
THE LONG TERM RESULTS OF HEMORRHOID BANDING

USING THE O'REGAN DISPOSABLE SUCTION LIGATOR®



CLEATOR IAIN G.M.¹ AND CLEATOR MARIA M.²

¹Emeritus Professor of Surgery, UBC

MB, ChB Ed, FRCSE, FRCSC, FRCS, FACS

²Research Coordinator, Cleator Clinic, MD



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**Short Title: Study Of Hemorrhoid Banding
Using The O'Regan Suction Ligator®**

Address for Correspondence:

Cleator Clinic

#310, 943 West Broadway,

Vancouver, BC V5Z 4E1

E-mail: cleator@interchange.ubc.ca

E-mail: mcleator@shaw.ca

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FORWARD

Recognizably by health care providers in clinical practice, hemorrhoidal disease is a very prevalent problem for their patients. As the treatment paradigm for definitive intervention (e.g. using infrared coagulation or hemorrhoidal surgery) has historically been quite morbid for patients, the majority of health care providers have been reluctant to refer patients for therapy. A composite approach using topical therapies for steroids and analgesics has for some patients provided temporary relief, but overall quite ineffective long-term effective treatment results. Dr. Iain Cleator, a renowned surgeon from Vancouver BC has had long-term interest in effective hemorrhoidal therapy. His seminal work using the O'Regan rubber band ligation system has highlighted a new approach for effective intervention. In this monograph, Dr. Cleator presents his clinical results – which is the single largest experience in the world – involving the placement of over 20,000 bands in 6,690 patients. The results of Dr. Cleator's work highlight the safety and efficacy of the O'Regan system. The publication of this work provides a foundation of knowledge highlighting the vast clinical experience and impressive results and will be an invaluable resource reference for physicians interested in providing optimal and definitive hemorrhoidal treatment!

David A. Johnson MD FACG FASGE

Past president, American College of Gastroenterology

Bergein F. Overholt MD MACG FASGE

*Past president,
American Society of Gastrointestinal Endoscopy*

PREFACE

We have published this material as a short book because it is too long for a conventional journal.

I started my surgical contact with hemorrhoids in Edinburgh at a clinic under the guidance of Mr. Charles Falconer in 1964. Patients also had a rigid sigmoidoscopy and exam to check for cancer. Over the years the techniques for treating hemorrhoids improved, and the advent of Mr. Barron's rubber ligation represented a huge advance.

In the early 1970s in Vancouver I met Dr. Denis Burkitt and was very impressed by his linkage of diet to hemorrhoids and colo-rectal cancer. In the late 1990s I met Dr. P. O'Regan and his device and in 2001 met Mr. Marc Morin who showed me the improvements in the O'Regan ligator and I immediately started up the Cleator Clinic for hemorrhoid banding and later joined the company owning the ligator as a shareholder and then medical director and research board and board member. My wife and co-author is also a shareholder.

When I was asked to write about my experience with the ligator by Mr. Edward Wright CEO of CRH Medical Corporation, as the company is now called, I was reluctant because I clearly have a conflict of interest. I decided to undertake this as it is unlikely that there will ever be as large a series of treated hemorrhoids as this one and it is important to document these and set down my experiences for confirmation by others. The practical techniques will help anyone undertaking hemorrhoid banding.

A surprise to me was the strong association of colo-rectal cancer with hemorrhoids and Dr. Burkitt's idea of both diseases being linked to lack of fiber do seem on the mark.

We wish to acknowledge the encouragement of Dr. Mitch Guttenplan, Dr. Tony Holler and Dr. Bergein Overholt.

We are very grateful to Dr. Dave Johnson for editing the manuscript.

Iain Cleator MD

Emeritus Professor of Surgery, University of British Columbia

ABSTRACT

OBJECTIVES: Hemorrhoids are troublesome to patients and treatment can lead to a poor outcome or have painful prolonged recovery periods. The aim of this study is to describe the detailed characteristics and follow-up of a large group of patients with hemorrhoids who were treated with the CRH O'Regan banding ligator.

METHODS: This is a single center retrospective analysis of 6,690 patients treated with the CRH O'Regan banding method. The facility performs 41% of all banding in British Columbia, Canada. Data was recorded prospectively and analyzed by SCARL (Statistics at UBC).

RESULTS: 49% of those treated were women and the age of onset was younger in women. 20,286 bandings were performed for an average of 3.03 per person. 8% had a full recurrence and 5% a partial recurrence over a mean period of 42 months. Complication rates were 0.36% post band (PB) bleeding, 0.15% PB pain, 0.06% urine hesitancy, and 0.03% loss of work. There were no deaths or sepsis or other complications. 46% patients reported first degree relatives (1st DR) with colo-rectal cancer and polyps over the follow-up period. 8% of all patients had colo-rectal cancer before or during the follow-up period, but in those with 1st DR the incidence was 9.9%. 23% of all patients had polyps before or during the follow-up period, but in those with 1st DR the incidence was 44%.

CONCLUSIONS: The CRH O'Regan banding ligator is safe, effective and free of complications. We ascribe this to its gentleness in using suction, positioning the band more proximally in the L angle[®], to simple techniques developed for the instrument including nudging the band to a more proximal position with the finger, banding one hemorrhoid at a time and the use of Nitroglycerin to reduce pressure and promote healing. The ligator is one use and can be performed without fear of complications. The increasing frequency of cancer, polyps and 1st DR in our study raises the question of a common cause of hemorrhoids and colon cancer and we may be able to use hemorrhoids as a marker for colon cancer.

INTRODUCTION

Hemorrhoids are a common cause of distress and their treatment is often unsatisfactory due to recurrence or complications. The results of the CRH O'Regan ligator for this condition have been very favorable but limited so far. In this study we evaluate the results in 6,690 patients treated with this ligator and our methods.

The aims in this report were to examine the results of banding hemorrhoids with the CRH O'Regan ligator and to compare the results with the results of other methods of treatment. Additionally, we examined the findings in this large group of prospectively recorded patients to establish whether the commonly accepted clinical characteristics of hemorrhoids were supported in the study.

Hemorrhoid treatment has undergone changes since the initial introduction of the Barron band ligator in 1963[1] which was based on modifications of Dr. Blaisdell's ideas[2]. Prior to that time, the common options were surgical hemorrhoidectomy or injection sclerotherapy[1]. Banding is deservedly successful as relief from hemorrhoids is obtained by a method that does not entail hospitalization or loss of time from work. The procedure has some drawbacks which have enabled other ideas to gain acceptance: the procedure is not as free from pain as in Mr. Barron's hands, and there are some other complications encountered over the years which are troublesome.

