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ORIGINAL CONTRIBUTION

Five-Year Follow-up of the Double-Blinded Randomized Controlled Trial Comparing Laser Hemorrhoidoplasty With Sutured Mucopexy and Excisional Hemorrhoidectomy

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BACKGROUND: Patients randomly assigned to laser hemorrhoidoplasty, excisional hemorrhoidectomy, and sutured mucopexy were followed up at 5 years after surgery.

OBJECTIVE: The aim of this study was to compare the long-term results of laser hemorrhoidoplasty, excisional hemorrhoidectomy, and sutured mucopexy.

DESIGN: A follow-up of randomized, parallel-group, double-blinded, single-center prospective study.

SETTINGS: Treatment was provided between April 2016 and April 2017 at a single center.

PATIENTS: Patients with symptomatic second- or third-degree hemorrhoids 5 years after surgery were interviewed via telephone or online questionnaire.

MAIN OUTCOME MEASURES: Recurrence of symptoms was the primary outcome; patients' quality of life, fecal incontinence, and patients' evaluation of treatment were secondary outcomes.

RESULTS: A total of 102 patients were evaluated at 5 years (34 per group). Kaplan-Meier estimates of 5-year symptom recurrence were 24% for excisional hemorrhoidectomy, 29% for laser hemorrhoidoplasty, and 44% for sutured mucopexy; these differences did not reach statistical significance (log-rank $p = 0.076$). Although recurrence-free probability was numerically higher in the excisional hemorrhoidectomy and laser hemorrhoidoplasty groups, the timing of events varied across cohorts. Specific recurrences included bleeding in 18% (excisional hemorrhoidectomy), 31% (sutured mucopexy), and 31% (laser hemorrhoidoplasty) and prolapse in 12% (excisional hemorrhoidectomy), 23% (laser hemorrhoidoplasty), and 34% (sutured mucopexy). General health evaluation scores were highest in the laser hemorrhoidoplasty group. A mixed-effect model for repeated measures analysis showed a continued trend of improvement in physical and social activity between 1 and 5 years across all groups ($p = 0.021$). Decision regret was lowest in the sutured mucopexy group (mean score 1.33).

LIMITATIONS: This is a single-center study with a relatively small sample size.

CONCLUSIONS: Patients who underwent excisional hemorrhoidectomy reported the best outcomes; however, laser hemorrhoidoplasty produced only slightly worse

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results with a significantly shorter and less painful postoperative course. See **Video Abstract**.

SEGUIMIENTO A CINCO AÑOS DEL ENSAYO CLÍNICO ALEATORIZADO DOBLE CIEGO QUE COMPARA LA HEMORROIDOPLASTIA LÁSER CON LA MUCOPEXIA SUTURADA Y LA HEMORROIDECTOMÍA POR ESCISIÓN

ANTECEDENTES: Se realizó un seguimiento a pacientes, asignados aleatoriamente a hemorroidoplastia láser, hemorroidectomía por escisión y mucopexia suturada, a los 5 años de la cirugía.

OBJETIVO: El objetivo de este estudio fue comparar los resultados a largo plazo de la hemorroidoplastia láser, la hemorroidectomía por escisión y la mucopexia suturada.

DISEÑO: Estudio prospectivo, unicéntrico, doble ciego, aleatorizado, de seguimiento y con grupos paralelos.

ÁMBITO: Entre abril de 2016 y abril de 2017, se incluyeron 121 pacientes en el estudio.

PACIENTES: Se entrevistó telefónicamente o mediante cuestionario en línea a pacientes con hemorroides sintomáticas de segundo o tercer grado, 5 años después de la cirugía.

PRINCIPALES MEDIDAS DE RESULTADO: La recurrencia de los síntomas fue el resultado primario; la calidad de vida de los pacientes, la incontinencia fecal y la evaluación del tratamiento por parte de los pacientes fueron resultados secundarios.

