ORIGINAL ARTICLE

Treatment Outcomes of Radiofrequency Ablation Using the Rafaelo Technique for Internal Hemorrhoids

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Objective: Hemorrhoidal disease impacts quality of life. While hemorrhoidectomy is the standard for grades 3 and 4 internal hemorrhoids, its pain is a downside. The Rafaelo technique, using radiofrequency ablation (RFA), is a promising non-excisional alternative. The present study investigated postoperative outcomes of this innovative approach.

Materials and Methods: The authors conducted a single-center study performed by a single surgeon between January and December 2022. The surgical procedures were performed using a combination of intravenous sedation and perianal block.

Results: Forty patients underwent the Rafaelo technique, with a mean age of 49.7±15.1 years. Among them, 24 (60%) were male, and 16 (40%) were female. Thirteen patients (32.5%) had grade 2 hemorrhoids, while 27 patients (67.5%) had grade 3 hemorrhoids. The visual analog scale (VAS) scores were consistently low within the first 24 hours after surgery with VAS 1.1±1.4 at 4 hours, 1.18±1.54 at 8 hours, and 0.58±1.04 at 12 hours. Ninety-seven-point-five percent of the patients could be discharged on the first day, and eighty-five percent resumed their daily activities after discharge. Additionally, two cases developed thrombosed hemorrhoids as the postoperative complication, which were successfully treated conservatively. The symptoms severity score significantly decreased from 4.15±1.69 preoperatively to 1.03±1.37 at two weeks and 0.00 at three months. There were no cases of recurrence within the 6-month postoperative period.

Conclusion: The Rafaelo technique has demonstrated remarkable safety and effectiveness in treating grade 2 and 3 internal hemorrhoids. Notably, it minimizes postoperative pain and yields favorable outcomes at six months.

Keywords: Radiofrequency ablation; RFA; Rafaelo; Hemorrhoids; Case series

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Hemorrhoids represent the most prevalent benign anorectal condition, exhibiting a considerable prevalence ranging from 2.9% to 29.7%[1,2]. Beyond its substantial prevalence, hemorrhoids can significantly impact the quality of life for affected individuals, often leading patients to hesitate in seeking medical attention, which underscores the importance of effective and patient-friendly interventions for its management[3]. The pathophysiology of hemorrhoids is attributed to the redundancy of the anal cushion, a complex anatomical structure comprising veins, sinusoids, arterioles, smooth muscle fibers, and connective tissue situated in the anal canal[4].

The management of hemorrhoids depends on the severity of the disease, and the grading system introduced by Goligher et al. in 1980 has been widely adopted for this purpose. The system categorizes hemorrhoids into four grades[5]. Grade 1 hemorrhoids typically warrant lifestyle modifications with or without medications. For Grade 2 hemorrhoids, outpatient-based procedures such as rubber-band ligation (RBL), hemorrhoidal artery ligation (HAL), or sclerosing therapy are considered viable treatment options[6]. Notably, these procedures exhibit comparable outcomes[7].

Hemorrhoids classified as Grade 3 and 4 often necessitate excision hemorrhoidectomy, considered the "gold standard" for treatment[8]. Milligan-Morgan introduced one of the most well-known techniques for hemorrhoidectomy in 1937[9]. While hemorrhoidectomy effectively reduces the recurrence of hemorrhoids, it is associated with drawbacks, including substantial postoperative pain requiring significant analgesic intervention and a heightened risk of complications[3,10]. These considerations

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highlight the need for alternative approaches to address the challenges associated with conventional excision hemorrhoidectomy.

