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ORIGINAL ARTICLE

Long-term follow-up of Starion™ versus Harmonic Scalpel™ hemorrhoidectomy for grade III and IV hemorrhoids

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KEYWORDS
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Summary *Background:* This study represented an effort to design an alternative to Harmonic Scalpel™ with the same effectiveness but at a lower cost. The concomitant use of Starion™ and Harmonic Scalpel™ had been evaluated to determine the differences in terms of the effectiveness immediately after the operation and 3 years post-operatively.
Methods: 114 patients in the SH group (Starion™ hemorrhoidectomy) and 107 patients in the HSH group (Harmonic Scalpel™) were contacted for cumulative inspection 1 week, 4 weeks, and 3 years post-operatively to check for the recurrence rate.
Results: No significant difference in the pain score was observed at post-operative week 1, with the SH group scoring 2.08 ± 0.96 and the HSH group scoring 2.29 ± 1.00 ($p = 0.112$). No significant difference in patient satisfaction was observed at post-operative week 4, with the SH group scoring 8.63 ± 1.28 and the HSH group scoring 8.60 ± 1.32 ($p = 0.847$). No significant difference in wound healing was observed, with the SH group showing 18.24 ± 3.13 days and the HSH group showing 18.21 ± 2.96 days ($p = 0.943$). The post-operative recurrence rate was 3.5% (4/114) in the SH group at the 3-year follow-up compared to 4.7% (5/107) in the HSH group without any statistically significant difference ($p = 0.662$).
Conclusions: Starion™ was a safe, rapid, and effective method for the treatment of Grade III or IV hemorrhoids.

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1. Introduction

Many physicians currently use various surgical options and treatment methods to treat hemorrhoids, which is the most prevalent anal disease. Three important points need to be considered while deciding the treatment options for hemorrhoids. First, it is crucial to determine patients' symptoms such as pain, bleeding, or protrusion. Second, it is imperative to lower the post-operative pain. Third, it is the physicians' task to reduce the recurrence rate. Majority of the patients visiting the doctor's office with hemorrhoids are diagnosed with both internal and external hemorrhoids. In this case, the standard treatment option is radical hemorrhoidectomy.

Stapled hemorrhoidectomy is a recent alternative to conventional hemorrhoidectomy, and various studies have investigated other alternate treatments as well.[1–5] However, many studies have reported varying post-operative results and pain.[6–10] Among the various hemorrhoidectomies, the most conventional method is open hemorrhoidectomy. Starion™ (Starion Instruments Corp., Saratoga, CA, USA) has reported positively[11] about the effectiveness of Harmonic Scalpel™ (Ethicon Endo-Surgery, Cincinnati, OH, USA).[12] Many studies have pointed to the effectiveness of Harmonic Scalpel™.[12,13] However, the cost of this device has prompted physicians to search for alternate and more accessible surgical tool. Starion™ is known to reduce pain with the least amount of tissue damage via scalpel's vessel coagulation and tissue welding technology.[11,14]

Therefore, the study investigators have tried to discover an alternate tool that has the same effectiveness but costs less than Harmonic Scalpel™. The concomitant use of Starion™ and Harmonic Scalpel™ has been investigated in terms of the effectiveness immediately after the operation and 3 years post-operatively.

2. Patients and methods

2.1. Patients selection

From January 2011 to October 2013, total of 1426 patients, who were diagnosed with at least grade III mixed hemorrhoids from Golgher's classification, were selected. These very patients were then randomized into 2 groups: SH group (Starion™ hemorrhoidectomy) and HSH group (Harmonic Scalpel™ hemorrhoidectomy).

759 patients were in the SH group while 667 patients were in the HSH group. Out of these patients, 737 patients from the SH group and 651 patients from the HSH group received the follow-up examination 1-week and 4-week post-operation. Patients were recommended, through a telephone call, to receive a follow-up examination 3-year post-operation. Total of 114 patients from the SH group and 107 patients from the HSH group were included in the research after they went through the interview process and the physical examination process as well (Fig. 1). These cases were retrospectively reviewed from a prospectively designed database system.