RESULTADOS: Se evaluó a un total de 102 pacientes a los 5 años (34 por grupo). Las estimaciones de Kaplan-Meier de la recurrencia de los síntomas a los 5 años fueron del 24% para la hemorroidectomía por escisión, del 29% para la hemorroidoplastia láser y del 44% para la mucopexia suturada; estas diferencias no alcanzaron significación estadística (log-rank p = 0,076). Si bien la probabilidad de ausencia de recurrencia fue numéricamente mayor en los grupos de hemorroidectomía por escisión y hemorroidoplastia láser, el momento de los eventos varió entre las cohortes. Las recurrencias específicas incluyeron sangrado en el 18% (hemorroidectomía por escisión), 31% (mucopexia suturada) y 31% (hemorroidectomía láser), y prolapso en el 12% (hemorroidectomía por escisión), 23% (hemorroidectomía láser) y 34% (mucopexia suturada). Las puntuaciones de evaluación de salud general fueron más altas en el grupo de hemorroidoplastia láser. El modelo de efectos mixtos para el análisis de medidas repetidas mostró una tendencia continua de mejora en la actividad física y social entre 1 y 5 años en todos los grupos (p = 0,021). El arrepentimiento por la decisión tomada fue menor en el grupo de mucopexia suturada (puntuación media de 1,33).

LIMITACIONES: Este es un estudio unicéntrico, con un tamaño de muestra relativamente pequeño.

CONCLUSIONES: Los pacientes sometidos a hemorroidectomía por escisión reportan los mejores resultados; sin embargo, la hemorroidoplastia láser produce resultados solo ligeramente peores, con un postoperatorio significativamente más corto y menos doloroso. *(AI-generated translation)*

KEY WORDS: Excisional hemorrhoidectomy; Laser hemorrhoidoplasty; Long-term outcomes; Mucopexy; Randomized controlled trial; Recurrence.

Excisional hemorrhoidectomy (EH) is considered the most effective invasive treatment for hemorrhoids.[1,2] However, it is associated with severe and long-lasting postoperative pain and a long healing time.[2] Rubber-band ligation is as effective and significantly less costly than hemorrhoidal artery ligation.[3] Laser hemorrhoidoplasty (LHP) was reported to be an effective procedure with limited intensity and relatively short duration of postoperative pain, with similar results to EH 1 year postoperatively.[4,5]

Few studies have evaluated the long-term outcomes of surgical treatment for hemorrhoids, and to our knowledge, no studies have compared 5-year outcomes of LHP with other treatment modalities for hemorrhoidal disease.

The present study aimed to compare the results of LHP, EH, and sutured mucopexy (MP) 5 years after surgery.

MATERIALS AND METHODS

Patients

This is a follow-up of patients in a randomized, double-blinded, parallel-group (1:1:1), single-center prospective study.[6] In short, patients with second- and third-degree hemorrhoids who failed conservative and outpatient treatments and were referred for surgery were invited to participate. Those who agreed to be blinded to the treatment method until 1 year after surgery were randomly assigned to 1 of the 3 treatment options: EH, LHP, and MP. The surgeons who evaluated the results 1 year after surgery were also blinded to the type of surgery performed. The inclusion and exclusion criteria for patients, preoperative patient evaluation, randomization, blinding, concealment, and details about the operative procedure have been described previously.[6] Power calculation was performed in the original trial: A sample size of 40 patients in each randomized group would provide 84% power to detect an effect size of 0.30 in the recurrence of symptoms at 1 year across the randomized groups, with an alpha of 0.05.

Follow-up

Follow-up 5 years after surgery was performed remotely depending on the patient's preference: by asking questions on the phone or asking them to fill out an online survey. The patients were asked to complete a custom questionnaire measuring relevant symptoms, including bleeding, prolapse, and pain; the Wexner incontinence score; and 36-Item Short Form (SF-36) scores. The surgeons performing the follow-up surveys were blinded to the operation the patients had undergone.

Outcomes

The primary outcome of this study was the incidence of recurrence as described by the patient. Secondary outcomes were the presence and severity of rectal bleeding and prolapse, Wexner incontinence score, quality-of-life score on the SF-36 questionnaire, and patient-reported surgery evaluation on a visual analog scale from 1 to 10.

Statistical Analysis

Statistical analysis of the data was performed using the R statistical software package version 4.3.3 (The R Foundation for Statistical Computing), RStudio 2023.12.1 Build 402 (2009–2024 Posit Software, PBC), IBM SPSS Statistics version 23, and G*Power version 3.1.9.4 (Universität Düsseldorf, Düsseldorf, Germany).