Radiofrequency ablation (RFA) is slowly introduced as a novel approach for the treatment of advanced hemorrhoids with comparable outcomes and reduced postoperative pain. The benefits of RFA extend to benign and malignant conditions[11], and its efficacy has been established for various anorectal disorders[12]. In the context of hemorrhoids, the physiological basis of RFA involves introducing 4 MHz radiofrequency energy through a needle probe, destroying hemorrhoidal vascular tissue[13]. Among the RFA procedures for hemorrhoid treatment, the Radiofrequency Treatment of Haemorrhoids under Local Anesthesia (Rafaelo) technique stands out, having demonstrated efficacy in multiple studies[13-19]. This technique minimizes postoperative pain, reduces the need for general anesthesia and recurrence rates, and significantly improves patients' quality of life. Notably, there is a dearth of studies providing case series evaluations of the efficacy and safety of the Rafaelo technique in the Southeast Asia (SEA) region. Therefore, the present study aimed to explore the efficacy and safety and provide a pool of data on the Rafaelo technique in managing hemorrhoids.

Hence, the primary objective of the present study was to investigate the efficacy and safety of the Rafaelo technique in managing hemorrhoids, contributing to the pool of data on this innovative approach. Through, the present research aimed to provide valuable insights into the applicability and outcomes of the Rafaelo technique in the unique context of SEA, therefore, enhancing the understanding of its potential benefits for patients in this geographical region.

Materials and Methods

The present study presented a unifocal retrospective case series derived from a single surgeon's well-designed, systematically collated electronic medical records spanning the temporal interval between January and December 2022. The study has been reported in line with the PROCESS criteria[20]. The present study cohort comprised individuals aged between 18 and 80 years, each diagnosed with grade 2 to 3 internal hemorrhoids. All subjects underwent the Rafaelo technique. Notably, exclusion criteria encompassed patients diagnosed concurrently with external hemorrhoids and those subjected to external hemorrhoid treatment concomitant with the operative procedure.

The surgical procedure was conducted with the patient positioned in the prone jackknife orientation. Employing a strategy aimed at minimizing patient stress, the anesthesiologist administered total intravenous anesthesia (TIVA). Local anesthesia was administered through a perianal block, utilizing a mixture of 1% xylocaine with adrenaline and 0.5% Marcaine in a 1:1 ratio, totaling 20 mL. Subsequently, a proctoscope was introduced to assess the internal hemorrhoidal condition. The proctoscope, featuring a simple space on one side, facilitated the protrusion of one hemorrhoidal tissue while compressing the remaining anorectal cushion during the procedure. To mitigate the risk of injection-related injury to the internal anal sphincter, the same mixed solution was employed to elevate the submucosal plane. The surgical intervention utilized The Rafaelo® device equipped with the disposable HPR45i probe (MedFocus Co., Ltd., Thailand). Energy levels of 2000 J and 2500 to 3000 J were applied for grade 2 and 3 internal hemorrhoid, respectively. The probe was fully inserted into the target hemorrhoidal tissue at a depth of 5 to 10 mm and oriented at an angle of approximately 30 degrees to the hemorrhoidal tissue. Energy application persisted until the hemorrhoidal tissue exhibited a whitish discoloration. Subsequently, a cold saline-soaked gauze was gently applied to the hemorrhoidal tissue to arrest bleeding. Any residual bleeding was addressed through coagulation. Total joules and operative time were recorded. Post-operatively, patients were transferred to the ward and administered routine anesthesia, including oral paracetamol and arcoxia. Additionally, intravenous opioid analgesia in the form of morphine, at a dosage of 0.05 to 0.1 mg/kg per dose, was prescribed on an as-needed basis every 3 to 4 hours for breakthrough pain management.

Patient demographic information, crucial for a comprehensive analysis, was systematically gathered, encompassing gender, age in years, body mass index (BMI), comorbidities, preoperative symptom severity score (SSS), grade of hemorrhoid, presenting symptoms, prior treatment modalities, number of present hemorrhoidal columns, energy applied as measured in kilojoules (KJ), and operative time in minutes. This inclusive dataset provided a comprehensive overview of the patient profile, facilitating a thorough examination of potential factors influencing surgical outcomes and patient experiences.

