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## ORIGINAL ARTICLE

# Short- and long-term results of harmonic scalpel hemorrhoidectomy versus stapler hemorrhoidopexy in treatment of hemorrhoidal disease



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**Summary Purpose:** In this prospective randomized study, our aim is to compare the short- and long-term results of harmonic scalpel hemorrhoidectomy (HSH) and stapler hemorrhoidopexy (SH) methods in the surgical treatment of Grade III and Grade IV hemorrhoidal disease. **Methods:** Ninety-nine consecutive patients diagnosed with Grade III or Grade IV internal hemorrhoidal disease were included in the study. Patients were randomized to HSH ( $n = 48$ ) or SH ( $n = 51$ ) treatments. Data on patient demographic and clinical characteristics, operative details, postoperative pain score on a visual analog scale, additional analgesic requirement, postoperative short- and long-term complications, and recurrence of hemorrhoidal disease were also recorded. Patients were regularly followed for a total period of 24 (6–36) months.

**Results:** The patient demographic and clinical characteristics were similar in the two groups. The operative time was significantly shorter in the HSH group compared with the SH group. Overall pain scores were not significantly different between the groups, although severe pain was significantly more common in the HSH group. Recurrence was significantly lower in the HSH group compared with the SH group.

**Conclusion:** HSH and SH are both safe and effective methods for surgical treatment of Grade III and Grade IV hemorrhoidal disease. In our study, the HSH method was determined to be safer, easier, and faster to perform, and associated with fewer long-term recurrences than the SH method.

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## 1. Introduction

Hemorrhoidal disease is a very common anorectal disorder, occurring in approximately 5% of the general population, and more frequently in individuals who are older than 40 years.<sup>1,2</sup> Surgical treatment is required in cases having symptomatic Grade III and Grade IV hemorrhoids. Additionally, surgery may be required when medical treatment fails or in the presence of concomitant conditions such as anal fissures or ulcers. There are various techniques used in the surgical treatment of hemorrhoidal disease. Conventional techniques include Ferguson's closed hemorrhoidectomy and Milligan–Morgan's open hemorrhoidectomy, which can be performed with scalpel or electrocautery. Additionally, a variety of devices and methods have been introduced to help facilitate the procedure and minimize patient discomfort in the postoperative period.

Harmonic scalpel (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA), which was introduced for the first time in 1992, uses ultrasound energy to cut and coagulate soft tissue, with minimal thermal damage to the surrounding tissue.<sup>3</sup> Harmonic scalpel has been used extensively in general surgery procedures such as cholecystectomy, hemorrhoidectomy, and thyroidectomy; gynecological procedures such as myomectomy; and to cut internal mammary artery in thorax surgery.<sup>4</sup> Currently, harmonic scalpel hemorrhoidectomy (HSH) is used as a routine technique in many centers. In HSH, postoperative pain is purported to be minimal, as thermal damage to the surrounding tissue is avoided. During the surgery, harmonic scalpel seals bleeding vessels and forms protein coagulum. When used in hemorrhoidectomy, this method minimizes bleeding of large hemorrhoids and decreases operative time.

It has been 15 years since Longo<sup>5</sup> introduced the use of stapler hemorrhoidopexy (SH) in prolapsed hemorrhoidal disease in 1998. The initial results of five randomized trials conducted in 2000 were encouraging when comparing SH with conventional hemorrhoidectomy.<sup>6–10</sup> In addition to obliterating submucosal vessels, SH aims to bring prolapsed rectal mucosa back to a natural level and rectify the topographic relation between the anorectal mucosa and the underlying muscle.<sup>5</sup> In this method, a ring of rectal mucosal–submucosal tissue is resected approximately 3–4 cm above the dentate line, disrupting distal branches of superior rectal artery feeding the hemorrhoids and restoring the prolapsed hemorrhoidal plexus to original anatomical position.<sup>11</sup> Because SH involves the rectum where pain sensation is absent instead of the anoderm, theoretically it promises less postoperative pain and shorter hospitalization compared to conventional methods. Following its introduction, thousands of patients were operated on with this technique in Europe.<sup>12</sup>