Descriptive statistics were used to describe interval and ratio variables in terms of medians, first and third quartiles (Q1 and Q3), means and SDs, and ranges (minimum–maximum). Normality of data was checked using Shapiro-Wilk and Kolmogorov-Smirnov (K–S) tests. Nominal and ordinal variables were described using frequencies and percentages. To account for the longitudinal nature of the quality-of-life data (SF-36), changes in general health scores from baseline to 1- and 5-year follow-up were analyzed using a Mixed-Effect Model for Repeated Measures. The model included fixed effects for treatment group, time point, and the treatment-by-time interaction. An unstructured covariance matrix was used to model the within-subject correlation. This approach allowed inclusion of all available data from patients, including those with missing follow-up assessments, under the assumption of data missing at random. Spearman correlation coefficient (rS) was used to determine the effect size between interval variables. The rank epsilon squared effect size (ε2) was used to evaluate the effect size between interval variables that did not meet the condition for normal distribution, and Cramer V (ϕc) effect size was used to measure the strength of association between nominal variables. Effect sizes were classified according to Funder and Ozer.[7] The effect size is considered to be tiny if ε2, ϕC, rS <0.05, very small if 0.05 ≤ ε2, ϕC, rS < 0.1, small if 0.1 ≤ ε2, ϕC, rS < 0.2, medium if 0.2 ≤ ε2, ϕC, rS < 0.3, large if 0.3 ≤ ε2, ϕC, rS < 0.4, and very large if ε2, ϕC, rS ≥ 0.4. A p value of <0.05 was used to determine statistical significance, and a statistical test power of 1-ß equal to 0.95 (1-ß = 0.95) was used. Time-to-recurrence was analyzed as a time-to-event outcome. The probability of remaining recurrence-free during the 5-year follow-up period was estimated using the Kaplan-Meier method for each treatment group (EH, LHP, and MP). Differences in recurrence-free survival between the groups were evaluated using the log-rank test. Patients who died or were lost to follow-up before experiencing a recurrence were censored at the time of their last contact. Statistical significance for the log-rank test was set at a p value of <0.05.

Ethical Approval and Registration

The trial was approved and registered with the Regional Bioethics Committee of Vilnius, Lithuania, registration number 158200–15–792-322, and registered at ClinicalTrials.gov, registration number NCT03757728. All patients signed informed consent forms.

RESULTS

From April 2016 to April 2017, a total of 121 patients were included in the study: 40 in the EH group, 41 in the MP group, and 40 in the LHP group. These patients participated in scheduled 1-year postoperative follow-up visits and completed the required follow-up per the protocol until April 2018. Five-year remote follow-up was completed in May 2022 (see Supplemental Table 1 at https://links.lww.com/DCR/C648). Three patients had died (2 in the mucopexy group and 1 in the LHP group), and 16 patients did not respond (6 in EH and 5 in both the MP and LHP groups). One hundred two of 121 patients responded to the questionnaire at a mean of 66 months (60–72 months) after initial surgery (see Supplemental Table 1 at https://links.lww.com/DCR/C648).

Demographic and clinical characteristics were similar between the groups at the beginning of the study, with no statistically significant differences observed.[6] No adverse events or infections were reported after the surgery. In addition, no late complications were identified in patients during the follow-up period.

Recurrence of symptoms of hemorrhoids, as defined by the patients, was 24% in the EH group, 44% in the MP group, and 29% in the LHP group (Fig. 1); the difference between groups did not reach statistical significance. The intensity and frequency of recurrent bleeding are presented in Figure 2. There was no statistically significant difference among the groups, with 68%, 62%, and 59% of patients reporting no bleeding in the EH, MP, and LHP groups, respectively. There was a statistically significant difference in intensity and frequency of recurrent prolapse, with 79%, 59%, and 71% reporting no recurrent prolapse in the EH, MP, and LHP groups, respectively ($p = 0.021$).