The primary objective of the present study was to assess postoperative pain, with secondary outcomes

Symptom severity score*						
Score	Itching	Pain	Prolapse	Bleeding	Soiling	Gas incontinence
0	Never	None	Never	Never	Never	Never
1	Occasional	With stool	With straining	Spotting	Mucus discharge	Occasional < 1/week
2	Regular	Constant	Reducible	Dripping into pan	Occasional	Frequent > 1/week
3	Persistent	Pressure	Permanent	Without stool	Incontinent	Persistent
4				Staining underpants		
Disease severity score (how troublesome are your piles?)						
No trouble		Mild	Moderate	Severe	Really bad	
1		2	3	4	5	

Figure 1. Symptom severity score (SSS) and disease severity score (DSS).

encompassing patient satisfaction, patient symptoms, postoperative opioid administration, length of hospital stay (LOS), postoperative complications, and readmission rates. Postoperative pain evaluation was conducted from immediate postoperative status up to one year postoperatively, utilizing the visual analog scale (VAS). The 24-hour postoperative VAS score was recorded, and subsequent assessments occurred at one week, two weeks, one month, three months, six months, and one year, employing face-to-face interviews or telephone surveys. The VAS scores were meticulously collected and categorized into distinct domains, specifically pain scores at rest and pain scores during defecation. Patient satisfaction was collected using the Likert scale before discharge and at postoperative intervals of one week, two weeks, one month, three months, six months, and one year. Assessment of patient symptoms involved the utilization of the SSS, which included variables such as itching, pain, prolapse, bleeding, soiling, and gas incontinence. Each variable was scored on a scale of 0 to 4, resulting in a cumulative SSS ranging from 0 to 19 (maximum). Additionally, a questionnaire assessing disease severity score (DSS) prompted respondents to rate the severity on a scale from 1 to 5, representing a continuum from "no trouble" to "really bad" (Figure 1)[21]. These comprehensive evaluations provide a robust framework for understanding the multifaceted postoperative outcomes and patient experiences in the context of surgical intervention.

The requirement for informed consent was waived because the dataset does not contain personal identification or other personal identifiers. Ethical approval for the study was obtained from the Vajira Institutional Review Board (VIRB), Faculty of Medicine, Vajira Hospital (Bangkok), number 047/65 FB.

The present study statistical analysis used descriptive statistics to present continuous variables, reporting means with their corresponding standard deviations (SDs). Frequencies and 95% confidence intervals (CIs) were outlined for categorical variables. Linear mixed-effect models were applied to delve into the dynamics of postoperative outcomes, VAS, SSS, and DSS. This sophisticated modeling approach allowed for a nuanced exploration of longitudinal data, considering both fixed and random effects. The entirety of the statistical analysis was executed using Stata, version 13 (StataCorp LP, College Station, TX, USA). A significance level of p-value equal to or less than 0.05 was adopted to discern statistically significant findings, and it is noteworthy that no imputation of missing data was undertaken in the present investigation. This rigorous analytical framework ensured the robustness and reliability of the reported results.

Results

Forty patients underwent hemorrhoid treatment utilizing the Rafaelo technique, and none were excluded based on predetermined criteria (Table 1). The entire cohort was included for subsequent analysis. Of the patients, 60% were male, with a mean age of 49.78. The mean BMI was 22.16 kg/m². A quarter of the patients presented with comorbidities. The mean SSS was 4.15, with an SD of 1.69. A detailed breakdown of SSS revealed specific scores for itching (0.50±0.64), pain (0.65±0.66), prolapse (1.75±0.63), bleeding (1.15±0.70), soiling (0.10±0.44), and no gas incontinence in the preoperative SSS. The DSS was 3.12±0.69.

Grade 3 hemorrhoids were predominant, accounting for 67.5% of cases (27 patients). The most common presenting symptoms were prolapsed in 77.5% and bleeding in 72.5%, while only 17.5% of patients reported pain or discomfort at the onset. Nine patients (22.5%) had received prior treatments including three with medical treatment, one with medical treatment and RBL, two with RBL, and three with previous hemorrhoidectomy. The median number of hemorrhoidal columns was 3, with an interquartile range (IQR) of 2.25 to 3, and the energy application per column was 1,378.80±435.54 J for grade 2 hemorrhoids and 2,418.25±599.60 J for grade 3 hemorrhoids. The median operative time was 20 minutes (IQR 20 to 28.75). All patients received a perianal block as the chosen anesthetic method.