2.2. Outcome measurements

All patients were exposed to saddle-block anesthesia and were placed in a jack-knife prone position during the surgery. Initially, the surgeon needed to determine the number of hemorrhoids in case of patients with grade III or IV internal hemorrhoids targeted for resection along with the range of resection. The very first step was to grab a portion of anal skin tail using the forceps and dissect the hemorrhoids without damaging the anal sphincter using either Starion™ or Harmonic Scalpel™. The proximal part of internal hemorrhoids was eliminated to the dentate line without ligation of proximal pedicle. Bleeding was prevented using Starion™ or Harmonic Scalpel™. After the elimination of hemorrhoids, open type hemorrhoidectomy was carried out.[5] For post-operative pain control, patients were administered 10 mg of Ketorolac tromethamine (Tarasyn tablet®, Korea Roche) 3 times a day for 3 days from the date of surgery. As needed, 30 mg of Ketorolac tromethamine (Tarasyn ample®, Korea Roche) was injected as an intravenous bolus once or twice on the day of the surgery.

After the surgery, two groups were compared in terms of operating time, the pain score at week 1 post-operatively, patient satisfaction 4 weeks post-operatively, and the wound healing time. For the evaluation of complications, post-operative urinary retention, bleeding within 4 weeks, anal stricture and anal skin tag were analyzed. Further, the visual analog scale was used to objectify the scale of pain. The pain scale ranged from 0 to 10, 10 being the most painful. The patient satisfaction also ranged from 0 to 10, 10 being the most satisfactory. Analysis was conducted by contacting the patients for a follow-up examination 3 years post-operatively. During the follow-up, patients were evaluated for any evidence of recurrence or late complications such as anal stenosis.

To determine post-operative complications and recurrence during the patients' follow-up, physical examination, digital rectal examination and history taking were carried out. Anoscopy was used when patients expressed discomfort in anus or recurrence was suspected.

2.3. Statistical analyses

IBM® Statistics SPSS® for Windows 23.0 (SPSS Inc., Chicago, IL, USA) was used to perform all statistical analysis and an independent-samples T-test was used to verify consecutive variables including comparison of outcomes and patient's age. Chi-squared test was used to verify categorical variables including complications and sex. When p value was less than 0.05, the value was considered as statistically significant. The data of this study was expressed as mean $\pm$ standard deviation.

2.4. Ethics

This study was approved by the Institutional Review Board of Ajou University Hospital, Republic of Korea (No. AJIRB-MED-MDB-18-015). The Institutional Review Board exempted the requirement for informed consent because of retrospective analysis based on de-identified data.