In this prospective study, we compared the short- and long-term results of HSH and SH, two techniques that are routinely used all over the world, in the surgical treatment of Grade III and Grade IV hemorrhoidal disease, and presented our results in comparison with the existing literature. It might seem more logical to compare HSH with the traditional electrical energy of diathermy or traditional open hemorrhoidectomy (Milligan–Morgan), but it should be noted that we are using both SH and HSH techniques in the

treatment of hemorrhoidal disease in our surgical department. Additionally, there is only one prospective randomized study comparing these techniques in literature. So, our aim was to contribute to the literature with this study.

## 2. Materials and methods

Patients presenting to the General Surgery Department of Istanbul Okmeydani Training and Research Hospital, Istanbul, Turkey with various complaints related to the anal area were screened in a time span of 4 years; after physical and sigmoidoscopic examination, 99 patients diagnosed with Grade III or Grade IV internal hemorrhoidal disease were included in the study. The exclusion criteria were previous anorectal surgery, acute thrombosed hemorrhoid, external hemorrhoids, concomitant anal diseases such as anal fissure, fistula, or abscess, hematologic disease, anticoagulant use, and cancer. Medical history and current symptoms were investigated in detail. Detailed physical examination and rigid rectosigmoidoscopy were performed on all patients. All patients with indication for surgical treatment were informed about the procedures. Purgative enema was applied 1 day prior to the surgery. All 99 patients were operated on while they were in the lithotomy position, under general anesthesia. Local adrenal infiltration, local anesthesia, or pudendal nerve block methods were not performed. Prophylactic single-dose first-generation cephalosporin (cephazolin sodium) was delivered parenterally to all patients. Patients were randomized to surgery using HSH ( $n = 48$ ) or SH ( $n = 51$ ) methods.

HSH cases were operated using the Ethicon Harmonic Scalpel 300 (Ethicon Endo-Surgery Inc.). Suture was not used; islands of at least 8–10 mm were left between the excised hemorrhoid and the skin. A PPH01 Kit (Ethicon Endo-Surgery Inc.), which consisted of a circular anal dilator (CAD 33), a purse-string suture anoscope (PSA), a suture threader, and a 33-mm hemorrhoidal circular stapler, was used while SH was being performed. The purse-string was done between 3 cm and 4 cm above the dentate line; the purse-string was completed with six to eight stitches, which included only the mucosal and submucosal layers, and hemostatic stitches using a 3–0 vicryl (Ethicon Endo-Surgery Inc.) suture on a round body 16–18 mm needle were used in case of bleeding.

Evaluation parameters included age, sex, presenting symptoms, disease grade, operative time, duration of hospitalization, return to daily activities, postoperative complications, and postoperative pain. Short- and long-term complications were assessed on follow-up outpatient visits at postoperative Month 1, Month 6, and Month 24. Patients with Grade III and Grade IV disease were evaluated together and separately.

Postoperative pain was assessed with a linear visual analogue pain scale (VAS) by the patient, surgeon, and an independent blinded assessor. The VAS scores were grouped as mild (0–3), moderate (4–6), and severe (7–10).<sup>13</sup> The analgesic given was diclofenac sodium with a maximum dose of 2.5 mg/kg/d (intramuscularly in the first 24 hours and via the oral route thereafter). In severe pain, opioid analgesic (pethidine 1 mg/kg) was given in one or two doses

in the 1<sup>st</sup> day. Patients with moderate or high levels of pain requiring additional doses of analgesics were recorded.

## 2.1. Statistical analysis

Statistical analysis was performed using Number Cruncher Statistical System NCSS 2007 and PASS 2008 Statistical Software (Kaysville, UT, USA). Study data were summarized using descriptive statistics (mean, standard deviation, frequency). Student *t* test was used for group comparisons of continuous variables, whereas Chi-square test and Fisher's exact test were used for group comparisons of categorical variables. The level of statistical significance was set at  $p < 0.05$ .