ClinicalEvidence[3] labels rubber band ligation as "beneficial", but closed hemorrhoidectomy, infrared coagulation/photocoagulation, open excisional (Milligan-Morgan/diathermy) and stapled hemorrhoidectomy are only "likely to be beneficial" and hemorrhoid artery ligation, injection sclerotherapy and radiofrequency ablation are "unknown effectiveness". The difficulty with these designations is that from a patient's point of view the procedure must be safe, effective, painless and free from adverse

effects. However, there are significant adverse effects from many of these procedures including death, sepsis, severe pain, bleeding, impotence, urinary retention and anal stenosis[4-24].

Our contention is that the O'Regan ligator fulfils the goals of safety, effectiveness painlessness, and freedom from adverse effects better than any other device or treatment so far described. It builds on the ideas of Mr. Barron by using a disposable device, employing a gentle suction rather than grasping and penetrating with metal forceps. Our methodology puts the band more proximally than Mr. Barron, avoiding the pain fibers and drawing the hemorrhoidal tissue upwards and tacking it in rather than leaving the tissue outside. We also employ nitroglycerin ointment to accelerate healing and promote relaxation of the anal sphincter and increased blood supply which enables us to band once every 7 days rather than once every 10 days as Mr. Barron did[1]. However we retain his concepts of checking for other pathology, one band at a time, recognition that pain when it occurs is immediate after banding. We relieve any pain by "nudging" the band upwards from the dentate line (we apply one only to facilitate this maneuver) and freeing it from underlying muscle as an essential part of our technique and teaching. Mr. Barron would remove the bands (he used two) with a forceps when this occurred[1]. Our adoption of the O'Regan device has resulted in very low complication rates from pain, bleeding, urinary hesitancy, loss of work and no sepsis, stricture or deaths[25].

MATERIALS AND METHODS

The Patients

I opened a clinic devoted to hemorrhoid treatment with the O'Regan ligator in January 2003. My experience as a general surgeon with a special interest in gastrointestinal work had involved extensive experience with other forms of treatment of hemorrhoids including the Barron ligator and surgery.

The clinic is a referral clinic and was successful from the beginning. It has developed into the largest clinic of its kind in British Columbia and has grown entirely on word of mouth recommendation. This year we performed 41.5% of the hemorrhoid banding procedures in British Columbia (J. Grant, Manager Professional Relations, BCMA, Vancouver).

Patient Population

Vancouver is a cosmopolitan city with more than half the population of Asiatic descent. The clinic numbers reflect this mix.

Over the time period we have treated 6,690 patients and performed 20,286 ligations. There were 3,842 patients with fissures. The average patient had 3.03 ligations in each treatment course for complete healing of hemorrhoids and fissure.

Protocol

At the first visit, the patient's history is taken, rectal and rigid procto-sigmoidoscopy performed and a physical exam performed. Typically on this first visit, the first band is applied, and then the patient is provided with high fiber diet recommendations, written instructions and access to the Clinic's website <http://www.haemorrhoids.ca/> Subsequent visits are for banding the other two

hemorrhoids. Typically we band the left lateral hemorrhoid on the first visit followed by the right posterior and right anterior at weekly intervals, and a final visit three weeks later to check that all is healed and arrange a fecal occult blood test (FOBT) and recommend continuation of the nitroglycerin ointment for three months and high fiber diet indefinitely.

Methods Used for this Study

This is a single center retrospective analysis of an 8-year database of 6,690 patients treated with the CRH O'Regan band ligator.

At each appointment the details of the findings and procedures are entered and a detailed data sheet is thus available for further study. The patient is instructed to follow up with the clinic in the event of any problems of any kind.

After completion of treatment if a problem arises the patient is referred again and the data and treatment recorded electronically.

When there are items of information not on the data sheet an IT program looks for the critical words in the doctor's letter and these charts are pulled up manually and checked. When a test is ordered and not recorded, again these are pulled up by the IT program and manually checked.

Definitions

Internal hemorrhoids are dilated complexes of arterioles and veins and are covered by columnar epithelium. Traditionally, it had been assumed that hemorrhoids were dilated veins between the systemic and portal venous systems. Thulesius and Gjores however showed that the blood had a PO^2 the same as arterial blood[26]. This finding explained why hemorrhoid bleeding is bright red. Recent work has suggested that the increased pressure associated

with hemorrhoids is associated with hypertension (engorgement) of the hemorrhoid plexus and not with hypertrophy of the anal sphincter[27]. Banov's classic paper and grading for internal hemorrhoids [28] are adopted and used: Grade I: tuft of tissue, no hemorrhoids; Grade 2: prolapse and go back after defecation; Grade 3: prolapse and have to be pushed back (Photos 1 & 2 on page 9); Grade 4: prolapse and stay out.

External hemorrhoids appear in the perianal tissues and are due to dilation of veins in the systemic venous system. The external veins drain along a venous connecting channel to the internal hemorrhoids. Rarely there is enlargement of internal, external and connecting veins and this is called a compound hemorrhoid.

An anal fissure can be acute (same color as endoderm) and is a linear and longitudinal break in continuity of the squamous epithelium of the anal canal. If chronic there is a white ulcer base due to penetration of the fissure through the lamina propria to the muscle coat.

Diet

“The only way to keep your health is to eat what you don't want, drink what you don't like, and do what you'd rather not.” (Mark Twain)

In the early part of the 20th century Dr. Cleave wrote about the link between the saccharine diet (refined food and sugar) and Western diseases[29]. Dr. Denis Burkitt adopted some of these ideas and the concept of lack of fiber as being important in the development of hemorrhoids and colon cancer started to be considered[30]. Denis Burkitt made the case for high fiber in preventing hemorrhoids and a variety of other conditions[30], and we now believe that daily 30 to 35 grams of soluble fiber for men and 25 grams of soluble fiber for women are necessary for prevention of hemorrhoids and reduction of incidence of colon cancer. This is stressed at all times in the Clinic but is often not adhered to by the patients after treatment. Furthermore, it has been our observation that patients with recurrence did not follow the increased use of soluble fiber in their diet. Dr. Burkitt's ideas were largely based on epidemiological evidence and observation of diet, as with Dr. Cleave[29], and it is interesting that Dr. Ani in 1983 found a higher incidence of ano rectal disease than expected in Western Nigeria[31] and attributed this in part to increased use of Western diet.