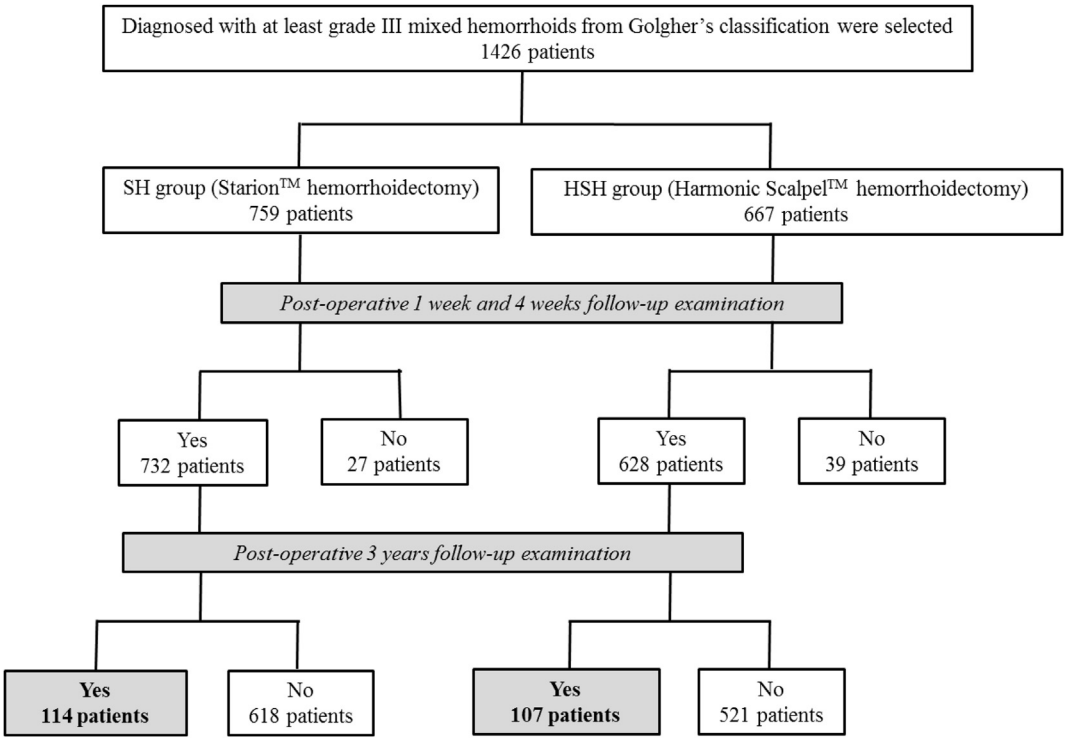

Fig. 1 Flow diagram of patients selection.

3. Results

3.1. Baseline characteristics

The average age of patients in the SH group was 46.08 ± 11.03 years while the average age of patients in HSH group was 48.78 ± 10.13 years ($p = 0.060$). Both groups showed no difference in terms of gender ratio. The SH group showed a gender ratio of 79:35, and the HSH group showed a gender ratio of 72:35 for their Goligher's grade of hemorrhoids (III or IV) ($p = 0.748$) (Table 1).

3.2. Comparison of outcomes

The average operation time of patients in the SH group was 15.56 ± 2.52 min while the average operation time of patients in the HSH group was 15.40 ± 2.45 min. Statistically significant difference was observed between the two operation times ($p = 0.634$).

Table 1 Baseline characteristics.

Parameter	SH	HSH	*p* value
No. of patients	114	107	
Sex ratio, male: female	74:40	65:42	0.522
Age (years)	46.08 ± 11.03	48.78 ± 10.13	0.060
Goligher's grade, III:IV	79:35	72:35	0.748

SH = Starion™ hemorrhoidectomy; HSH = Harmonic Scalpel™ hemorrhoidectomy.

No significant difference in the pain score was found in post-operative week 1, with the SH group scoring 2.08 ± 0.96 and the HSH group scoring 2.29 ± 1.00 ($p = 0.112$). No significant difference in the patient satisfaction was found in post-operative week 4, with the SH group scoring 8.63 ± 1.28 and the HSH group scoring 8.60 ± 1.32 ($p = 0.847$). No significant difference in terms of wound healing was shown, with the SH group showing 18.24 ± 3.13 days and the HSH group showing 18.21 ± 2.96 days ($p = 0.943$). Finally, no statistically significant difference was shown in the recurrence rate, which was analyzed post-operatively 3 years in a follow-up examination, with the SH group having 3.5% (4/114) and the HSH group having 4.7% (5/107) recurrence rate ($p = 0.662$) (Table 2).

Table 2 Comparison of outcomes.

Parameter	SH ($n = 114$)	HSH ($n = 107$)	*p* value
Operating time (minutes)	15.56 ± 2.52	15.40 ± 2.45	0.634
Pain score (0–10) after PO 1 week	2.08 ± 0.96	2.29 ± 1.00	0.112
PSS (0–10) after PO 4 weeks	8.63 ± 1.28	8.60 ± 1.32	0.847
Wound healing (days)	18.24 ± 3.13	18.21 ± 2.96	0.943
Recurrence rate after PO 3 years (%)	3.5	4.7	0.662

SH = Starion™ hemorrhoidectomy; HSH = Harmonic Scalpel™ hemorrhoidectomy; PO = Post-operative; PSS = Patient satisfaction score.

3.3. Complications

Anal stricture was not one of the complications that were found between the two group 4 weeks post-operation.