## 3. Results

This study was conducted in the General Surgery Department of Okmeydani Training and Research Hospital, on 60 males (60.6%), and 39 females (39.4%), yielding a total of 99 patients. The male/female ratio was 28:20 for the HSH group and 32:19 for the SH group. Out of 48 cases in the HSH group, 33 (68.8%) had Grade III and 15 (31.2%) had Grade IV disease.

Out of 51 cases in the SH group, 34 (66.7%) had Grade III and 17 (33.3%) had Grade IV disease. Demographic, perioperative, and follow-up data of patients are summarized in Table 1.

Patient age ranged from 23 years to 73 years. The mean age of patients in the HSH and SH groups was 44.9 years and 44.3 years, respectively. The presenting symptoms were pain, bleeding, mucous discharge, pruritus ani, prolapse, and flatulence. Hospital stay was 2.4 days in the HSH group and 2.6 days in the SH group. Patients in the HSH and SH groups returned to daily activities in 6.1 days and 6.2 days, respectively. No statistically significant difference was found between the groups in terms of disease grade, age, sex, clinical characteristics, additional analgesic requirement, hospital stay, and time to return to daily activities.

**Table 1** Demographic, perioperative and follow-up data of HSH versus SH.

|                                      | HSH<br>( <i>n</i> = 48) | SH<br>( <i>n</i> = 51) | <i>p</i> |
|--------------------------------------|-------------------------|------------------------|----------|
| Age (mean)                           | 44.9                    | 44.3                   | NS       |
| Sex (M/F)                            | 28/20                   | 32/19                  | NS       |
| Grade III/grade IV                   | 33/15                   | 34/17                  | NS       |
| Operation times (min)                | 17                      | 22                     | <0.05    |
| Mean hospital stay (d)               | 2.4                     | 2.6                    | NS       |
| Time to return to daily activity (d) | 6.1                     | 6.2                    | NS       |
| Postoperative pain (total)           | 34 (70.8%)              | 37 (72.6%)             | NS       |
| Mild pain                            | 16 (33.3%)              | 22 (43.1%)             | NS       |
| Moderate pain                        | 12 (25%)                | 14 (27.5%)             | NS       |
| Severe pain                          | 6 (12.5%)               | 1 (2%)                 | <0.05    |
| Additional analgesic requirement     | 18 (37.5%)              | 15 (29%)               | NS       |

HSH = harmonic scalpel hemorrhoidectomy; NS = not significant; SH = stapler hemorrhoidectomy.

The mean duration of follow-up was 24 (6–36) months. The mean operative time for the HSH and SH groups was 17 and 22 minutes, respectively. The mean operative time for the HSH group was significantly shorter than that for the SH group.

According to the VAS scores, postoperative pain within the first 24 hours was mild in 16 patients (33.3%), moderate in 12 patients (25%), and severe in six patients (12.5%) in the HSH group. The same pain scoring showed mild pain in 22 patients (43.1%), moderate in 14 patients (27.5%), and severe in only one patient (2%) in the SH group. The number of patients requiring additional analgesic dose was 18 (37.5%) in the HSH group and 15 (29%) in the SH group. Overall pain scores were not significantly different between the two groups. However, significantly more patients had severe pain in the HSH group compared with the SH group.

Short-term complications in the HSH group included wound problems in six cases (12.5%), bleeding in five cases (10.4%), and edema in five cases (10.4%). Long-term complications included recurrence in one case (2.1%), stenosis in two cases (4.2%), and wound problems in two cases (4.2%). Short-term complications in the SH group included bleeding in eight cases (15.6%) and wound problems in eight cases (15.6%), whereas long-term complications included recurrence in seven cases (13.7%) and perianal fistula in one case (1.9%; Table 2). There was no significant difference between the two groups in terms of wound problems—including irritation, itching, and moisture. Bleeding as a short-term complication was higher in the SH group compared with the HSH group. No septic complications occurred in our study. During the follow-up assessment, none of the patients complained of fecal urgency or of liquid or solid incontinence.