Over the next 30 years there were different studies with no confirmation of this work until a study of over half a million people in Europe showed that high fiber resulted in 40% less colon cancer[32]. We subscribe to the view that fiber is essential during and after hemorrhoid treatment and use several varieties of soluble fiber to bring the daily intake to 30-35 g for men and 25 g for women daily and ask the patients to drink 7 to 8 glasses of water daily and not sit on the toilet longer than 2 minutes for a bowel movement.

Nitroglycerin

Our patients use nitroglycerin ointment (NTG) (0.13% in petroleum jelly) whenever there is an accompanying anal fissure or spasm of the anal canal. There is literature to document that anal fissures are the result of ischemia on the anal canal lining with the principal weakness site on the posterior wall[33].

Our rationale is that the NTG is a smooth muscle relaxant and also brings increased blood supply to the area. There is literature that suggests that the anal sphincter has higher manometric pressures in patients with hemorrhoids[27, 34, 35] and some of the long-term beneficial results of surgical hemorrhoidectomy are attributable to the reduction in anal pressure following surgical hemorrhoidectomy[36]. There is a contrary view however to suggest that there is no hypertrophy of the anal sphincter muscle but instead the high pressure is from hypertension of the internal hemorrhoidal plexus[22]. This would imply that removal of tissue by hemorrhoidectomy or banding is important. There is support for this view from a prospective randomized clinical trial of 32 patients which showed that even in early-stage hemorrhoids, the anal pressures are significantly raised, but after successful treatment with band ligation or injection sclerotherapy, these pressures return to normal, showing that they do not play a pathogenic role but are secondary to the congested hemorrhoidal cushions[37]. This would suggest that the anal pressure variances do not play a pathogenic role but are secondary to the congested hemorrhoidal cushions[37]. The NTG ointment is applied directly to the fissure by inserting the patient's gloved index or middle finger into the anus with a pea sized amount of ointment to the posterior wall of the anal canal TID. When healed the ointment is continued twice a day for three months to permit more complete healing and to decrease recurrence. Comparison of surgical with chemical sphincterotomy over 5 years showed

recurrence of 10% with lateral sphincterotomy. 57.5% with nitroglycerin)-0.13%, 65% with diltiazem and 52.5% with onabotulinumtoxinA[38]. If headache occurs with NTG the patient is encouraged to persist with smaller amounts and apply more frequently. If not tolerated, 2% diltiazem cream is prescribed to be given transanal with the same instructions for use as the NTG cream. NTG also promotes healing after hemorrhoidectomy from the increased blood supply[39, 40].

Occasionally we have used onabotulinumtoxinA for patients with severe pain and spasm from their fissure. Using a syringe and #22 gauge needle 10 units of onabotulinumtoxinA in 5ml of saline are injected 1.5 cm lateral to the anus on each side, inserting the needle fully and injecting the internal sphincter as the needle is withdrawn. Nitroglycerin ointment is continued. Half the patients received some benefit in our series. Other techniques that help are injecting 2.5ml bupivacaine 0.25% again with a #22 needle inserted deeply to the same two areas. This is a pudendal nerve block if most of the bupivacaine is injected on deep insertion. Another great help is asking the patient to sit in warm water for 5 to 10 minutes as this relaxes the anal spasm (this is called a Sitz bath if a little salt is added).

The CRH O'Regan Bander and the CRH Anoscope

The ligator is inserted directly or through an anoscope with a cutout into the distal rectum orienting the instruments somewhat posterior to accommodate the direction of the lumen. The purpose is to apply suction to the area at the L angle[®] of the lower rectum (Figure 1) and by applying suction by drawing back the plunger, entrap the hemorrhoid in the barrel, sucking up the portion hanging down (Figure 2 with anoscope and Figure 3 without anoscope), wait 20 seconds and then apply the band (Figure 4). A key difference in our technique is that the placement of the

band is at the L angle[®] which in most patients is higher than the one or 2 centimeters proximal to the dentate line. It is more likely to be 2 or 3 centimeters above the dentate line. After this the banded hemorrhoid is checked with the finger to assess if any muscle has been picked up (should be mobile side to side). If not, or if the patient has pain, a nudge with the tip of the finger moves the band up sufficiently to resolve the problem (Figures 4 and 5). The band can be applied with the use of an anoscope with a cut out pointed to the hemorrhoid to be banded (Figure 2) or with the instrument alone – the touch technique (Figure 3). The photo shows a large grade 3 hemorrhoid before and after banding (photos 1 and 2). The touch technique is used most of the time for patient comfort. Even in a very obese patient or one with a fissure, the instrument is guided in on its own, past the mark on the pusher, and pointed towards the hemorrhoid to be banded. The hemorrhoids are banded one at a time – this is the technique that Barron used[1]. The importance of this has been forgotten over the years. On page 1223 of Schwarz's standard textbook of surgery the recommendation is to band all three quadrants in the operating room if the symptoms are severe or the patient has significant external hemorrhoids and other anorectal problems[41]. However Lee's paper clearly shows the huge increase in unacceptable complications from this practice in his study from the Mayo Clinic[9]. When multiple hemorrhoid banding was compared to single banding 29% had discomfort compared to 4.5%, there were more vasovagal attacks 5.2% vs. 0%, local swelling and edema 2.6% vs. 0% and urinary hesitancy and frequency 12.3% vs. 0%. It seems clear that much of the complications of hemorrhoid banding are related to this practice.

There is a variation in our technique of banding hemorrhoids – we band the left lateral at 3 o'clock, the right posterior at 7 o'clock but the right anterior is banded between 9 and 10 o'clock rather than at 11 o'clock (please

note the hemorrhoids are depicted as being in the location of the hours on a clock looking at the perineum: the 12 o'clock position is taken as the anterior aspect, position of the penis in the man and the vagina in the woman). Our reason for this is that there is a complex plexus of parasympathetic nerves between the prostate and the rectum in men[19]. Pilkington believes this to be important in the recorded rare impotence after sclerotherapy[6]. There is also a large body of literature referring to urinary retention and hesitancy after hemorrhoid treatment and it seems to us a good idea to stay away from this area[7-9, 12, 13, 20, 22, 42-44].

Dr. Corman has a description of the use of the ligator in his text book[45] and there are journal articles explaining the technique and results[25, 46, 47] and the favorable experiences of gastroenterologists[48, 49] with the technique. One study showed reduction of the size of the hemorrhoids after use of the CRH O'Regan bander[47, 50].