In the authors' investigation of the primary outcome, a statistically significant reduction in the VAS score at rest was observed from 12 hours post-operative to 24 hours postoperative (refer to Table 2,

Table 1. Demographic and clinical characteristics of patients

Characteristics	40 patients
Sex; n (%)	
Male	24 (60.0)
Age (years); mean±SD	49.78±15.16
BMI (kg/m^2); mean±SD	22.16±2.81
Underlying disease; n (%)	10 (25.0)
Symptom severity score; mean±SD	4.15±1.69
Itching	0.50±0.64
Pain	0.65±0.66
Prolapse	1.75±0.63
Bleeding	1.15±0.70
Soiling	0.10±0.44
Gas incontinence	0.00±0.00
Disease severity score	3.12±0.69
Hemorrhoid grade; n (%)	
Grade 2	13 (32.5)
Grade 3	27 (67.5)
Symptoms of patients; n (%)	
Prolapse	31 (77.5)
Bleeding	29 (72.5)
Pain/discomfort	7 (17.5)
Previous treatment; n (%)	9 (22.5)
Medication	3 (7.5)
Medication with RBL	1 (2.5)
RBL	2 (5.0)
Hemorrhoidectomy	3 (7.5)
No. of hemorrhoids (No. of columns); median (IQR)	3 (2.25 to 3)
Energy applied (J) per column; mean±SD	
Grade 2	1,378.80±435.54
Grade 3	2,418.25±599.60
Operative time (minutes); median (IQR)	20 (20 to 28.75)
Type of anesthesia; n (%)	
Perianal block	40 (100)

BMI=body mass index; RBL=rubber-band ligation; SD=standard deviation; IQR=interquartile range

Figure 2a), with a p-value of 0.005. Furthermore, during the entire follow-up period, the VAS score at rest exhibited a consistent and significant decline, reaching a score of 0 from one month postoperative up to one year postoperative (refer to Figure 2b), with a p-value less than 0.001. Regarding the pain score during defecation, the analysis revealed a

Table 2. Pain score (VAS)

Follow up time	VAS mean±SD	Mean difference (95% CI)	p-value
Pain score at rest			
Postoperative			
• 4 hours	1.10±1.46	Reference	
• 8 hours	1.18±1.54	0.06 (–0.23 to 0.35)	0.684
• 12 hours	0.58±1.04	–0.53 (–0.89 to –0.16)	0.005*
• 16 hours	0.50±1.06	–0.60 (–1.01 to –0.19)	0.004*
• 20 hours	0.23±0.58	–0.88 (–1.31 to –0.44)	<0.001*
• 24 hours	0.18±0.55	–0.93 (–1.38 to –0.47)	<0.001*
Follow up			
• 1 week	0.90±1.24	Reference	
• 2 weeks	0.60±0.98	–0.30 (–0.56 to –0.04)	0.026*
• 1 month	0.10±0.50	–0.80 (–1.10 to –0.50)	<0.001*
• 3 months	0.00±0.00	–0.90 (–1.20 to –0.60)	<0.001*
• 6 months	0.00±0.00	–0.90 (–1.21 to –0.59)	<0.001*
• 1 year (n=18)	0.00±0.00	–0.90 (–1.28 to –0.52)	<0.001*
Pain score at defecation			
Postoperative	1.10±1.58	Reference	
1 week	1.28±1.54	0.18 (–0.17 to 0.52)	0.324
2 weeks	1.03±1.39	–0.08 (–0.49 to 0.34)	0.720
1 month	0.00±0.00	–1.10 (–1.53 to –0.67)	<0.001*
3 months	0.00±0.00	–1.10 (–1.54 to –0.66)	<0.001*
6 months	0.00±0.00	–1.10 (–1.55 to –0.65)	<0.001*
1 year (n=18)	0.00±0.00	–1.10 (–1.65 to –0.55)	<0.001*