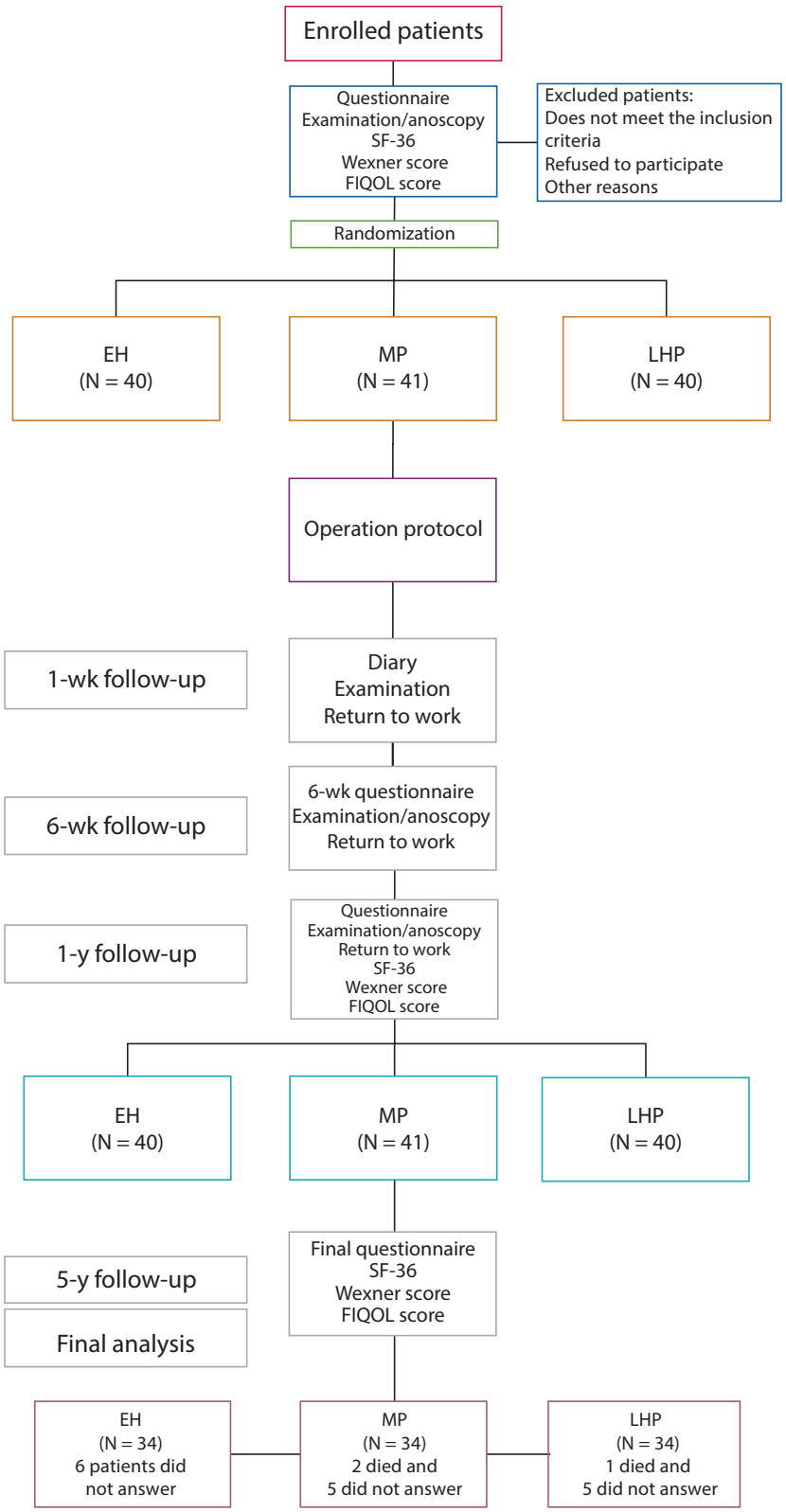


FIGURE 1. Flow chart of hemorrhoid symptoms: bleeding, prolapse, and incontinence. EH = excisional hemorrhoidectomy; FIQOL = Fecal Incontinence Quality of Life; LHP = laser hemorrhoidoplasty; MP = sutured mucopexy; SF-36 = 36-Item Short Form.