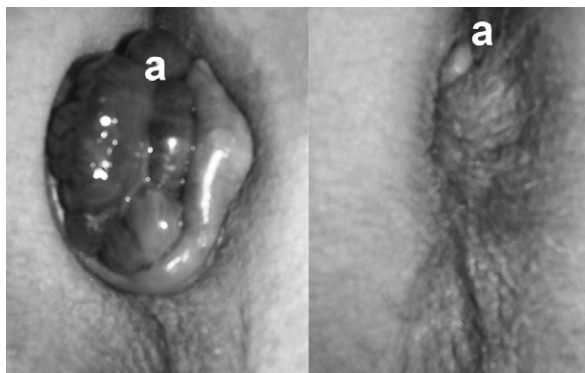
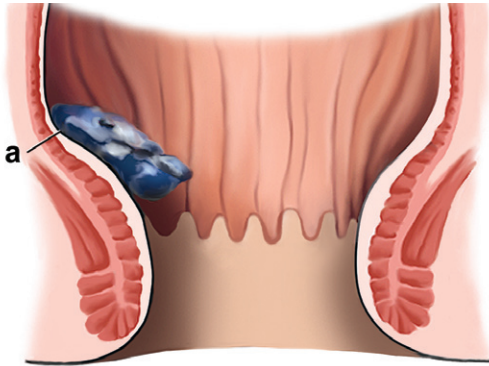


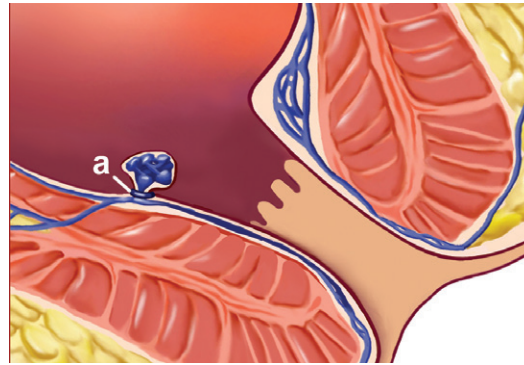
Photo 1 and 2 - a is Grade 3 hemorrhoid before and immediately after banding

Figure 1.



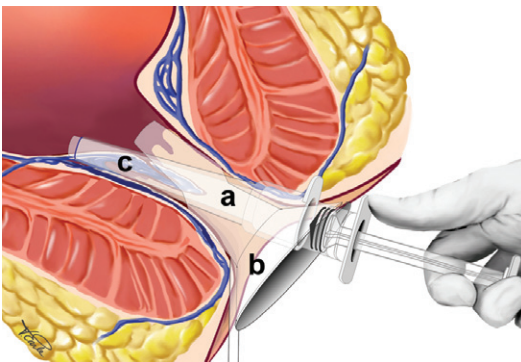
a is the L angle[®] where the hemorrhoid is aspirated by the ligator.

Figure 4.



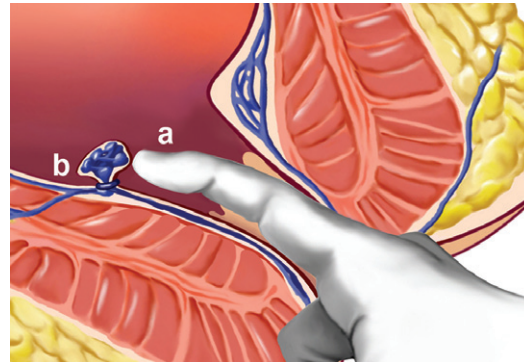
a is the banded hemorrhoid

Figure 2.



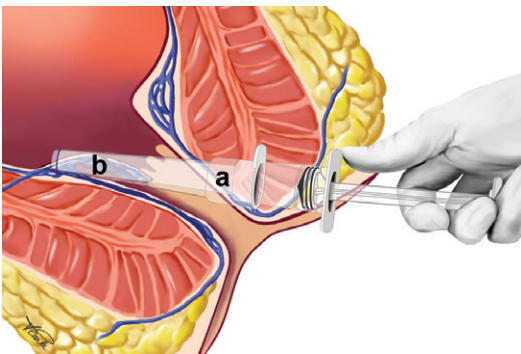
a is the ligator, b is the anoscope, c is the aspirated hemorrhoid

Figure 5.



b shows the banded hemorrhoid being nudged to free the band from underlying muscle

Figure 3.



a is the ligator, b is the aspirated hemorrhoid

Anal Spasm, Fissure and the "Black Spot"[®]

We have observed several black spots on proctoscopy in patients coming in with a lot of pain. These accompany a fissure and anal spasm. They appear as black spots the size of a grain of rye (3 x 2 mm) in the longitudinal axis of the distal anal canal and under the endoderm. They are clearly visible on rigid proctosigmoidoscopy. We believe they represent tiny thrombosed vessels or dark blood in small vessels from blocked drainage due to bulky internal hemorrhoids or straining.

RESULTS

There were 6,690 patients with an average age of 49.3 years and 49% were women. Each patient had an average of 3.03 bands. There was an 8% recurrence of all three hemorrhoids over an average of 42 months, and a 5% partial recurrence (one or two hemorrhoids). 3,082 of the patients were noted to have first degree relatives with colo-rectal cancer or neoplastic polyps during the study. 4,616 were treated with NTG and 381 had diltiazem instead for one or two weeks and then usually went back to the NTG without headache or problems (Table 1).

During the course of the study, either on the first or subsequent visits, 508 (8%) patients had colo-rectal cancer reported or found and 1527 (23%) had neoplastic polyps (Table 2).

