectomy.

Methods

In a prospective clinical trial and after approval from the Ethics Committee at the Tehran University of Medical Sciences and obtaining written informed consent from the participants, 60 consecutive adult patients of American Society of Anesthesiologists (ASA) physical status I-II, age more than 18 years with symptomatic internal hemorrhoid disease third to fourth degree and non-respond to medical treatment, scheduled for hemorrhoidectomy surgery between January 2010 and 2011 were included in this randomized double-blind placebo controlled trial. Exclusion criteria were huge or prolapsed hemorrhoids, substance use, anorectic problems such as concurrent fisher, cardiovascular disease, hepatic disease or kidney injury, or history of drug sensitivity. The patients were randomly allocated by drawing blocked randomization to undergo either Milligan-Morgan hemorrhoidectomy (n=30) or intrahemorrhoidal coagulation with 980 nanometer diode laser (n=30). At surgery room and after setting ECG monitoring and pulse oxymetry, intravenous line was secured with 18G i.v canula and ringer lactate infusion (5cc/kg) was started. All patients were uniformly premedicated with Midazolam 1.0 mg, and then anesthesia was induced with sodium thiopental (5 mg/kg) and Sufentanil (0.1 µg/kg). For maintaining anesthesia, N2O 50% and isoflurane 0.5% to 1.5% were used. All patients received Sufentanil 5mg and Atracurium 10 mg (0.5 mg/kg) every 30 minutes.

All participants in lithotomy position underwent anoscopy and hemorrhoid pockets were determined.

The patients in Milligan-Morgan hemorrhoidectomy operated on using a standard open hemorrhoidectomy technique [12]. In laser method, hemorrhoid pockets were coagulated in parallel and with 5 mm intervals with radial laser fibers 980 nm, the laser power 15 watt and 3 seconds pulses. At the end of the operation, neostigmine (40µg/kg) and atropine (20µg/kg) were intravenously injected for antagonizing residual neuromuscular blockade. Blood pressure, pulse rate, and arterial oxygen saturation were monitored and recorded intraoperatively and every 5 minutes. At recovery room, patients were connected to a Patient-controlled analgesia (PCA) system including morphine sulfate (30 mg) at normal saline (30 ml). In any cases with pain, morphine 1 mg was injected with an 8-minute lock out time. After the operations, the patients were transferred to the wards. Pain was assessed every 6 hours within 24 hour after the procedures using a visual analog scale (VAS) in which 0 corresponds to "no pain" and 10 to "maximum pain" [13]. Postoperative complications and event including Intraoperative and postoperative bleeding, Urinary retention, wound infection, postoperative hospital stay, and Consumed morphine dose based on the PCA recording were assessed. Regressed hemorrhoid pockets were also recorded as complete or partial regression. The main criteria for discharge of the patients were: tolerating food, appropriate control of pain, and absence of bleeding. A follow-up examination was performed 1 week, as well as 1, 3, and 6 months postoperatively to assess improvement in clinical signs.

Results were presented as mean ± standard deviation (SD) for quantitative variables and were summarized by absolute frequencies and percentages for categorical variables. Categorical variables were compared using chi-square test or Fisher's exact test when more than 20% of cells with expected count of less than 5 were observed. Quantitative variables were also compared *t* test or Mann-Whitney U test. Multivariable linear regression analysis was used to determine differences in pain severity and bleeding between the two therapeutic procedures. Statistical significance was determined as a p value of ≥ 0.05. All statistical analysis was performed using SPSS software (version 16.0, SPSS Inc., Chicago, Illinois).

Results

In this study, totally 60 patients (30 patients who underwent Milligan-Morgan hemorrhoidectomy (mean age 47.2 ± 14.0 years, 40.0% male), and 30 patients who underwent intrahemorrhoidal coagulation with 980 nanometer diode laser (mean age 43.3 ± 13.8 years, 65.5% male) were evaluated. One of the patients were excluded from the laser group because of the lost to follow-up. The two groups were significantly comparable in terms of gender ratio and age. Also, both groups were matched for the number of packets. With respect to the postoperative pain severity based on VAS score within 24 hours after the operation (Table 1 & Figure 1), although pain severity during first 6 hours

Table 1. Baseline characteristics and pain severity within 24 hours of operation in the patients who treated with intrahemorrhoidal coagulation with 980 nanometer diode laser or Milligan-Morgan hemorrhoidectomy.

