Comparison of Effects of Vessel-Sealing Devices and Conventional Hemorrhoidectomy on Postoperative Pain and Quality of Life

The aim of this study was to investigate the early and late results of use of LigaSure, Harmonic Scalpel, and conventional hemorrhoidectomy in hemorrhoidectomy, to determine the least painful method, and to investigate the relationship between pain perception and personal differences in hemorrhoid bundles.

Material/Methods: Ninety patients undergoing hemorrhoidectomy between 2014 and 2017 were retrospectively evaluated. We investigated the duration of hospitalization and the presence of bleeding, incontinence, perianal wetness, urinary retention, stenosis, and recurrence during follow-up after surgery. Analgesic requirement was determined by Patient-Controlled Analgesia, as well as pain score by use of the Visual Analog Score and patient satisfaction by Short Form-36. We also assessed the relationship between pain and lateral thermal damage, the number of peripheral nerves, number of excised bundles, and the number of thrombosed vessels, as determined by histopathological examination.

Results: No differences were found among the 3 methods in the duration of hospitalization, the presence of bleeding, fecal incontinence, perianal wetness, urinary retention, anal stenosis, recurrence rate, VAS, analgesic consumption, or results of the SF-36. There was no difference in the number of bundles, thrombosed vessels, or number of nerve fibers in a bundle, but the LigaSure Hemorrhoidectomy had more lateral thermal damage (p<0.001). While there was a difference between VAS of day 1 and 7 according to the hemorrhoid bundles, there was no difference in the other parameters.

Conclusions: There was no difference among the 3 methods in terms of complications, postoperative pain, or patient satisfaction, and pain intensity was positively correlated with the number of excised bundles.

MeSH Keywords: Equipment Safety • Hemorrhoidectomy • Postoperative Complications • Quality of Life

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Background

Hemorrhoids are one of the most common diseases of the anorectal region [1]. The most common complaint of patients is rectal bleeding and pain and the mass that can be felt by hand. The general approach to the treatment of the disease in phases 1 and 2 is medical, while surgical hemorrhoidectomy is used in phases 3 and 4 [2]. “Open” Milligan Morgan (MM) and “closed” Ferguson method are the most common conventional hemorrhoidectomy (CH) techniques [3,4]. Although hemorrhoidectomy is the most effective treatment, the presence of postoperative pain and complications is the main reason why patients do not want the operation [5].

Although the presence of postoperative pain is common, its cause is not clear. Tissue damage and inflammatory response during surgery cause pain, while rapid healing and minimizing tissue damage can reduce pain [5,6]. It has also been reported that third-degree burn injury in the wound area terminates pain sensation in the nerves [7]. Other factors that can affect the initiation of pain, such as age, phase of disease, complaint period, working, and the number of excised bundles, may also affect the severity of pain. However, most of the major studies have shown that these parameters are insignificant [5].

In addition, early and late postoperative complications (e.g., urinary retention, bleeding, fecal and/or flatus incontinence, perianal wetness, anal stenosis, and recurrence) can affect patient satisfaction and success of the surgery.

As a result of the studies carried out to overcome these problems, various devices were developed and have become the part of treatment. The Harmonic Scalpel™ and LigaSure™ are 2 of these devices. By using bipolar energy, LigaSure™ can close the vascular structures up to 7 mm fully and permanently. Minimal adhesion, burning, and thermal damage have been reported [8]. Thermal damage was reported to be up to 2 mm, causing rapid healing [9]. The Harmonic Scalpel™ system causes coagulation by vibrating at 55 000 Hz and provides adhesion (fusión, sealing) in vascular structures up to 7 mm [10]. Studies revealed that Harmonic Scalpel hemorrhoidectomy (HSH) and LigaSure™ hemorrhoidectomy (LSH) are effective, fast, and safe techniques.

When examining the history of the literature on hemorrhoidectomy, it can be seen that many studies have been carried out to find the ideal technique and device. In addition, these studies compared the differences between LSH and CH, HSH and CH, or LSH and HSH, but we observed that these 3 techniques were seldom compared at the same time. In the present study, these 3 different tissue-cutting techniques were compared. The main purpose of the study was to compare the early and late postoperative results of the LSH, HSH, and CH. The secondary purpose was to determine the tissue-cutting method that caused the least amount of pain. The tertiary aim was to investigate whether individual differences and changes in excised hemorrhoids bundles are related to pain perception.