Additionally, no significant differences in bleeding or urinary retention were found between the two groups. Anal skin tags were observed in 4.39% of the patients in the SH group while it was 1.87% of the patients in the HSH group. Despite the lack of statistical significance ($p = 0.286$), the result shows that the patients in the SH group had a higher chance of anal skin tag occurrence. None of the patients in either groups were found with flatus incontinence. Furthermore, none of the patients in either groups were found with anal stenosis during the 3-year follow-up examination (Table 3).

4. Discussion

During defecation, the normal hemorrhoid tissue connects the blood vessels with connective tissues to completely close the anus by providing a cushion effect, which ultimately results in protection of the anal sphincter. The mechanism of diseased hemorrhoids involves several steps. First, congestion associated with hemorrhoids is caused by the repetitive process of defecation. Second, the connective tissue, which fixes the blood vascular tissues to the muscles, loses flexibility. While symptom relief is one of the most important goals of treating hemorrhoids, amelioration of the pathophysiology is also an important goal. To achieve this goal, re-insertion of the anoderm, which is the sliding component of the anus, and the resection of the excessive hemorrhoid tissue into the anal canal is needed.[6]

Depending on the progression of the disease, different treatment methods of hemorrhoids are available. Despite novel therapeutic interventions such as Doppler-guided hemorrhoidal artery ligation,[15] diode coagulation treatment,[16] and aluminum potassium sulfate and tannic acid sclerotherapy,[17] any hemorrhoids that are grade 3 and above are indication for surgical treatment.[18] Recurrence rate after complete removal of hemorrhoids and pain reduction after the surgery are the biggest challenges associated with hemorrhoidectomy. Several treatment methods, along with therapeutic and surgical tools, have been developed to address these issues.

Depending on the process of resection and stitching up of the hemorrhoids, the treatment modalities for hemorrhoids are divided into open, closed, and semi-closed types. Open hemorrhoidectomy has been widely used since its introduction by Milligan and Morgan. However, the procedure involves resection of the hemorrhoids, which ultimately leaves the wound open, resulting in anal canal scar formation via secondary healing and thus leading to traction of the anal canal.[18] Therefore, it was thought that the procedure, compared to closed or semi-closed types, resulted in worse pain and slower scar healing. However, there was no sign of difference in terms of length of hospital stay, recurrence rate, and the pain level between open and closed hemorrhoidectomies.[6–8] Additionally, comparison of open and semi-closed hemorrhoidectomy showed no differences in terms of length of stay in the hospital or recurrence rate. Semi-closed hemorrhoidectomy led to severe pain due to suturing of the anal mucosa with epithelium.[9,19] Instead of completely resecting the area where the hemorrhoid is located, stapled hemorrhoidectomy resects rectal mucosa and submucosa layer circularly and pushes the prolapsed internal hemorrhoids upward to their original position, which reduces mucosal congestion and blocks the distal end of the superior hemorrhoidal artery, resulting in reduced risk of bleeding. All of these processes reduce the post-operative pain and contribute to rapid recovery.[2,20,21] However, this procedure does not resect the hemorrhoids, while resulting in increased recurrence rate.[22,23] Furthermore, because it is not possible to resect the rectal mucosa by naked eye, there is a high probability that a portion of muscula propria layer gets resected as well, resulting in abscess in the posterior peritoneal cavity or rectal perforation.[24,25]

While several tools have been developed for the treatment of hemorrhoids, the most widely used tool is Harmonic Scalpel™ and many studies demonstrated its effectiveness.[12,14,26] The end point of the Harmonic Scalpel™ blade rotates 55,500 times per second at 50—100 μm width to disrupt the hydrogen bond, resulting in protein degeneration, which eventually acts as a coagulant to stop the bleeding from vessel or the tissue. Bleeding cessation allows the sharp blade to resect the coagulated tissue without any ligation. The overall lateral conduction of the heat energy ranges from 1.2 to 1.5 mm, resulting in minimal collateral damage to the nearby tissues. The advantages of Harmonic Scalpel™ are: 1. Scalpel can stop the bleeding while resecting the tissue at the same time; 2. Electrical energy is not transferred to the patients; 3. Heat conduction is minimal; 4. Tool replacement is minimal; and 5. Minimal burning or smoke. Other advantages include shortening of the operation time, lowering of the pain level, and lowering the recurrence rate of bleeding and other complications.[12,14,26] Recently, Starion™, which has similar advantages to Harmonic Scalpel™, was created. Starion™ contains a microfilament at the center of the blade, which emits heat and pressurizes the tissue, while coagulating and resecting at the same time. The surrounding microfilament is coated with ceramic, which minimizes tissue damage from the heat energy. Ligasure™ uses heat energy to modify elastin and collagen, resulting in bleeding control and anastomosis between the restrained tissues. When using Ligasure™, no sutures are needed during closed hemorrhoidectomy. The post-operative pain level and the length of hospital stay were reduced.[27]