At the end of 2 years postoperatively, only one case (2.1%) with Grade IV disease recurred in the HSH group, whereas a total of seven cases [3 (8.8%) with Grade III disease and 4 (23.5%) with Grade IV disease; 13.7%] recurred in the SH group. The recurrence rate was significantly lower in the HSH group compared with the SH group.

## 4. Discussion

The treatment for hemorrhoidal disease aims to provide a long-term relief from present symptoms and complaints,

**Table 2** Short- and long-term complications.

|                          | HSH ( <i>n</i> = 48) | SH ( <i>n</i> = 51) | <i>p</i> |
|--------------------------|----------------------|---------------------|----------|
| Short-term complications |                      |                     |          |
| Wound problems           | 6 (12.5)             | 8 (15.6)            |          |
| Bleeding                 | 5 (10.4)             | 8 (15.6)            |          |
| Edema                    | 5 (10.4)             | —                   |          |
| Long-term complications  |                      |                     |          |
| Recurrence               | 1 (2.1)              | 7 (13.7)            | <0.05    |
| Stenosis                 | 2 (4.2)              | —                   |          |
| Wound problems           | 2 (4.2)              | —                   |          |
| Perianal fistula         | —                    | 1 (1.9)             |          |

Data are presented as *n* (%).

HSH = harmonic scalpel hemorrhoidectomy; SH = stapler hemorrhoidectomy.

especially pain. Another important aim is to increase the quality of life. These aims can be achieved through a dependable surgical technique and preservation of ano-rectal functions. As postoperative pain is thought to be caused by thermal damage, and harmonic scalpel results in less thermal damage compared with laser and electrocautery, HSH was proposed as a less painful operation.<sup>14</sup> However, other studies found no evidence of reduced pain levels with HSH, and showed that, owing to the use of disposable materials, HSH turns out to be 10 times more expensive than hemorrhoidectomy using regular cautery.<sup>4,15</sup>

In a first and foremost study, Chung et al<sup>3</sup> compared the HSH and SH techniques in 88 patients and reported significantly lower VAS scores of postoperative pain, shorter hospitalization, faster return to daily activities, and higher patient satisfaction in the SH group. In our study, mean scores of overall pain did not reach statistical significance between the two groups. However, severe pain was reported significantly more with HSH than with SH. In only one case of severe pain in the SH group, distance between the stapler line and the dentate line was seen to be approximately 1 cm.

Ramadan et al<sup>16</sup> reported postoperative pain in 4.3% of patients undergoing HSH, whereas in a prospective study Armstrong et al<sup>14</sup> showed significantly less postoperative pain in HSH compared with electrocautery hemorrhoidectomy. In a prospective randomized study comparing diathermy and HSH, Tan and Seow-Choen<sup>4</sup> did not find a significant difference between the two groups in terms of postoperative pain.

Although Longo's<sup>10</sup> technique was popularized by studies reporting low pain scores and short hospital stay with SH,<sup>5,6,17–20</sup> later studies with opposite findings created confusion. Cheetham et al<sup>21</sup> reported pain in 31% of patients who underwent SH; by contrast, Ravo et al,<sup>22</sup> in their study encompassing 12 centers and including 1107 patients, reported severe pain in 5% of patients at postoperative Week 1. These findings concur with Oughriss et al's<sup>23</sup> study, where early and late complications of the technique were investigated and the presence of severe pain was determined in 2.3% of cases. In a multicenter randomized clinical trial, Thaha et al<sup>24</sup> compared SH and closed hemorrhoidectomy and defined "pain after defecation" as a special complication related to stapler use, although it was not demonstrated in following studies. Despite these results, the number of studies reporting the superiority of SH in postoperative pain control compared with conventional methods is high. In support of these latter reports, we also find the frequency of pain higher in the HSH group than in the SH group.