TABLE 1: Results

ID	#
# of patients	6690
Average age (years)	49.3
#bands	20286
Average# bands	3.03
Recurrence	8%
Partial recurrence	5%
Averagefollow up months	42
STDEV FU months	23
1st degree relative with colo-rectal cancer	3082
Weight loss	27
Hep, HIV, Herpes, Warts	132
Anal Ca	7
Pruritus ani	143
Nitroglycerin	4616
Diltiazem	381
FOBT -ve	2076
FOBT +ve	114
Latex allergy	4
Recto-sigmoid ca	19
Recto sigmoid IBD	38
Recto sigmoid other	36

TABLE 2: Results by Grade of Hemorrhoids

	Grade 1	%	Grade 2	%	Grade 3	%	Grade 4	%	All Grades	%
# Patients	372		3729		2208		381		6690	
Female	181	49	1703	46	1169	53	196	51	3249	49%
Thrombosed	5	1	38	1	4	0	215	56	262	4%
Bleeding	223	60	3056	82	1916	87	296	78	5491	82%
Itching	155	42	2135	57	1333	60	231	61	3854	58%
Pain	181	49	2334	63	1541	70	293	77	4349	65%
Incontinence	38	10	141	4	113	5	20	5	312	5%
Leakage	6	2	38	1	65	3	10	3	119	2%
Coumadin or heparin	6	2	32	1	16	1	7	2	61	1%
Constipation	53	14	25	1	776	35	57	15	911	14%
Diarrhea	16	4	55	1	62	3	4	1	137	2%
Constipation & diarrhea	2	1	27	1	28	1	2	1	59	1%
Regular	301	81	3622	97	1342	61	318	83	5583	83%
IBD	25	7	35	1	9	0	0	0	69	1%
IBS	11	3	91	2	38	2	6	2	146	2%
Posterior Fissure	209	56	1467	39	1933	88	194	51	3803	57%
Anterior & Posterior fissure	2	1	6	0	5	0	1	0	14	0%
Anterior fissure	6	2	13	0	4	0	2	1	25	0%
Colo-rectal cancer	52	14	320	9	104	5	32	8	508	8%
Polyps	48	13	1124	30	264	12	91	24	1527	23%

Complications were 0.2% per band or 0.6% per course of treatment (3.03 bands). Bleeding recorded was substantial. There is much more blood than usual, the patient is faint and diaphoretic. Pain recorded is substantial. The patient cannot perform usual activities. Urinary hesitancy means that the patient can pass urine, but it is slow to initiate or diminished flow (Table 3).

TABLE 3: Complications

Complication	#	% per patient	% per band
Death	0	0%	0.00%
Severe PO bleed	24	0.36%	0.12%
Severe PO pain	10	0.15%	0.05%
PO Urine hesitancy	4	0.06%	0.02%
PO Urine retention	0	0.00%	0.00%
PO Sepsis	0	0.00%	0.00%
PO stricture	0	0.00%	0.00%
PO Loss of Work	2	0.03%	0.01%
TOTAL	40	0.60%	0.20%

For the recurrence rate a very detailed analysis was undertaken. The difficulty with recurrence rates for a banding study like ours is that some patients did not have any banding on first or later visit. This could have been because of pregnancy (we only band after delivery), or travel, or the patient feels better and does not return until there are more symptoms. We therefore made up a Table 4 which allowed us to decide on true recurrence and partial recurrence. We suggest this as a possible model for others to report their results.

Statistical analysis consisted of 28 comparisons. All comparisons involve at least one categorical variable and most involve two. To compare two categorical variables the data are first tabulated and the independence of the variables is tested using a Pearson's Chi-squared test. When a numeric variable and a categorical variable are compared, the numeric variable is first summarized within each level of the categorical variable by the average (MEAN), standard deviation (SD), and a five-number summary which consists of the sample minimum, lower quartile, median, upper quartile and maximum. The data are then compared using a non-parametric rank test (Wilcoxon or Kruskal-Wallis rank sum test). There are 28 tests performed so we must adjust our definition of significance for multiple comparisons by a factor of 28. If you wish to consider a false positive rate of 5% then the p-value for a test must be less than $0.05/28$ or 0.0018 before we consider there to be a statistically significant association between the two variables. This is called a Bonferroni correction. Another consideration is the sample size. Large sample sizes (6,690) will make even weak associations appear statistically significant. Statistical significance is not the same as biological significance. One is a function of the particular statistical method and the sample size; the other is a matter of practical interest. In most comparisons, the p-value was very small and a statistically significant association was detected, even after adjustment for multiple comparisons[51]. 24 of the 28 comparisons were significant and are listed on the next page. R. White, Director of SCARL, UBC, Vancouver calculated statistics. Please see Supplementary Figures 1 and 2 online for details of tests used and actual calculations.

1. History of hemorrhoidectomy 23/383=6% of grade 4 hemorrhoids, whereas 109/6307=2% of grades 1 to 3.
2. There is no evidence of a relationship between previous hemorrhoidectomy and posterior fissure.
3. Mean # of bandings is 0.078 of grade 1 hemorrhoids, compared to at least 3.3 in grades 1 to 3.
4. Patients who chose to have tags removed had a mean age of 47.3 years compared to those who did not at 49.5.
5. Women are mean age 39.7 years at onset of hemorrhoids compared to men at 42.6.
6. Constipation (hard or less frequent stools or difficulty in passing stools) is present in 448/4047 =11% of grade 1 hemorrhoids, whereas constipation is 835/2643=32% of grade 3 and grade 4.
7. CR Ca is present in 52/374=14% of grade 1 hemorrhoids, compared to 456/6316=7% of grades 2 to 4.
8. 304/3082=9.9% of patients with 1st degree relatives with CR Ca have CR Ca themselves compared to 204/3608=5.7% with no 1st degree relatives.
9. Diarrhea is present in 16/374=4% of grade 1 hemorrhoids, whereas diarrhea is 121/6316=2% of grades 1 to 3.
10. There is no evidence of a relationship between combined diarrhea and constipation vs. grade.
11. Incontinence (involuntary loss of complete stool) is present in 38/374=10.2% of grade 1 hemorrhoids compared to 274/6316=4.3% of other grades.
12. Leakage is present in 75/2643=2.8% of grade 3 & grade 4 hemorrhoids, compared to 44/4047=1.1% of grade 1 & grade 2.
13. Bleeding is present in 223/374=60% of grade 1 hemorrhoids, whereas bleeding is 5268/6316=83% of grades 2 to 4.
14. Bleeding occurs in 637/2887=22% when no fissure is present compared to 562/3803=15% when a fissure is present.
15. Itching is present in 155/374=41% of grade 1 hemorrhoids, whereas itching is 3699/6316=58% of grades 2 to 4.
16. There is no evidence of a relationship between itching and posterior fissure.
17. Pain is present in 181/374=48% of grade 1 hemorrhoids, whereas pain is 4168 /6316=66% of grades 2 to 4
18. 1761/2887=61% of patients without post fissure have pain compared to 2588/3803=68% when a fissure is present.
19. Polyps are present in 48/374=12.8% of grade 1 hemorrhoids, compared to 1479/6316=23.4% of grades 2 to 3.
20. 1365/3082=44.2% of patients with 1st degree relatives with CR Ca have polyps compared to 162/3608=4.5% with no such relatives.
21. Women have 1639/3249=50% tags diagnosed compared to men with 1350/3441=39%.
22. Women have 411/3249=13% tags removed compared to men with 190/3441=6%.
23. 215/262=82% of thrombosed hemorrhoids are grade 4, whereas thrombosed hemorrhoids in grades 1 to 3 are 47/6428=0.7%.
24. 166/262=63% of thrombosed hemorrhoids have no post fissure compared to non thrombosed hemorrhoids at 2721/6428= 42%.
25. Mean reported time on the toilet is 8.45 minutes with grade 3 hemorrhoids, whereas mean time on toilet is less than 5.00 for each of the other grades.
26. Mean time on the toilet is 7.86 minutes in patients with posterior fissure compared to 1.31 in patients without fissure.