Table 3 Complications.

Parameter, n (%)	SH ($n = 114$)	HSH ($n = 107$)	p value
Bleeding	2 (1.75)	1 (0.93)	0.599
Anal stricture	0	0	NS
Urinary retention	1 (0.88)	1 (0.93)	0.964
Flatus incontinence	0	0	NS
Anal skin tag	5 (4.39)	2 (1.87)	0.286
Anal stenosis	0	0	NS

SH = Starion™ hemorrhoidectomy; HSH = Harmonic Scalpel™ hemorrhoidectomy; NS = not significant.

Ligasure™ is mainly used for closed hemorrhoidectomy while Starion™ is mainly used for open hemorrhoidectomy. Harmonic Scalpel™ showed that the post-operative pain got reduced, compared to the conventional treatment method.[12] Harmonic Scalpel™ was associated with longer operation time and worse post-operation pain, compared to Ligasure™.[27]

In a comparative study of Starion™ and Ligasure™,[11] no differences were observed in terms of average blood loss, operating time, hospital admission period, and the time it took for patients to return to work or to normal activities. However, Starion™ hemorrhoidectomy yielded a better result than Ligasure™ hemorrhoidectomy in terms of pain score and the frequency of injection of post-operative analgesia intravenously. This study has also shown that Starion™ hemorrhoidectomy, in terms of 1 day post-operation pain level and patient satisfaction, was superior than the Harmonic Scalpel™ hemorrhoidectomy. However, no sign of difference was observed in terms of 4-week post-operative patient satisfaction. We believe that these results suggest similar levels of patient satisfaction with both tools upon the completion of wound healing. While no significant complications were associated with both Starion™ hemorrhoidectomy and Harmonic Scalpel™ hemorrhoidectomy, Starion™ hemorrhoidectomy showed more remnants of anal skin tag 4 weeks post-operatively. This is believed to be the case because of the heating ability of Starion™ microfilament, which directly transfers heat to the anal tissue.

After more than 1 year of follow-up, patients diagnosed with grade III or IV hemorrhoids were evaluated for long-term recurrence. Conventional hemorrhoidectomy was associated with a recurrence rate of 0—6.25%,[22,28,29] Ligasure™ hemorrhoidectomy with 0%,[29] and stapled hemorrhoidopexy with 50—53.3%.[22,28] This study found that Starion™ hemorrhoidectomy has the recurrence rate of 3.5% while Harmonic Scalpel™ hemorrhoidectomy was associated with the recurrence rate of 4.7%, 3 years post-operation. It is believed that these two methods showed no statistical difference and were both effective surgical options.

As the results show, even though Harmonic Scalpel™ is associated with successful hemorrhoidectomy, it is also associated with steep price tag. The cost factor is a huge challenge in Korea because hospitals cannot charge the patients for the usage of such an expensive tool due to the national insurance system. Therefore, Starion™, which only costs a third of the price of Harmonic Scalpel™ and exhibits almost similar effect as Harmonic Scalpel™, is believed to be an appropriate alternative tool.

5. Conclusions

Starion™ was more accessible than Harmonic Scalpel™ while not showing any significant difference in terms of post-operative pain score, patient satisfaction, wound healing, and complications. Additionally, no significant difference was detected in the recurrence rate during the 3-year post-operative follow-up. It is believed that Starion™ is a safe, fast, and an effective treatment modality for hemorrhoids.

Conflict of interest

All authors declare no conflicts of interest.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.asjsur.2018.05.002.

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