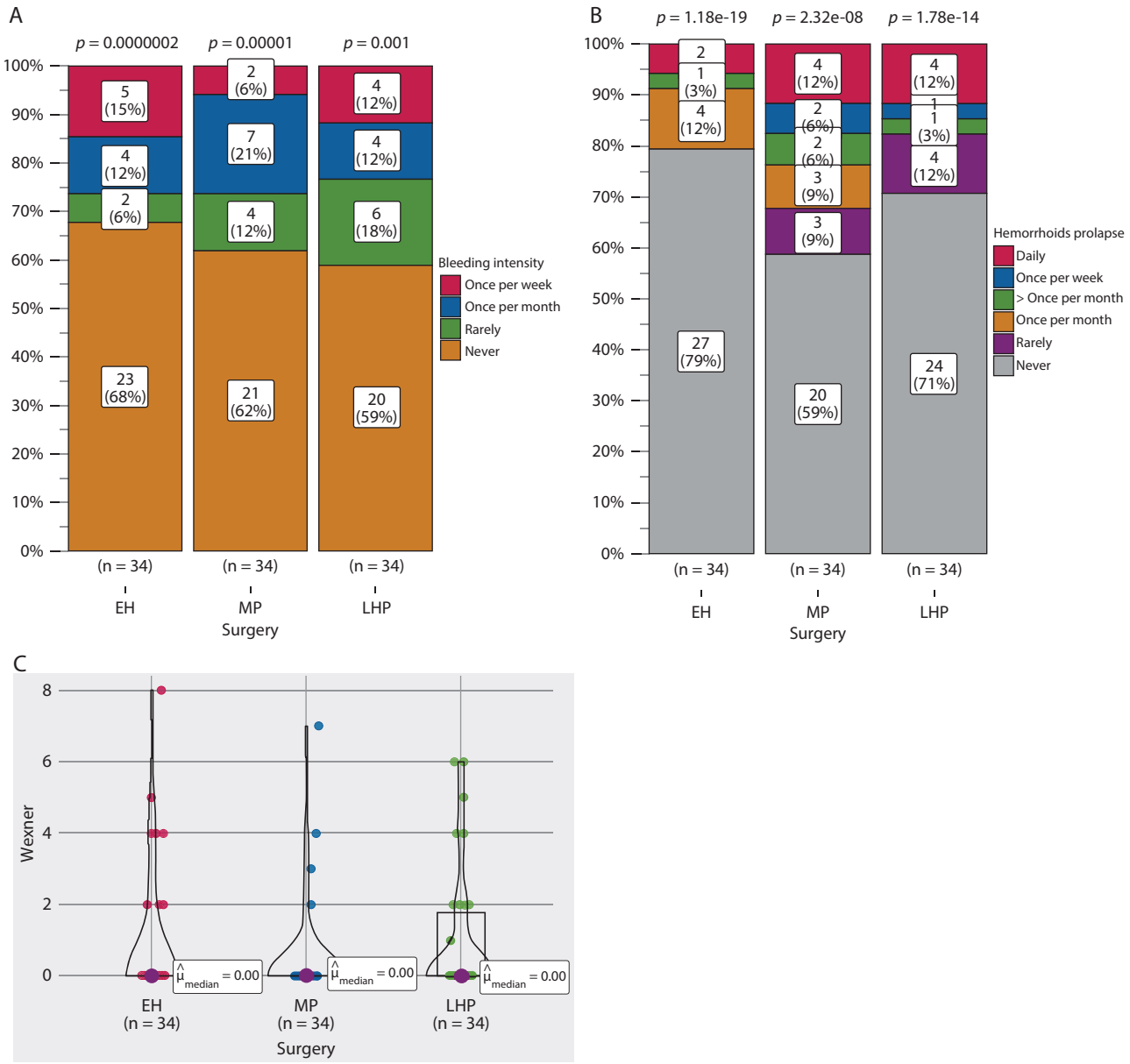


FIGURE 2. Symptoms 5 y after surgery. A, bleeding. B, prolapse. C, Wexner incontinence scores (range 0–20, where 0 indicates complete continence and 20 indicates complete incontinence). EH = excisional hemorrhoidectomy; LHP = laser hemorrhoidoplasty; MP = sutured mucopexy.

The incontinence scores were low and not different between the groups (Fig. 2).