SD=standard deviation; CI=confidence interval
* Significant at p<0.05

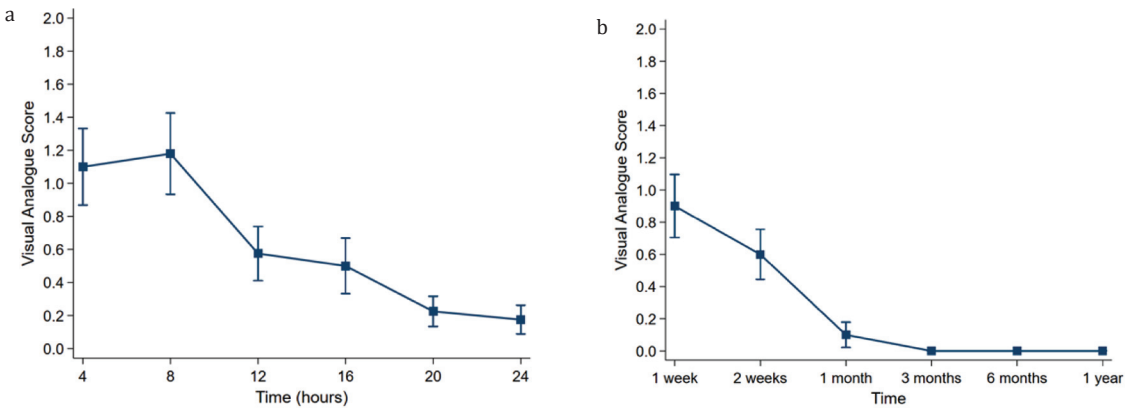

Figure 2. VAS score at rest (95% CI); (a) VAS score at the postoperative period, (b) VAS score at the follow-up period.

Table 3. Patient satisfaction scores (Likert scale)

Follow up time	Completely comfortable n (%)	Quite comfortable n (%)	Slightly discomfortable n (%)	Painful n (%)	Very painful n (%)	Mean	SD
Before discharge	24 (60.0)	10 (25.0)	6 (15.0)	0 (0.0)	0 (0.0)	1.55	0.75
1 week	19 (47.5)	14 (35.0)	6 (15.0)	1 (2.5)	0 (0.0)	1.73	0.82
2 weeks	26 (65.0)	11 (27.5)	2 (5.0)	1 (2.5)	0 (0.0)	1.45	0.71
1 month	38 (95.0)	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	1.08	0.35
3 months	40 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1.00	0.00
6 months	40 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1.00	0.00
1 year (n=18)	18 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1.00	0.00

SD=standard deviation

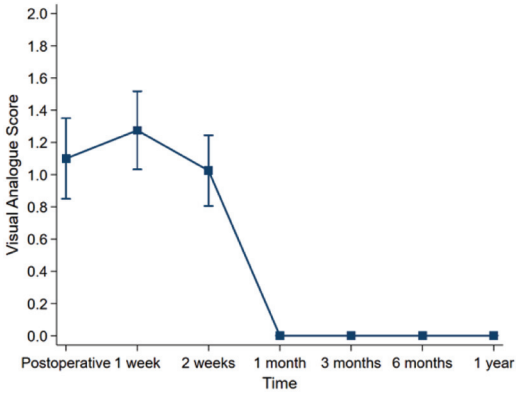

Figure 3. VAS score during defecation (95% CI).