Pain severity (VAS)	Laser group (n=29)	Surgery group (n=30)	p-value
Male gender	19 (65.5)	12 (40.0)	0.050
Age (yr)	43.3±13.8	47.2±14.0	0.287
Number of pocket			0.232
1	0	6 (20.0)	
2	13 (44.8)	9 (30.0)	
3	16 (55.2)	14 (46.7)	
4	0	1 (3.3)	
6 hours later	5.69±1.50	5.17±1.30	0.151
12 hours later	3.97±0.92	5.30±1.06	< 0.001
18 hours later	3.00±1.28	4.33±0.99	< 0.001
24 hours later	1.48±1.43	2.87±1.03	0.001

was nonsignificantly higher in the diode laser group, but pain severity was significantly more decrease in this group compared with the surgical hemorrhoidectomy group. This significance was also confirmed by the repeated measured ANOVA test ($p < 0.001$). Both intraoperative and postoperative bleeding was more severe in the Milligan-Morgan hemorrhoidectomy group (Table 2). The time of operation was significantly higher in Milligan-Morgan hemorrhoidectomy group than laser group (52.3±15.1 min versus 32.8±7.0 min, $p < 0.001$). Also, hospital stay was longer in Milligan-Morgan hemorrhoidectomy group as well as the dose of consumed morphine after the procedure was significantly lower in those who treated with coagulation with 980 nanometer diode laser. None of the study groups experienced postoperative local infection. Two patients in the laser group experienced thrombosis 3 to 4 days after the surgery that both were medically treated. The mean discharge analgesic for laser and Milligan-Morgan hemorrhoidectomy groups was 5.4 ± 1.9 and 7.0 ± 2.2, respectively ($p = 0.002$). The two groups were not different in terms of the prevalence of postoperative urinary retention, the number of regressed hemorrhoidal pockets, and also improvement of clinical signs within six months follow-up time (Table 3).

According to the multivariable linear regression analysis (Table 4), postoperative pain severity was significantly lower in the patients treated with intrahemorrhoidal coagulation with 980 nanometer diode laser than another technique. Also, this analysis showed that the patients who underwent former therapeutic technique experienced less intraoperative and postoperative bleedings when adjusted for gender and age.

Table 2. Intraoperative and postoperative results intrahemorrhoidal coagulation with 980 nanometer diode laser and Milligan Morgan hemorrhoidectomy

Pain severity (VAS)	Laser group (n=29)	Surgery group (n=30)	p-value
Time of surgery	32.8±7.0	52.3±15.1	< 0.001
Intraoperative bleeding	12.76±4.55	22.83±8.27	< 0.001
Postoperative bleeding	1.55±2.35	5.00±3.47	< 0.001
Urinary retention	11 (37.9)	(23.3)	0.223
Hospital stay:			
One day	26 (89.7)	18 (60.0)	0.009
Two days	3 (10.3)	12 (40.0)	0.015
Consumed morphine dose	(11.33±4.86)	16.18±6.94	0.003
Regressed hemorrhoid pockets:			
Complete regression	11 (37.9)	18 (60.0)	0.090
Partial regression	18 (62.1)	12 (40.0)	0.120
Improvement in clinical signs:*			
Complete improvement	17 (58.6)	22 (73.34)	
Partial improvement	12 (41.4)	7 (23.3)	0.230
No improvement	0 (0.0)	1 (3.3)	

* After 6-month follow-up

Disussion

Our study findings were particularly based on the superiority of the use of intrahemorrhoidal coagulation with 980 nanometer diode laser in comparison with Milligan-Morgan hemorrhoidectomy in patients with symptomatic hemorrhoid non-responded to medical treatment. This more effectiveness was observed in terms of pain severity, severity of intraoperative and postoperative bleeding, length of postoperative hospital stay, and dosage of consumed morphine for pain relief. However, no difference was revealed regarding prevalence of urinary retention, postoperative wound infection, regression of hemorrhoidal pockets, and improvement of clinical signs of hemorrhoid 6 months after the operation.

