A Randomized Comparison of Single and Multiple Rubber Band Ligations

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One hundred consecutive office patients with internal hemorrhoidal disease were treated by rubber band ligations. They were assigned randomly to one, two, or three ligations at one session. No statistically significant differences in morbidity or complications resulted from multiple ligations, as compared with one ligation. No serious complications were encountered in any of the treatment groups. These results confirm that multiple rubber band ligation is as safe and effective a procedure for managing internal hemorrhoidal disease as single ligations. [Key words: Hemorrhoids, internal; Ligation, rubber band]

IN OUR OWN PRACTICE surgical hemorrhoidectomy (closed hemorrhoidectomy with local anesthesia) is the preferred method for treating third- and fourth-degree hemorrhoidal disease.5 However, rubber band ligation is an invaluable alternative for first- and second-degree cases or for more severe cases whenever surgery is declined by the patient, symptoms recur after surgery, or surgery is contraindicated because of systemic disease. Since the practice of ligating internal hemorrhoids was initiated by Blaisdell,2 and advanced by Barron,3,4 it has been an accepted modality for office treatment of first- and second-degree hemorrhoidal disease. Clinical evaluations have demonstrated the simplicity, safety, and patient acceptance of this procedure. The long-term assessments have confirmed its efficacy.5-7

Usually only one ligation is performed per session in the belief that this will minimize discomfort and complications. Groves et al.5 found that 26 percent of the patients experienced discomfort lasting for more than three days, but only 9 percent experienced pain severe enough that they declined further treatment. On long-term follow-up, Steinberg et al.6 found 89 percent of patients were cured or satisfied with the results of single ligation treatment, although complete absence of symptoms was reported by only 44 percent. Similarly, Wrobkleski et al.7 found that after single ligation at three years 80 percent of the patients were improved and 69 percent were asymptomatic.

Four studies suggest that multiple rubber band ligations may be as safe and effective as single ligations.8-11 Keighley et al.8 reported that only 18 percent of their patients were unimproved following double rubber band ligation as compared with 26 percent of those who underwent anal dilatation, 56 percent who had cryosurgery, 63 percent who had sphincterotomy, and 75 percent who were treated with high-fiber diet. Murie et al.9 reported a similar success rate following triple band ligation in patients with second- and third-degree hemorrhoids. Of 43 patients who were surveyed one year after treatment, 38 (88 percent) had an acceptable outcome and 36 (84 percent) were willing to undergo rubber band ligation again. When Murie et al.10 followed another group of 39 patients who had received triple rubber band ligations 42 months previously, only two (5.1 percent) were classified as little improved. In the most extensive multiple banding study, Lau et al.11 ligated three first- or second-degree hemorrhoids in 221 patients. More than 90 percent were asymptomatic or showed minimal symptoms at follow-up. Moderate to severe pain was noted by 28.7 percent. Further nonoperative treatment was required in 13.9 percent, and six patients (3.0 percent) eventually required hemorrhoidectomy.

Although outcomes of multiple banding studies seem equivalent to those using single bands, no direct comparison of single and multiple banding has been conducted. The possibility of differences in technical skills of physicians or differences in patient groups between previous single and multiple ligation studies cannot be ruled out. This present study was designed to control for these differences and provide a direct comparison. Patient differences were controlled by randomly assigning patients to one, two, or three ligations in a prospective fashion.
Since the same physician treated all patients, technical skills were constantly applied across all conditions. This procedure allowed a direct experimental comparison of the differences in outcomes between single and multiple ligations.

**Methods and Patients**

The randomized trial included 100 patients treated in the office setting with rubber band ligations as their only therapy. The indication for treatment was symptomatic hemorrhoidal disease, using American Classification B. The distribution of patients according to this classification is depicted in Table 1. On each patient's first visit to the office, the number of ligations was assigned randomly by a blind draw of a chit inscribed with one, two, or three. Patients returned at three weekly intervals until all hemorrhoidal complexes were treated.

One rubber band (outside diameter 5mm; inside diameter 1.5 mm) was removed from the nonsterile plastic pouch and loaded on a nonsterile but clean Barron applicator. Contrary to Shub's recommendations, no prior bowel preparation or local preparation of the site was used. Through a nonsterile anoscope, a conservative amount of tissue was grasped, well above the dentate line (at least 1 cm), and an enquiry was made of the patient, lying in a jack-knife position, regarding any discomfort. If the patient responded affirmatively, either the procedure was abandoned or a more proximal site was grasped. If no complaint of pain was elicited, the instrument was fired. The resultant "polyp" was no larger than 1 cm in diameter. When pressure or discomfort was reported after the application, the offending rubber band was removed immediately with a crochet hook. For patients who had been selected for two or three ligations, this procedure was repeated once or twice, respectively.