Material and Methods

After obtaining approval of the Ethics Committee of Hitit University Medical Faculty (2017/57), patients undergoing hemorrhoidectomy were retrospectively evaluated in the general surgical clinic of Hitit University Erol Olçok Training and Research Hospital between 2014 and 2017. During this period, 90 patients who underwent surgery were included in the CH, HSH, and LSH groups, with 30 patients in each group. The criteria for admission to the study were: male and female patients over the age of 18 years with stage 3–4 hemorrhoid disease. Exclusion criteria were: additional anorectal disease (fissure, fistula), thrombosed hemorrhoids, anal dilatation and sphincterotomy during surgery, neurological deficit, and hematological and inflammatory intestinal disease.

After the application of a preoperative single-dose rectal enema, spinal anesthesia with 3 cc Marcaine heavy 0.5% (bupivacaine hydrochloride 5 mg dextrose monohydrate 80 mg) was applied to all patients by using a 25-gauge ×90 mm QUINCKE needle, from the vertebral gap of lumbar 4–5. The blocked sensory level was assessed by pinprick test. The level of sympathectomy was assessed by measurement of heat, and the motor evaluation was assessed by Bromage scale [11].

After the effect of spinal anesthesia in the postoperative period had completely disappeared, patient-controlled analgesia (PCA) was used. The PCA protocol was 500 mg. Tramadol was added in 100 ml 0.9% NaCl (concentration: 5 mg/ml, infusion rate: 0 mg/h, bolus dose: 20 mg, locked-out time: 20 min).

Preoperative period

Conventional hemorrhoidectomy was performed as described in the MM technique (3). Harmonic ACE + 7 mm Shears (Ethicon Inc., Cincinnati, OH, USA) and LigaSure™ fine-tipped hand tool (Valleylab, Boulder, Colorado, USA) were used for HSH and LSH, respectively. The hand tool was placed at the base of the bundle and along the line extending from the muco-cutaneous line to the pedicle, and the burning and cutting process was repeated until the entire hemorrhoid bundle was removed. No saturation was done for hemostasis.

The duration of operation was recorded as the time between the onset of the first incision and the end of the hemostasis control.
Postoperative period

While discharging patients, Ornidazole 500 mg 2×1 tablet, Diclofenac sodium 100 mg 2×1 tablet, and a laxative-purging (Lactulose) agent were administered following standard procedure. Duration of hospitalization and the return to work were recorded. Recurrence cases were recorded in all patients who were followed up for 3 months. Bleeding was assessed on days 1, 7, and 14 by the amount of sponge contaminated in the perianal region (sponge/24 h). Patients were asked about occurrence of urinary retention, fecal and/or flatus incontinence, and perianal wetness at weeks 1, 6, 12. The presence of anatomic anal stenosis was classified according to the severity of stenosis and the level in the anal canal, and was evaluated at weeks 1, 6, and 12 [12].

In addition, the groups were combined independently from the technique to determine the relationship between the pain perception and the individual differences in the hemorrhoids bundle. Histopathological evaluation parameters (lateral thermal damage and the number of thrombosed vascular structures, peripheral nerves, and excised bundles) were divided into homogeneous subgroups. VAS values of subgroups were checked at days 1, 2, 7, 14, and 42.

Pain assessment was determined by the patients by use of the Visual Analog Score (VAS) (0=no pain and 10=very severe pain) at days 1, 2, 7, 14, and 42. In addition, the amount of analgesic substance used in the first 24 h was recorded as mg/24 h by using PCA.

The Quality of Life Assessment Short Form-36 (SF-36) questionnaire was filled out by the patients in the preoperative period and at postoperative month 3.

Hematoxylin-Eosin (HE)-stained slides were prepared to evaluate the depth of burns and thrombosis in excised bundles in a histopathological examination. To determine the number of peripheral nerves, the slides were stained with S100 in a Ventana fully automated immune-histochemical device. Lateral thermal damage was measured as the maximum depth (mm) of the burn effect by examining collagen degeneration.