One of the most important short-term complications of hemorrhoidectomy is bleeding. Some authors have proposed severed branches of superior hemorrhoidal artery as the cause of short-term abundant bleeding. Contrary to the results of Chung et al,<sup>3</sup> in our study, postoperative bleeding was less in the HSH group compared with the SH group. In a study by Armstrong et al<sup>25</sup> conducted on 500 patients undergoing HSH, none of the patients had short-term postoperative bleeding, and only three patients (0.6%) had secondary bleeding in postoperative Days 7–14. In the study of Tan and Seow-Choen,<sup>4</sup> a reasonable postoperative

bleeding rate of 4% was reported. In the literature, postoperative bleeding rates for SH vary from 6% to 25%.<sup>26–29</sup> In a study comparing the hemorrhoidectomy results of Grade III versus Grade IV hemorrhoids, Finco et al<sup>12</sup> determined the postoperative bleeding rate as 10.5% in Grade III, 23.8% in Grade IV, and 12.9% overall.

In our study, five patients in the HSH group developed edema as a short-term complication, whereas no patients had edema in the SH group. This was regarded as an adverse side effect of HSH compared with SH. In our study, the mean operative time was significantly shorter in the HSH group compared with the SH group (17 minutes vs. 22 minutes). By contrast, no significant time difference was determined by Chung et al.<sup>3</sup>

Incontinence is a short-term complication and one of the most important parameters affecting patient comfort and satisfaction. In our study gas, incontinence was not encountered in the HSH group; in the SH group, only one patient whose primary complaint prior to the surgery was gas incontinence, continued to have the same complaint (2%). Endoanal ultrasonography showed no sphincter defect in this patient. The rate of gas incontinence was 0.2% in the Armstrong et al<sup>25</sup> study on HSH. In the study conducted by Riss et al<sup>30</sup> on SH including 242 patients, the number of patients with gas incontinence was 11 (4.5%) and the technique was reported to have no adverse effect on anal functions. Ho et al<sup>31</sup> used endoanal ultrasonography to evaluate internal sphincter function following SH and found it within normal limits. In another study, patients were evaluated pre- and postoperatively by anal manometry and three-dimensional ultrasonography, but no sphincter defect was detected.<sup>32</sup> In other studies comparing conventional and SH techniques using the continence score, no significant differences were reported.<sup>31,33,34</sup>

In our study, we did not encounter complications such as urinary retention,<sup>3,16,25</sup> abscess, fistula, fissure, and pseudo-obstruction,<sup>25</sup> which have been reported in association with the HSH technique, or sphincter damage,<sup>35</sup> rectal or vaginal perforation,<sup>36</sup> Fournier disease,<sup>37,38</sup> and permanent postoperative rectal pain,<sup>35,39</sup> which have been reported in association with the SH technique.

No septic complication was seen in our study; however, it must be remembered that all surgical and interventional methods recommended for hemorrhoid treatment carry a risk of life-threatening sepsis. Post-SH sepsis is more frequent,<sup>40</sup> possibly because of the increased recent interest in the technique. Rectal perforation and peritonitis are SH-specific complications; peritonitis is rarely seen in other methods. SH may result in severe sepsis, which has a 10% mortality. Thus, the surgeon performing SH should be very careful and examine the patients presenting with high fever and severe pain in the operation room, under anesthesia. Early recognition of septic complications can prevent severe morbidity.<sup>41</sup> Rectal obstruction, anal stenosis, rectal pocket syndrome or rectal diverticulum, rectovaginal fistula, anorectal stricture, rectocele, and rectal intussusception are other rare complications that can occur following the SH procedure.<sup>42,43</sup>