TABLE 4: Recurrence of Hemorrhoids

1st referral	Banding	2nd referral	Banding	# treated	3rd referral	Banding	# treated	
849	No band	271	No band	72	17	No band	6	
						Band 1 or 2	2	
						Band 3 or more	9	
						Band 1 or 2	30	
						Band 1 or 2	4	
						Band 1 or 2	1	
						Band 3 or more	3	
						Band 3 or more	169	
770	Band 1 or 2	187	No band	48	24	No band	2	
						Band 1 or 2	11	
						Band 3 or more	11	
						Band 1 or 2	88	
						Band 1 or 2	11	
						Band 1 or 2	4	
						Band 3 or more	5	
						Band 3 or more	51	
5071	Band 3 or more	923	No band	196	115	No band	40	
						Band 1 or 2	28	
						Band 3 or more	47	
						Band 1 or 2	239	
						Band 1 or 2	61	
						Band 1 or 2	19	
						Band 3 or more	35	
						Band 3 or more	444	
						115	No band	3
							Band 1 or 2	35
							Band 3 or more	77

DISCUSSION

6,690 patients were referred to the clinic of which 49% were women. This means either that men and women have an equal incidence of hemorrhoids, or that one group tolerates hemorrhoids better without treatment. However women developed hemorrhoids at an earlier age (39.7 vs. 42.6) and had more tags than men (50% vs. 39%) suggesting that pregnancy brings them on earlier and results in more tags. Women also were more likely to want their tags removed, basically a procedure, which promotes cleanliness, and cosmesis but involves discomfort (13% vs. 6%).

When patients returned after a previous surgical hemorrhoidectomy, they were more likely to have huge grade 4 hemorrhoids than the other grades (6% vs. 2%). This could be because of reluctance to seek treatment or because they were higher grade to begin with or because of inadequate counseling on preventative measures.

Constipation was commoner in those with larger hemorrhoids than smaller (32% vs. 11%). The average prevalence for constipation was 19%, which compares to a postal health survey in Australia of 41,724 women with a prevalence of 14.1%. The prevalence of hemorrhoids in the Australian study were 3.2% for women 18-25 years 17.7% middle aged (45- 50years) and 18.3% older women (aged 70-75 years)[52]. Our data reflects the fact that we are looking at the data from the perspective of patients with hemorrhoids coming for treatment, and our patients are skewed to the older patients. In the study by Dia from Dakar 84% of 168 patients with hemorrhoids had constipation, but their group was different – younger (39) and mostly male (1.66:1)[53]. There has been reported a positive family history in 118/332 patients with constipation[54]. Diarrhea was uncommon but when it occurred was more frequent in grade 1 hemorrhoids than the other

grades (4% vs. 2%). The big finding in our patients was that most of the patients with hemorrhoids have regular bowel movements (83%). This does make it difficult to persuade the patient to change their diet.

The higher incidence of cancers and polyps in grade 1 hemorrhoids compared to other grades may be due to these patients presenting with bleeding and symptoms from colo-rectal cancers and coincident hemorrhoids at an early stage were seen (a red herring).

Sitting for a long time on the toilet was commoner in grade 3 hemorrhoids than the other grades (8.3 minutes vs. less than 5 for the other grades. A long time on the toilet (> 2 minutes for a bowel movement) was also associated with posterior fissure – 7.86 minutes vs. 1.31 for those without a fissure. It could be that the longer time was causative for worse hemorrhoids and occurrence of fissure as we have always thought, or it could be that it takes longer to have a bowel movement with grade 3 hemorrhoids and or a posterior fissure.

There was no evidence of a relationship between anal pruritus and posterior fissure. Patients reported pruritus ani less frequently with grade 1 hemorrhoids than the other grades (41% vs. 58%) suggesting that patients with larger hemorrhoids have more pruritus ani.

Bleeding was less frequent in grade 1 as opposed to the other grades suggesting that smaller hemorrhoids bleed less than bigger ones (60% vs. 83%). Bleeding was less frequent if a posterior fissure was present than if there was no fissure (15% vs. 22%). We know that fissure is associated with high sphincter pressure and this may decrease bleeding from hemorrhoids.

Pain (related to defecation or sitting or walking or standing) is less frequent in grade 1 compared to the other grades (48% vs. 66%). This suggests that there is more pain from larger hemorrhoids. Pain is more frequent in patients with an anal fissure than those without (68% vs. 61%). This

supports the results of a study of 807 patients with benign anal disease (BAD) with 33.7% pain[55]. A fissure should always be looked for when pain is present, but we found pain can also occur without a fissure.

The prevalence of contagious diseases such as Human Immunodeficiency Virus (HIV), hepatitis A, B, and C, condyloma accuminata, warts, genital herpes and other sexually transmitted diseases was 2% overall. There is some literature to suggest that hemorrhoids are less common in HIV than the general population[56]. In patients with portal hypertension rectal varices can occur, and we do not band these and treat with NTG only for associated fissure or friability. With this treatment approach we have not seen severe hemorrhage from rectal varices in our clinical practice (they are included in our overall analysis).

There were 61 patients on coumadin or fully heparinized (1 patient) and 150 bandings performed with one post band bleed of one and a half pints. The bleed settled with the patient lying down in my office for 30 minutes, silver nitrate cautery to the bleeding site (a fissure), 2 glasses of water PO and stopping the nitroglycerin ointment for two days. No transfusion was required. This is not a preferred treatment, we prefer to stop the anticoagulant for 5 days prior to treatment to allow us to band, but can be done with this technique when indicated. We know of no other reports of such success with this problem. Nelson[16] comments that in 605 bands in 364 patients there were 23 complications involving bleeding from rubber band ligation when the antithrombotic therapy was held for 7-10 days following the procedure. The claim is that this is not different from the 1-2% expected in patients with banding and no anti-thrombotic therapy[16].