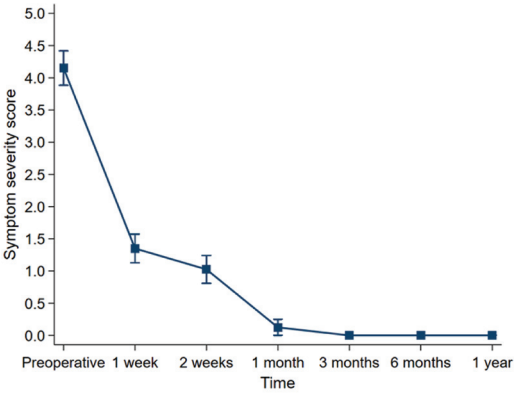

Figure 4. Symptom severity score (95% CI).

notable and statistically significant decline in the VAS score during defecation, reaching 0 from one month postoperative up to one year postoperative (refer to Table 2, Figure 3), with a p-value <0.001. It was noted that a significant proportion of patients, specifically 22 individuals (55%) were lost during the follow-up period and could not be contacted by telephone at the 1-year follow-up.

In evaluating patient satisfaction, the Likert scale revealed that a minor proportion of patients (2.5%) reported complaints of pain from one to two weeks postoperatively. However, it is noteworthy that patients reported 100% complete comfort at three months postoperatively, as evidenced by the patient satisfaction scores (refer to Table 3).

In the SSS context, the authors' analysis revealed a statistically significant decline from 4.15±1.69 SD preoperatively to 1.35±1.41 SD at one week postoperative, with a p-value of less than 0.001. This decline in SSS persisted over time, reaching 0 at three months postoperative, signifying a substantial reduction in symptom severity (refer to Table 4, Figure 4). Similarly, the DSS demonstrated a parallel trend, significantly decreasing from 3.12±0.69 SD preoperatively to 1.50±0.75 SD, with a p-value of less than 0.001. Notably, the DSS also significantly declined to scores of 1, indicating an absence of trouble (refer to Table 1) at three months postoperative (refer to Table 4, Figure 5).

Upon examining the postoperative opioid utilization, the majority of patients, accounting for 36 individuals (90%) did not require any postoperative opioids. Only a small proportion of patients, specifically three individuals (7.5%), used a single dose of postoperative intravenous morphine, while one patient (2.5%) required two doses. Regarding the LOS, nearly all patients, thus 39 patients (97.5%) were discharged after one day, with only one patient experiencing a two-day LOS. In terms of postoperative complications, a low incidence was observed, with only two patients (5%) encountering issues. Two patients developed thrombosed hemorrhoids subsequent to treatment. Conservative management was deemed appropriate for both cases. In one instance, a significant residual skin tag prompted the patient to request excision. Notably, no patients in the study required readmission (refer to Table 5).

Table 4. Symptom severity score

Follow up time	Score mean±SD	Mean difference (95% CI)	p-value
Symptom severity score			
Preoperative	4.15±1.69	Reference	
1 week	1.35±1.41	−2.80 (−3.25 to −2.35)	<0.001*
2 weeks	1.03±1.37	−3.13 (−3.59 to −2.66)	<0.001*
1 month	0.13±0.79	−4.03 (−4.49 to −3.56)	<0.001*
3 months	0.00±0.00	−4.15 (−4.62 to −3.68)	<0.001*
6 months	0.00±0.00	−4.15 (−4.62 to −3.68)	<0.001*
1 year (n=18)	0.00±0.00	−4.15 (−4.76 to −3.54)	<0.001*
Disease severity score			
Preoperative	3.12±0.69	Reference	
1 week	1.50±0.75	−1.63 (−1.81 to −1.44)	<0.001*
2 weeks	1.33±0.57	−1.80 (−2.00 to −1.60)	<0.001*
1 month	1.05±0.32	−2.08 (−2.28 to −1.87)	<0.001*
3 months	1.00±0.00	−2.13 (−2.33 to −1.92)	<0.001*
6 months	1.00±0.00	−2.13 (−2.33 to −1.92)	<0.001*
1 year (n=18)	1.00±0.00	−2.13 (−2.38 to −1.87)	<0.001*