In the Thrombosed Vascular Structure Score, 0=no thrombosis, 1=thrombosis in 1–25%, 2=thrombosis in 26–50%, and 3=thrombosis in >50%. The total number of peripheral nerves was determined by counting 5 areas at ×200 magnification.

Statistical analysis

Statistical analyses were performed using the SPSS (version 22.0, SPSS Inc., Chicago, IL, USA, licensed to Hittit University) package program. The homogeneity of the variances was determined by the Kolmogorov-Smirnov and Shapiro-Wilks tests, and normality distribution was assessed by the Levene test. Descriptive statistics are presented as a mean ± standard deviation, median (min-max) for continuous variables according to the normality assumption, and categorical data as number and percentage. For continuous variables, the t test was used for independent 2 group mean comparisons, the paired t test was used for dependent 2 group mean comparisons, the Mann-Whitney U test was used in independent groups with non-normally distributed data, and the Wilcoxon signed rank test was used in dependent groups. In more than 2 independent group sample mean comparisons, ANOVA was used for normally distributed data and the Kruskal-Wallis test was used for non-normal distributed data. A post hoc test (Mann-Whitney U) was used for binary comparisons to determine which groups were different from each other, by making Bonferroni corrections, in more than 2 group comparisons. The level of statistical significance was evaluated at the level of p<0.05.

Results

Of the 90 patients in the study, 84% (n=75) were males and 16% (n=15) were females. The mean age was 49 years (range, 19–87 years). There was no difference between the groups in terms of demographic data (p>0.05). There was no statistically significant difference between the duration of operation, hospitalization, or return to work time (Table 1).

In general complication assessment, there was no difference between the groups in terms of postoperative perianal hemorrhage at day 1 (p: 0.971), day 7 (p: 0.052), or day 14 (p: 0.073). No fecal and/or flatus incontinence, perianal wetness, urinary retention, or recurrence were observed in any of the patients.

Mild anal stenosis was determined at the lower level of the anorectal region of 2 patients in the MM group at weeks 6 and 12. In the HSH group, mild anal stenosis at the lower level of the anorectal region was detected in 1 patient at week 6 and in 2 patients at week 12. No anal stenosis was encountered in the LSH group. There was no significant difference between the groups (p: 0.318) (Table 2). There was no significant difference in the amount of Tramadol used in theVAS at days 1, 2, 7, 14, and 42 and in the first 24 h (Table 3).

There was no statistically significant difference between the groups factors that could affect postoperative pain, including the number of excised bundles, the amount of thrombosed vascular structure in an excised bundle, or the number of peripheral nerves, but there was a significant difference in lateral thermal damage (p<0.001) (Table 4). According to the number of excised hemorrhoids, significant differences were detected in the VAS1 and VAS7 evaluations for subgroups as follows;
Discussion

Hemorrhoidectomy is an operation in which patient satisfaction is low although it is a frequently performed operation surgery in current practice. The main cause of dissatisfaction is postoperative pain and complications. Therefore, the most important issue in hemorrhoidectomy is to control the pain to reduce early and late complications to a minimum level. The present study aimed to address this main problem using different techniques and different devices. Three different tissue-cutting techniques were used and compared.

Table 1. Descriptive statistics.

| Variables                  | Groups (n: 30) | Mean ±SD | Median (min–max) | p Value |
|---------------------------|----------------|----------|------------------|---------|
| Operation time            | 1              | 13.08±5.10 | 11 (7–25)        | 0.384   |
|                           | 2              | 11.67±4.84 | 11 (5–24)        |         |
|                           | 3              | 10.73±2.98 | 11 (4–15)        |         |
| Hospitalization time      | 1              | 2.92±2.36  | 2 (1–10)         | 0.406   |
|                           | 2              | 2.10±1.37  | 2 (1–7)          |         |
|                           | 3              | 2.33±1.17  | 2 (1–5)          |         |
| The return to work time   | 1              | 18.08±8.91 | 20 (3–30)        | 0.627   |
|                           | 2              | 16.29±9.17 | 14 (3–30)        |         |
|                           | 3              | 18.93±6.20 | 21 (7–30)        |         |

Groups 1 – CH; 2 – HSH; 3 – LSH.