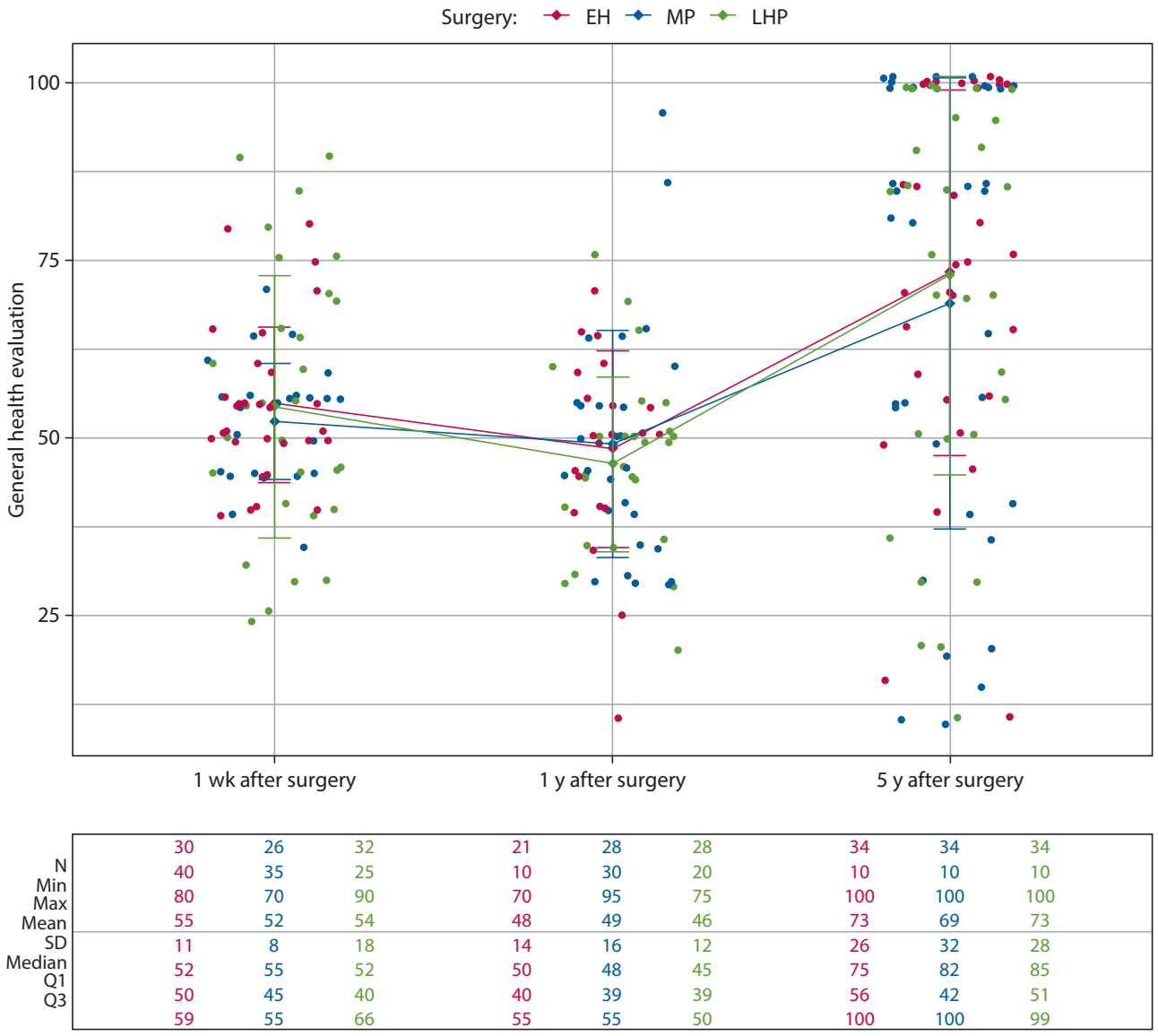
Quality-of-life scores of all patients improved at 1 week and 1 year after surgery, and there were no statistically significant differences between the groups (Fig. 3).

Patient subjective evaluations of their surgery (on a scale of 1–10) are detailed in Supplemental Table 1 at https://links.lww.com/DCR/C648. Although the MP group reported the highest mean evaluation score, this result is noteworthy because the group also experienced the highest incidence of clinical recurrence. Despite these numerical trends, pairwise comparisons revealed no statistically significant differences in patient evaluation scores when comparing MP to EH or LHP.

The decision regret scale results show that patients in the MP group experienced very low to no decision regret, with a decision regret score of 1.33 in the MP group (a score of 1 reflects no regret and 5 reflects complete regret). The highest regret was reported in the LHP group, 1.85 (1–2).