SD=standard deviation; CI=confidence interval
* Significant at p<0.05

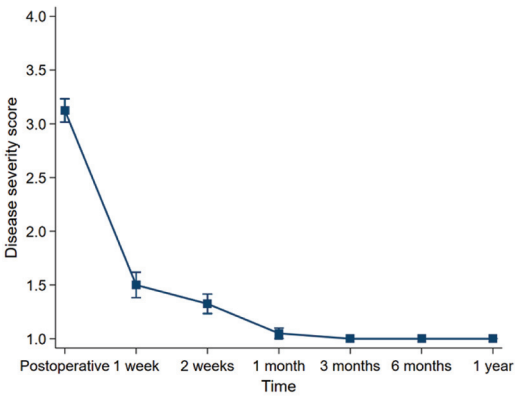

Figure 5. Disease severity score (95% CI).

Discussion

The application of RFA in treating hemorrhoids was initially proposed by Gupta et al. in 2002[22]. The initial investigations primarily focused on the management of early stage hemorrhoidal disease. Subsequent studies extended the scope of inquiry to include more advanced and aggressive forms of hemorrhoidal disease. These investigations consistently demonstrated the efficacy and safety of RFA across higher grades of hemorrhoidal disease. The accumulated evidence supports the utility of RFA as a therapeutic modality for various grades of hemorrhoids, reinforcing its clinical viability and safety profile in managing diverse presentations of this condition.

Table 5. Other secondary outcomes

Outcome	n (%)
No. of morphine use	
None	36 (90.0)
1	3 (7.5)
2	1 (2.5)
Length of hospital stay (day)	
1	39 (97.5)
2	1 (2.5)
Post operative complication	2 (5.0)
Type of complication	
Thrombosed	2 (5.0)
Readmission	0 (0.0)

The present study aimed to assess the efficacy and safety of the Rafaelo technique in treating grade 2 and 3 internal hemorrhoids. It represented a case series reflecting the outcomes of a single colorectal surgeon in a medical center situated in Bangkok, Thailand, within the SEA region. A substantial majority of the enrolled patients, 67.5%, manifested symptomatic grade 3 internal hemorrhoids and prolapsed internal hemorrhoids for 77.5%.

The present study's median number of hemorrhoidal columns was 3, with an IQR of 2.25 to 3, indicating a common clinical scenario. Notably, the Rafaelo technique demonstrated its efficacy and safety in managing this aspect of hemorrhoidal pathology. This aligns with the findings of a prospective two-center study specifically investigating the Rafaelo technique, which corroborated its safety and effectiveness even in cases involving more than 2 hemorrhoidal columns[3]. The current study, in conjunction with existing literature, further supports the applicability and robust performance of the Rafaelo technique across various column presentations of hemorrhoidal disease.

Regarding efficacy, the Rafaelo technique demonstrated a significant reduction in postoperative pain immediately postoperatively and during the follow-up period. Specifically, the VAS score decreased significantly to 0.58±1.04 SD in the immediate postoperative period. During this phase, only a minority of patients (10%) required postoperative rescue intravenous opioids. Similarly, in the follow-up period, the VAS score reached 0 at one month postoperative, signifying a significant reduction in postoperative pain. Comparatively, the average postoperative pain VAS score reported in a previous study utilizing the Rafaelo technique was 2.5[3]. This contrasts markedly with conventional

hemorrhoidectomy, RBL, and HAL, where reported average VAS scores range from 6.3 to 8.15[7,23,24]. Correspondingly, a study from India observed a significant reduction in the VAS score from 3 preoperatively to 1 postoperatively[10]. A study from the United Kingdom similarly reported a decline in the VAS score to 0 at 2 months postoperative[19]. These findings underscore the potential superiority of the Rafaelo technique in achieving notable reductions in postoperative pain compared to established hemorrhoid treatment modalities.