Table 2. Anal stenosis comparison.

| Groups | No (%) | Yes (%) | No (%) | Yes (%) | P  | No (%) | Yes (%) | P   |
|--------|--------|---------|--------|---------|----|--------|---------|-----|
| 1      | 100    | 0       | 85     | 15      |    | 85     | 5       | 0.318   |
| 2      | 100    | 0       | 95     | 5       | 0.225 | 90     | 10      |     |
| 3      | 100    | 0       | 100    | 0       |     | 100    | 0       |     |

Groups 1 – CH; 2 – HSH; 3 – LSH.

Table 3. Comparison of VAS score and the amount of analgesics.

| Groups | VAS 1 Median (min–max) | P   | VAS 2 Median (min–max) | P   | VAS 7 Median (min–max) | P   | VAS 14 Median (min–max) | P   | VAS 42 Median (min–max) | P   | Mean ±SD | Median (min–max) | P   |
|--------|------------------------|-----|------------------------|-----|------------------------|-----|------------------------|-----|------------------------|-----|----------|------------------|-----|
| 1      | 4 (0–8)                | 0.88| 3 (0–7)                | 0.21| 2 (0–8)                | 0.13| 0 (0–5)                | 0.63| 65.67±24.0            | 0.63| 67.31±47.0| 55 (25–170)    |     |
| 2      | 4 (0–9)                | 0.88| 3 (1–9)                | 0.21| 2 (0–8)                | 0.13| 0 (0–5)                | 0.63| 80.95±52.2            | 0.63| 80 (20–225)        |       |
| 3      | 3 (0–10)               | 0.88| 5 (1–8)                | 0.21| 3 (0–9)                | 0.13| 2 (0–5)                | 0.63| 65.67±24.0            | 0.63| 65 (25–120)        |       |

Groups 1 – CH; 2 – HSH; 3 – LSH.

(Group1=1–2, Group 2=3, Group 3 >3 (p<0.036) (p<0.022). There was no difference in other parameters (Table 5).
### Table 4. Comparison of histopathological results.

| Variables                        | Group (N: 30) | Mean ±SD  | Median (min–max) | p-Value |
|----------------------------------|---------------|-----------|------------------|---------|
| Thrombosed vascular structure amount |               |           |                  |         |
|                                   | 1             | 1.00 ± 1.26 | (0–3)            | 0.590   |
|                                   | 2             | 1.00 ± 1.08 | (0–3)            |         |
|                                   | 3             | 0.62 ± 0.96 | (0–3)            |         |
| Number of excised bundles         |               |           |                  |         |
|                                   | 1             | 2.77 ± 0.73 | (1–4)            |         |
|                                   | 2             | 2.76 ± 1.09 | (1–5)            | 0.996   |
|                                   | 3             | 2.80 ± 0.86 | (1–4)            |         |
| Peripheral nerve number           |               |           |                  |         |
|                                   | 1             | 8.40 ± 4.09 | (5–18)           |         |
|                                   | 2             | 8.39 ± 3.18 | (5–15)           | 0.333   |
|                                   | 3             | 7.08 ± 2.90 | (4–13)           |         |
| Lateral thermal damage (mm)       |               |           |                  |         |
|                                   | 1             | 1.41 ± 0.66 | (0–3)            | p<0.001*|
|                                   | 2             | 2.73 ± 0.99 | (1–4.5)          |         |

Groups 1 – CH; 2 – HSH; 3 – LSH.