Incontinence (involuntary loss of complete stool) was present in 10.2% of grade 1 hemorrhoids as compared to 4.4% of other grades. This suggests that incontinence is not related to larger hemorrhoids. There were 312 patients

with incontinence and 308 were cured or greatly improved by banding (big improvement after the second band) and Kegel's exercises. We got the idea for this approach in 1974 from Charles Pope[57] who suggested that hiatus hernia surgery worked because of calibration (narrowing) of a wide opening of the esophagus into the stomach. We have developed this over the years to help problems at the other end of the GI tract. We would encourage others to try this simple approach for a problem becoming increasingly common in our population. Leakage on the other hand seems commoner in large grade 3 and 4 hemorrhoids compared to grade 1 and 2 (2.8% vs. 1.1%) and these also respond well to banding.

The recurrence rate is 8% for full (all 3 hemorrhoids) recurrence and 5% for partial (1 or 2 hemorrhoid recurrence). This was the most involved part of the study to track the recurrences accurately through the data and we acknowledge the skill of Mr. R. McKeever who did the IT part of the data file in getting this ready (McKeevers Software Wizardry). The break down is shown in Table 4. The recurrence in other studies of hemorrhoid treatment has often been absent and I can find none that looked at number of hemorrhoids treated first visit and whether they really recurred. In our office patients often do not return after one or two treatments. Initially this was because we would not band until the fissure was treated, the patients felt well, and friends told them that banding was very painful, and they returned a year later for banding when there was another flare up. Or the patient was or became pregnant and our practice is not to band during pregnancy. Or the patient left for 6 or more months on business and returned as a further referral for the rest of the hemorrhoids (referral procedure in BC is for a further referral after 6 months). This recurrence rate is much lower than the rate usually given for banding. Iyer records failure in 29.5% of 805 patients with 2,114 bandings (average 2/patient)

followed for > or = 100 days and states that success was less in the group with 4 or more bands[58]. Use of our method of calculating recurrence would have been helpful.

The frequency of colo-rectal cancer (CR Ca) is 8% in our study and polyps is 23% and higher than any other similar study. In our first paper CR cancer was 2.5% discovered by us[25]. In this study we include those patients with cancer and polyps discovered at any time and also record those with 1st degree relatives with cancer. Over the longer time of follow up patients would come in with a parent or sibling with CR Ca and would be sent for colonoscopy, or would have a colonoscopy for clinical suspicion or +ve FOBT, or if the patient had cancer or polyps the 1st degree relatives would go for colonoscopy. This resulted in a large percentage of our patients having 1st degree relatives with CR Ca (3092=46%). The numbers of patients with cancers and polyps was high therefore but especially high when both hemorrhoids and family history of cancer were considered. To us this is one of the most important findings that following up a group of patients with hemorrhoids lead to the discovery of many cancers and polyps and this group have been underserved in the past. CR Cancer was present in 14% of grade 1 hemorrhoids as opposed to 7 % for other grades. We noted this in an earlier study – small hemorrhoids may require more suspicion of cancer than larger ones. Similarly polyps were commoner in grade 1 hemorrhoids than the other grades (44.2% vs23.4%). A study of 402 patients with minimal bright red bleeding per rectum showed 6.5% adeno-cancers and 7.5% adenomatous polyps in Tehran[59]. This was a one time study as opposed to our longer follow up, but does show a high yield for cancer and polyps. There was also no linkage between the presence or absence of hemorrhoids and presence of tumor. In our study when patients had a 1st degree relative with CR Ca the frequency of CR Ca was 9.9% compared to 4.5% if no such relatives. When patients had a 1st degree

relative with CR Ca the frequency of polyps was 44.2% compared to 4.5% if no such relatives.

Latex allergy was low in our clinic at 1% (61/6690). We use non-latex bands for these patients. Also our clinic uses non-latex gloves for all patients The incidence of latex allergies is less than 1% in the ordinary patient in the US [60] but almost 10% in nurses[61]. It is an allergy that started to appear recently.

Fissures were present in 57% of our patients. Of these 99% were posterior which ties in well with the work that suggests ischemia with reduction of blood flow to the posterior midline as the cause of fissure[33]. There were 325 patients with an anterior fissure. Jenkins suggested a different cause for these – the findings were of a predominance of young women and there was an association with obstetric injury and caution should be used with surgery. Our patients were 13/ 25 female, so we cannot confirm these findings. Our observation suggested the fissures were closer to the skin and more superficial. There were 14 with both anterior and posterior fissures and too few for comment.

There were 27 patients with weight loss (average 7kg). Three of these had colo-rectal cancer and one had a polyp. In our first paper we found 2/7 cancers in this group[25].

There were 65 patients with Inflammatory Bowel Disease (IBD). 38 had ulcerative colitis and were treated with 5-aminosalicylic acid and or mesalazine suppositories until symptoms improved and then sent to a gastroenterologist for investigations, follow up and treatment. Early investigations in the acute phase were avoided wherever possible. The other patients were mostly post irradiation proctitis and responded to mesalazine suppositories and treatment of fissure and or hemorrhoids with some post-infective proctitis and some unknown.

Irritable Bowel Syndrome (IBS) was 146 patients and they seemed no different in respect of hemorrhoids to other patients in terms of perianal disease.

There were 20,286 bands giving an average of 3.03 bands per patient. The mean number of bandings is 0.078 of grade 1 hemorrhoids, compared to at least 3.3 in any other grade. That being said, the average number of bands for the whole group of patients is 3.03 vs. the ideal of 3 – not a big difference but meaningful for a few outlying patients.

The vast majority of thrombosed hemorrhoids occurred mostly (82%) in grade 4 hemorrhoids and typically had no posterior anal fissure. The likelihood is that the mechanism is obstruction to flow of blood and the likelihood is that this is due to the physical bulk of the hemorrhoids more than the posterior fissure. Although the mechanism suggested is that the bulk of the hemorrhoids are the cause of the obstruction rather than increased pressure from the sphincter and anal spasm and fissure, we believe the latter is more causal and therefore advocate the use of an ointment that causes relaxation of the sphincter muscle. We concur that the case for use of the smooth muscle relaxants is proven by Perrotti's prospective, randomized, open design study of 98 patients, 43 treated with nifedipine with relief in 86% as compared to 50% of the control group[62].