The present study revealed a 5% incidence of complications associated with the Rafaelo technique, with these complications being minor in nature, encompassing instances of thrombosed hemorrhoids that were effectively managed conservatively. These findings align with a previous study reporting a less than 3% major complication rate[25]. Remarkably, no patient in the present study necessitated reoperation or readmission, indicating a favorable postoperative course. In contrast, a meta-analysis reported a readmission rate of 6.9% after applying the Rafaelo technique[14]. Additionally, a case series from the United Kingdom documented an 11.9% reoperation rate among their patient cohort[15]. The variability in reported reoperation rates across studies introduces a certain level of controversy. For instance, a French prospective multicenter study reported a notably lower reoperation rate of 2.3%[13]. This discrepancy underscores the need for continued research and investigation to understand better the factors influencing reoperation rates following the Rafaelo technique.

Regarding the severity score, the present study demonstrated a notable reduction in both the SSS and DSS starting from one week postoperative, reflecting the effectiveness of the Rafaelo technique in ameliorating the severity of hemorrhoidal symptoms and disease. These findings are consistent with previous studies that reported a reduction in the hemorrhoidal severity score (HSS) within the initial two months postoperative[10,19]. The observed alignment in outcomes indicates the reproducibility and generalizability of the positive impact of the Rafaelo technique on symptom severity across different study settings.

One of the favorable impacts of the Rafaelo technique is the positive trend in patient satisfaction in the postoperative experience. The present study revealed high patient satisfaction, with nearly all patients, at 95%, feeling completely comfortable at postoperative one month and achieving 100% satisfaction at three months postoperative. These findings align with previous studies that similarly indicated a significant decline in discomfort scores postoperatively[16,18].

As evidenced in the present study, an additional advantage of the Rafaelo technique is the shorter operative time. The present study reported an operative time of 20 minutes (IQR 20 to 28.75), which, although slightly higher than the meta-analysis average of 12.9 minutes[14], remains notably lower than the operative times associated with alternative techniques such as HAL, stapler hemorrhoidopexy, or conventional hemorrhoidectomy. For instance, one study reported a mean operative time ranging from 30 to 49 minutes for these alternative procedures[26]. The observed efficiency in operative time further positions the Rafaelo technique as a time-effective approach to managing internal hemorrhoids, contributing to its potential advantages in clinical practice. To the best of the authors' knowledge, the present study represents the first case series report of the Rafaelo technique employed for treating grade 2 and 3 internal hemorrhoids within the context of SEA. This contribution fills an existing gap in scientific literature, offering valuable insights into the application and outcomes of the Rafaelo technique, specifically in this regional setting. The unique perspective provided by the present study serves to enrich the body of knowledge concerning the efficacy and safety of this innovative approach for managing internal hemorrhoids in the SEA region.

In conclusion, the present study affirms the remarkable safety and efficacy of the Rafaelo technique in treating grade 2 and 3 internal hemorrhoids. The technique emerges as a promising intervention, notably minimizing postoperative pain and delivering favorable outcomes that persist up to six months postoperatively. These findings contribute to the growing body of evidence supporting the viability of the Rafaelo technique as a valuable option in managing internal hemorrhoids, emphasizing its potential benefits for patients in terms of safety, efficacy, and postoperative comfort.

Limitation

A limitation of the present study is its design as a retrospective case series, and future research would benefit from a comparative prospective clinical trial for a more robust assessment of the Rafaelo technique compared to other interventions. Additionally, the present study encountered a 55% loss to follow-up at the one-year postoperative mark,

limiting the duration of the conclusions to the initial six months postoperatively. The inherent challenges in achieving comprehensive long-term follow-up data highlight the need for more concerted efforts in future investigations to minimize loss to follow-up and ensure a more comprehensive understanding of the sustained outcomes associated with the Rafaelo technique.

What is already known on this topic?

RFA has shown efficacy and safety in treating hemorrhoids, with the Rafaelo technique emerging as a promising method to reduce postoperative pain and complications.

What does this study add?

This study demonstrates the efficacy and safety of the Rafaelo technique for managing grade 2 and 3 hemorrhoids in the Southeast Asia region, showing significant reductions in postoperative pain and symptom severity.

Conflicts of interest

The authors declare no conflict of interest.

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