### Table 5. Comparison of histopathologic subgroups with VAS.

| Groups | VAS 1     | VAS 2     | VAS 7     | VAS 14    | VAS 42    |
|--------|-----------|-----------|-----------|-----------|-----------|
|        | Median (min–max) | Median (min–max) | Median (min–max) | Median (min–max) | Median (min–max) |
|        | p         | p         | p         | p         | p         |
| Peripheral nerve number          |           |           |           |           |           |
| ≤ 7   | 4 (0–10)  | 3 (0–8)   | 2 (0–5)   | 1 (0–7)   | 0 (0–5)   |
| ≥ 8   | 5 (0–10)  | 5 (1–9)   | 2 (0–8)   | 0.827     | 0.408     | 0.189     |
| Number of thrombosed vessels     |           |           |           |           |           |
| ≤ 0   | 4 (0–9)   | 4 (0–9)   | 2 (0–5)   | 0.25      | 0.189     |
| > 0   | 4 (0–10)  | 3 (1–8)   | 2 (0–8)   | 0.726     | 0.522     | 0.235     |
| ≥ 3   | 7 (0–9)   | 5 (2–9)   | 1 (0–7)   | 0 (0–4)   | 0 (0–0)   |
| Lateral thermal damage (mm)      |           |           |           |           |           |
| ≤ 0.5 | 6.5 (1–10)| 3.5 (1–7) | 3 (0–8)   | 1 (0–4)   | 0 (0–2)   |
| > 0.5 | 4.5 (1–9) | 2 (0–5)   | 2 (0–8)   | 0.876     | 0 (0–3)   |
| > 2   | 1.5 (0–10)| 1 (0–8)   | 0 (0–5)   | 0 (0–3)   |           |
| Number of excised bundle         |           |           |           |           |           |
| 1–2  | 2 (0–10)  | 4.5 (1–7) | 2 (0–5)   | 0 (0–3)   | 0 (0–3)   |
| > 2  | 3 (0–9)   | 0.56      | 2 (0–7)   | 0.22      | 0 (0–4)   | 0.875     |
| > 3  | 5 (0–10)  | 4 (2–8)   | 5 (2–9)   | 2 (0–7)   | 0 (0–5)   |

* Statistically significant (p<0.05). Thrombosed vascular structure score: Score 0 – no thrombosis; Score 1 – thrombosis in 1–25%; Score 2 – thrombosis in 26–50%; Score 3 – thrombosis in >50%. Number of peripheral nerves – total number of peripheral nerves counted in 5 areas at ×200 magnification.
demonstration of the superiority of the applied technique of hemorrhoidectomy. In this context, in studies evaluating duration of the operation, LSH has a shorter duration of operation compared to CH and HSH [5,6,13–16]. In this study, no significant difference was observed between the groups. In addition, some studies reported that there was no significant difference between LSH, CH, and HSH in hospitalization duration [5,6,16]. The results of the present study are consistent with the literature. Although it has been reported in the literature [5,6,14,15] that there was a significantly earlier return to work with use of LSH, the present study did not find this difference. We found no differences among the 3 tissue-cutting techniques in terms of duration of operation, hospitalization, and the return to work, which are the parameters determining the cost effectiveness of hemorrhoidectomy.

It is very important to evaluate early and late complications while determining the reliability, effectiveness, and superiority of the surgical technique. In this context, there is no significant difference between LSH and CH for postoperative hemorrhage evaluation in the literature [5,13,14]. There was no significant difference between the groups at day 1 (p: 0.971), day 7 (p: 0.052), and day 14 (p: 0.073). In addition, no differences were observed between LSH and CH or between LSH and HSH in studies comparing fecal and/or flatus incontinence [5,13,16]. Results of the present study are consistent with the literature. It has been reported that there was significantly less perianal wetness with use of KH compared to LSH [14], but no difference was observed in the present study.

A meta-analysis in which urinary retention was assessed showed no significant difference between LSH and CH, while another meta-analysis showed a significant difference in favor of LSH [13,15]. In Cochrane analysis, it was stated that LH had a non-significant increase [5]. There was no difference between LSH and HSH [16]. There was also no statistically significant difference in the present study.

In a meta-analysis, recurrence rates were reported to be significantly lower in the LSH group [14]. There was also no significant difference between LSH and HSH in a study [16]. In the present study, no recurrence was detected in any of the patients during 3 months of follow-up.

No significant difference was reported between LSH and CH in meta-analyses where anal stenosis was evaluated [13,15]. Cochrane analysis showed a non-significant increase in LSH, whereas, in another meta-analysis, anal stenosis was significantly lower in the LSH group [5,14]. There was no significant difference between LSH and HSH [16]. In the present study, mild anal stenosis at the level of the anorectal region was detected in 2 patients in the MM group and in 3 patients in the HSH group. The number of excised bundles from 2 individuals in the MM group was 2 and 3 and in 3 individuals in the HSH group it was 2, 3, and 4. A stenosis in a patient in the HSH group was thought to be due to the increased number of bundles (n: 4). None of the patients needed corrective surgery. There was no significant difference between groups. However, LSH was considered to be advantageous because no patients in that group developed anal stenosis.