Studies claiming to have successfully implemented Longo's<sup>10</sup> technique were supported by Pernice et al's<sup>27</sup> study, where patients with Grade III and Grade IV hemorrhoids were followed for a mean of 33 months and no recurrence

was found. By contrast, Ortiz et al<sup>44</sup> reported that SH was less successful in patients with Grade IV hemorrhoidal disease. Also, in a prospective study comparing SH with conventional techniques, Goulimaris et al<sup>17</sup> stated that SH has higher recurrence rates, which is the biggest factor accounting for its failure in Grade IV cases. Moreover, in another prospective study by Ortiz et al,<sup>45</sup> where SH was compared with diathermy, no recurrent cases were seen in the diathermy group, whereas eight of 15 cases had recurrent prolapse in the SH group, during a follow-up period of 4 months, and the authors concluded that SH was not an effective method in patient with Grade IV hemorrhoidal disease. Zacharakis et al<sup>46</sup> reported recurrence in 33 of 56 patients (58.9%) with Grade IV hemorrhoidal disease during a follow-up of 6 years. In a systematic review of 2279 cases, Burch et al<sup>47</sup> compared SH and conventional techniques and found no significant difference between them in terms of cost-effectiveness and complications; however, despite minimum postoperative pain, SH was determined to have a higher long-term recurrence rate. In a systematic review of seven randomized controlled trials including 537 cases, Jayaraman et al<sup>48</sup> determined 23 recurrences in 269 patients in the SH group compared with four recurrences in 268 patients in the conventional hemorrhoidectomy group. In our study, at the end of a 2-year follow-up there was recurrence in only one patient (2.1%) with Grade IV disease in the HSH group, as opposed to seven patients (3 patients with Grade III and 4 patients with Grade IV disease) in the SH group (13.7%). The rate of recurrence was significantly lower in the HSH group compared with the SH group.

Chung et al<sup>49</sup> compared the outcome of patients receiving hemorrhoidectomy using harmonic scalpel, bipolar scissors, and the conventional scissors excision–ligation technique (Milligan–Morgan). They reported that both HSH and bipolar scissors hemorrhoidectomy were superior to Milligan–Morgan hemorrhoidectomy in terms of reduced blood loss. HSH had the best pain score when compared with bipolar scissors hemorrhoidectomy and Milligan–Morgan hemorrhoidectomy. Also, HSH had the best satisfaction score among the three groups.<sup>49</sup> Recently, Bulus et al<sup>50</sup> evaluated harmonic scalpel and Ferguson's with electrocautery techniques in the management of hemorrhoidal disease. They reported that HSH is preferred for surgical treatment of Grade III or Grade IV hemorrhoids. Moreover, HSH is safe, effective, and causes less blood loss, postoperative pain, and complications compared to Ferguson's with electrocautery hemorrhoidectomy.<sup>50</sup>

The price of harmonic scalpel handpiece is approximately twice the price of Longo's<sup>10</sup> circular stapler. However, the cost-effectiveness of HSH is to be evaluated by a shorter operative time and lower recurrence rates. In addition, we only used one harmonic scalpel for each patient once in accordance with a suggestion by Ethicon Endo-Surgery Inc. in our study. However, Lester et al<sup>51</sup> reported that reprocessed harmonic scalpels that pass acceptance tests exhibit functional and safety capabilities that are equivalent to their new counterparts. According to this study, considering the reusability of the harmonic scalpel, compared with single use of circular staplers, HSH procedure can turn out to be more cost-effective than SH. Furthermore, we believe that there is a need for more studies on this topic.

## 5. Conclusion

Both the SH technique described by Longo<sup>10</sup> and HSH are routine procedures used in the surgical treatment of hemorrhoidal disease. In our series of 99 patients with a follow-up of approximately 24 months, the rate of severe pain in the early postoperative period was higher in the HSH group. However, both methods have considerable positive effects on patient comfort and satisfaction over the long term. Edema seen in HSH as an early postoperative complication is a disadvantage compared with SH. However, the significantly shorter operative time with HSH compared with SH is a major advantage of this method. Additionally, the significantly higher recurrence rates seen with SH compared with the more reasonable recurrence rates of HSH (13.7% vs. 2.1%) is an important reason to prefer HSH. Considering the 23.5% recurrence rate in Grade IV disease and the 8.8% recurrence rate in Grade III disease, SH can be regarded as more successful for Grade III disease. In conclusion, compared with SH, HSH was considered to be a safer and a faster technique associated with lower long-term recurrence rates.

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