DISCUSSION

To our knowledge, this is the first report of 5-year results after LHP compared to EH and suture MP. We found that



N	30	26	32	21	28	28	34	34	34
Min	40	35	25	10	30	20	10	10	10
Max	80	70	90	70	95	75	100	100	100
Mean	55	52	54	48	49	46	73	69	73
SD	11	8	18	14	16	12	26	32	28
Median	52	55	52	50	48	45	75	82	85
Q1	50	45	40	40	39	39	56	42	51
Q3	59	55	66	55	55	50	100	100	99

FIGURE 3. Changes in general health evaluation. Data are presented as means and their corresponding 95% CIs. General health scores are derived from the SF-36 questionnaire across 3 points: baseline, 1-y, and 5-y follow-up. SF-36 = 36-Item Short Form. EH = excisional hemorrhoidectomy; LHP = laser hemorrhoidoplasty; MP = sutured mucopexy.

EH is the most effective treatment, with slightly less common recurrent bleeding and significantly less common recurrent prolapse than mucopexy and with minimal advantages in effectiveness compared to LHP. However, EH is associated with significantly more intense and longer-lasting pain, pain medication use, and time off from regular activities.[6]

The recurrence rates reported in this study for EH group patients are similar to those in other studies that analyzed long-term EH outcomes. Recurrent symptoms were diagnosed in 17.5% to 44% of patients up to 127 months after EH.[8–13] Overall, EH results in 20% to 30% of patients having recurrent symptoms of hemorrhoids 3 to 10 years after surgery.

Mucopexy was chosen as an affordable alternative to Doppler-guided hemorrhoidal artery ligation.[14–17] Several reports found no benefit in using Doppler guidance at 6 months and 1 year after the procedure, with recurrent symptoms of up to 50%.[17] Current data suggest that control of hemorrhoidal symptoms in this procedure is associated with repositioning and fixation of the prolapsing anal cushions rather than control of the arterial inflow into the perianal area. It has also been shown that there is no significant difference between hemorrhoidal artery ligation and rubber-band ligation.[3] This surgical approach was chosen as a substitute for rubber-band ligation, which is not performed in the operating room under anesthesia and for which no effective patient blinding could be performed.

LHP was first described in 2009.[18] One 8-watt 3-second application of the 1470-nm diode laser results in a coagulation area approximately 4 mm in diameter,[19] which leads to shrinkage and subsequent fibrosis. Because anoderm or mucosa is not injured, this method results in relatively low postoperative pain.[6,19,20] Longer-term results of up to 1 year result in a slightly higher incidence of recurrent prolapse and bleeding than EH.[4–6,20,21]

Fecal incontinence scores in all patient groups were low and not different between the groups. A recent systematic review found a low incidence of fecal incontinence in patients after EH and stapled hemorrhoidoplasty. Early incontinence rates were 5% in randomized trials and 1% in nonrandomized trials, and late incontinence was 2.4% in randomized trials and 1.4% in nonrandomized trials.[22] We were also unable to account for other conditions or diseases that could have contributed to the occurrence of fecal incontinence symptoms from 1 to 5 years after surgery.

Patients undergoing all types of surgery reported improved quality of life compared to outcomes at 1 year. This has been reported in other randomized trials,[1] with EH resulting in better quality of life than stapled hemorrhoidectomy[1] and no differences in quality of life in patients after rubber-band ligation versus hemorrhoidal artery ligation.[3] Improvement in quality of life and reduction or adaptation to symptoms observed with increasing duration of time from surgery is also significantly observed in other conditions, such as low anterior resection syndrome.[23,24]

This study has its limitations. This is a single-center study with a relatively small sample size. However, efforts were made to improve the validity of the study: sample size was calculated to identify the differences in recurrence rates between the groups at 1 year; all 3 treatments were standardized, and the surgical technique was the same for all 3 different surgeons who performed the operations; patients were blinded to the technique chosen and remained so until 1 year after surgery; evaluating surgeons did not know the surgical technique used at 1 year and also at 5 years after operation. It is impossible to determine whether patients knew the technique of their operation at the 5-year follow-up. The follow-up was done through an online or telephone questionnaire, whichever was most practical for the patients. However, a similar follow-up was used in other long-term hemorrhoidectomy follow-up studies.[1,3,10,11]

CONCLUSIONS

LHP is a safe and effective treatment for hemorrhoids, with a slightly higher recurrence rate than EH and lower than MP, with relatively short duration and low intensity of postoperative pain.

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