Although in previous studies, the benefits of laser therapy was proved compared to other classic surgical treatments, our study seems to be unique because effectiveness of intrahemorrhoidal coagulation with 980 nanometer diode laser technique was evaluated for the first time and also compared with other techniques. Then laser is as effective as conventional surgery in the mid-term because of the efficacy of laser therapy symptoms relieved within 6 month follow up. According to this fact that in laser therapy compared with surgical treatments, postoperative

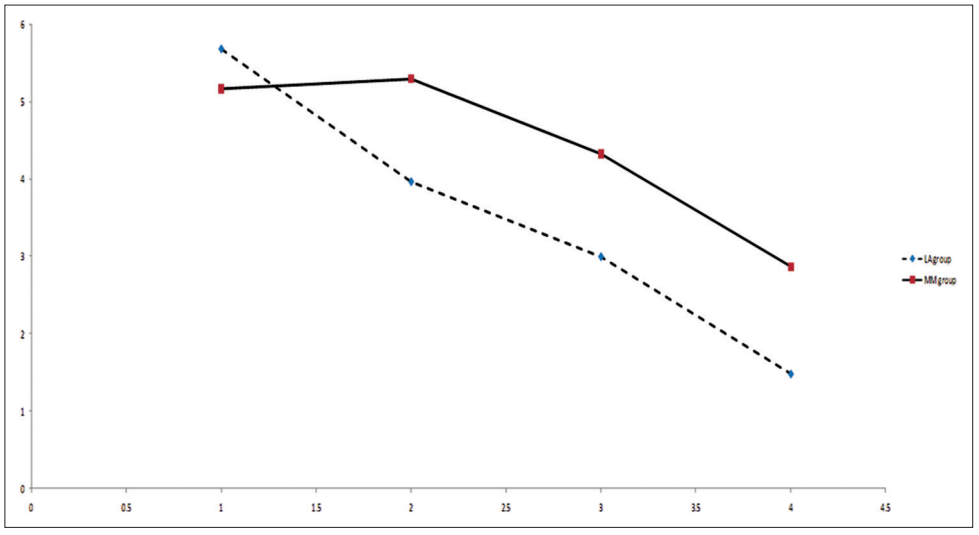

Figure 1. Baseline characteristics and pain severity within 24 hours of operation in the patients who treated with intrahemorrhoidal coagulation with 980 nanometer diode laser or Milligan-Morgan hemorrhoidectomy.

Table 3. Multivariate linear regression model for determining difference in pain severity between the two therapeutic procedures.

Variable	Beta	SE	P-value
6 hours later			
Procedure (MM vs. DL)	-1.144	0.265	< 0.001
Gender (M vs. F)	-0.236	0.265	0.378
Age	0.000	0.009	0.991
12 hours later			
Procedure (MM vs. DL)	1.233	0.251	< 0.001
Gender (M vs. F)	0.261	0.251	0.304
Age	0.009	0.009	0.322
18 hours later			
Procedure (MM vs. DL)	1.305	0.305	< 0.001
Gender (M vs. F)	-0.207	0.305	0.500
Age	0.021	0.011	0.057
24 hours later			
Procedure (MM vs. DL)	1.252	0.388	0.002
Gender (M vs. F)	0.018	0.388	0.962
Age	0.033	0.014	0.021

Table 4. Multivariate linear regression model for determining difference in bleeding between the two therapeutic procedures.

Variable	Beta	SE	P-value
Intraoperative			
Procedure (MM vs. DL)	9.000	1.688	< 0.001
Gender (M vs. F)	1.374	1.689	0.419
Age	0.186	0.060	0.003
Postoperative bleeding			
Procedure (MM vs. DL)	3.294	0.816	< 0.001
Gender (M vs. F)	0.260	0.816	0.752
Age	0.023	0.029	0.436

pain severity and bleeding were less prevalent and the procedure was performed using sedation and local anesthetic, patients' satisfaction is predictable. Moreover, because of local anesthesia, the complications of general anesthesia will be not appeared and thus the superiority of laser therapy will be warranted. Therefore, although we did not assess, the patients' satisfaction as well as their improved quality of life following laser therapy can be predicted.

However, our study had some limitations. First, although our study was performed on a greater sample in comparison with the previous studies, but according to no occurrence of death and wound infection, evaluation of the efficacy of intrahemorrhoidal coagulation with 980 nanometer diode laser with regard to these phenomena was not possible. In addition, follow-up time in our study was relatively short and therefore we could not assess long-term clinical improvement. In this context, further studies using greater size and with long-term following-up is recommended.

In conclusion, intrahemorrhoidal coagulation with 980 nanometer diode laser compared to Milligan-Morgan hemorrhoidectomy is more recommended because of its lower postoperative pain severity, less intraoperative and postoperative bleeding, shorter hospital stay, and no needed to high dosages of analgesics and sedatives.

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