In Cochrane analysis assessing patient satisfaction, the satisfaction rate with CH was significantly lower [5]. There was no difference between LSH and HSH [16]. In the present study, there was no significant difference between groups in the preoperative and postoperative SF-36 evaluation (p>0.05). We found no difference in patient satisfaction among the 3 groups in our study, and this result appears to be compatible with the lack of difference in the evaluation of pain and general complications.

In a meta-analysis comparing LSH and CH, VAS was found to be significantly lower in favor of LSH on days 1, 2, and 7, but the difference disappeared by day 14 [13]. Likewise, in all 3 meta-analyses, the first-day pain score was significantly lower in with LSH [6,14,15]. Cochrane analysis showed that the pain score on day 1 was significantly lower with LSH than with CH, but no difference was found on the other days [5]. LSH was also shown to have histologically negligible tissue damage, which is why the pain is significantly less than with use of CH [5,17]. Some studies comparing LSH and HSH did not show a significant difference, but 2 randomized and controlled studies showed that HSH was more painful [16–20]. In 2 different studies, similar pain scores were seen in LSH and HSH [21,22].

No significant difference was found between the groups in terms of VAS score. In addition, there was no difference between the groups (p: 0.632), although the amount of analgesia used at postoperative 24 h was higher in the HSH group. A study found the mean lateral thermal damage was 3.08 (±0.67) mm using LigaSure™ and 2.54 (±0.48) mm using Harmonic™ ACE +7 Shears, and the difference was statistically significant (p<0.003) [10]. In the present study, the mean value with LigaSure™ was 2.73±0.99 and 1.41±0.66 mm with Harmonic™ ACE +7 Shears, showing a significant difference (p<0.002). Although there was no statistically significant difference in pain evaluation, it appears that LSH, which had more lateral thermal damage, ended the pain sensation by affecting the perianal peripheral nerves, which is compatible with the literature [7]. In addition, it appears that VAS score is a more subjective evaluation and the use of PCA is more objective and accurate in the early evaluation of pain.

Among the factors that could affect postoperative pain, we found no significant difference between the groups in the number of excised bundles (p: 0.996), which is consistent with the
literature [5,23]. Unlike previous studies, we found no difference between groups in the amount of thrombosed vascular structure (p: 0.590) and the number of peripheral nerves (p: 0.333).

Regardless of the surgical technique, the relationship between the pain level and the personal differences in hemorrhoids bundle was examined and the differences between group 1 and 2 were determined on day 1 of VAS evaluation (p<0.036), showing there was more pain when there were 3 excised bundles than if there were ≤2. In the VAS evaluation on day 7, patients with >3 excised bundles showed more pain (p<0.022). Although, there are meta-analysis results supporting or not supporting the positive correlation between the number of bundles in the early period and the development of pain, our results showed a significant difference in pain (Table 5). Subgroups had no significant difference in pain.

Publications with similar or opposite results in the literature evaluating the pain of different surgical methods suggest that there is still no consensus on the method causing the least pain, and more research is needed. The present study is important in that it used PCA and determined the amount of lateral thermal damage, the amount of the thrombosed vascular structures, and the number of peripheral nerves.

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Conclusions

In conclusion, no differences were found in duration of operation, hospitalization, and the return to work, nor in the presence of hemorrhage, fecal and/or flatus incontinence, perianal wetness, urinary retention, recurrence rate, and patient satisfaction, when comparing these 3 different tissue-cutting techniques. Anal stenosis did not develop in LSH, being not statistically significant. There was no significant difference in postoperative pain, but it was higher in the HSH group. We also found that the number of excised bundles was related to the severity of pain. Lateral thermal damage and the number of thrombosed vascular structures and peripheral nerves had no effect on pain. As a result, there was no difference between these 3 tissue-cutting methods and all appear to be safe. The Harmonic Scalpel™ and LigaSure™ devices are more expensive but are easier to learn how to use.

Conflict of interest

None.