The longer the patient spends sitting on the toilet (> 2 minutes) the more likely she is to have grade 3 hemorrhoids and an anal fissure. This confirms all the standard teaching and recommendations. The only unusual finding is that grade 4 hemorrhoid patients did not spend a long time on the toilet – perhaps this indicates that there is a different etiology in grade 4 hemorrhoids. They may be more due to a laxness in attachment of the lining as suggested in a collagen autopsy study[63].

If the patients are on anticoagulants such as coumadin or heparin we will ask the referring doctor if the patient can come off these meds for 14 days total (5 days ahead of banding, 3 hemorrhoids banded over 4 days and 5 days before resuming the anticoagulants). If this is not possible, we have gone ahead with banding in 51 patients with severe

bleeding and have been successful on 150 bandings with one bleed of 1.5 pints that settled with lying down and two glasses of water. We always mention this risk to the patient. We are not aware of any other method of banding which sanctions banding or surgical treatment in this group of patients.

If the patient has rectal varices we will not band them. Instead we prescribe NTG per anal canal ointment to promote healing of abrasions and continue the emphasis on fiber and avoidance of constipation/straining.

We use NTG ointment (0.13%) extensively. We started this early on when we noticed the high number of patients with anal spasm and fissure accompanying their hemorrhoids. Some of these patients did not return for later banding because they felt so much better and also their friends told stories of the pain associated with older banding methods. Then a year or so later they were referred back and we banded them then. The NTG has the benefit of relieving pain and results also in accelerated healing of the band site that may account for some of our lower rate of complications. This accelerated rate of healing has been noted in other studies particularly with regard to surgical hemorrhoidectomy. We also continue the ointment for 3 months after healing of fissure spasm on the basis that the tissue would be expected to be around 40% to 70% strength after 4 weeks[64] (wound healing time). Many of the patients have external skin tags, and these can be removed under local but this is really a cosmetic procedure.

We were surprised at the low rate of infectious diseases in this group of patients. HIV, warts, hepatitis, herpes were all less than I expected and are recorded in Table 1. One article has shown that hemorrhoids are less common in HIV positive patients[56].

Anal cancer was in 7 of whom 4 were HIV positive and 2 were Human Papilloma Virus(HPV) positive.

Complications

In terms of complications, there were 24 substantial bleeds (Table 1). Only 4 required to be treated in hospital. The bleeds were such that the patient had symptoms of faintness and in her opinion a lot more than usual blood was passed. These did not include episodes where the patient had blood loss as usual for her hemorrhoids. Two patients had surgery one on admission to emergency from button bleed post banding and another after 3 days for low level bleeding from a hemorrhoid not yet banded. Two patients needed IV fluids on blood and one crystalloid. The rest resolved on lying down for 30 minutes with an ice cube in a sock applied to the anus and giving two glasses of water to drink. Of the ones I saw and scoped in the office half were from a button band site and half from a fissure. I applied a silver nitrate stick to the site and pressure for a minute and stopped the NTG ointment for two days. The cause of the bleeds in those I saw within 12 hours (all except 4) was a button in 10 (that is the small eschar left by the band dropping off), another non-banded hemorrhoid bleeding in 3, no site or bleeding found in 3 and fissure in 5. Apart from the 5 treated as above, we touched a stick of silver nitrate to the bleeding spot in 4, lay them flat and gave them water to drink, kept them for 30 minutes and monitored pulse and BP, checked their hemoglobin, stopped them using the NTG ointment for two days. There were no rebleeds in any. Any patient who called after the clinic was closed was asked to lie down for half an hour, apply ice in a sock to the anus, drink two glasses of water, and call back in a half hour. If no longer bleeding (always so far), they were asked to stop the NTG ointment and see me next day.

Pain as reported in 10 patients is substantial – not just a fullness feeling in the rectum. The patient has sufficient pain to be unable to work or go about their normal activities. There is no doubt about when they are in pain – they are pale and diaphoretic. This occurred in 10 patients after

they went home. We keep the patient usually for 5 minutes after banding. It is very rare for the patient to have pain if this does not come on initially. The pain comes on within 5 minutes of applying the band and is resolved by rolling the band upwards with the finger. This is why only one band must be used – two as recommended by others cannot be rolled. The pain is due to applying the band too close to the dentate line or picking up the muscularis with the band. Our figures are much lower than the experience of those using other banding techniques. We relate this first to the use of gentle suction: in a randomized prospective study of 100 patients suction band ligation was superior to forceps ligation for the treatment of second- and third-degree hemorrhoids in terms of pain tolerance, amount of analgesia consumed and intra-procedure bleeding. Suction band ligation was superior to forceps ligation for the treatment of second- and third-degree hemorrhoids in terms of pain tolerance, amount of analgesia consumed and intra-procedure bleeding[65]. Second, we relate placing the band at the L angle[®] – higher than most bands are placed, and well away from the dentate line so that there are no pain fibers there. Third, we relate the result to making sure that the underlying muscle is not picked up by the band by inserting an examining finger into the rectum, making sure the band is mobile from side to side, and nudging the band upwards if not right or if the patient has any discomfort apart from fullness. Fourth, by only banding one band at a time on the ligator, not two, to facilitate the nudge (a second band means the bands have to be cut off as they are locked if not rightly applied). Fifth, by only banding one hemorrhoid at a treatment session, as Mr. Barron[1] advised in his original description and as demonstrated in the Mayo Clinic by Lee[9]. This important article by Lee[9] showed that “patients with multiple hemorrhoidal banding in a single session when compared with patients with single banding had greater discomfort and pain (29 percent vs.

4.5 percent), but this discomfort was usually manageable with oral analgesia of limited duration". There were also more vasovagal symptoms (5.2 percent vs. 0 percent), local swelling and edema (2.6 percent vs. 0 percent), and urinary hesitancy and frequency (12.3 percent vs. 0 percent) in the multiple-banded patients. Sixth, the use of nitroglycerin ointment applied with the finger inserted into the anal canal resulted in further relief of discomfort and promoted more rapid healing[39].

Loss of work from banding occurred in 2 patients because of long distances from our clinic. The vast majority of the patients returned to work or came from work the same day as treated.

No major complication such as massive delayed bleeding and perineal or pelvic sepsis was noted. Sepsis is the dreaded complication of all anal procedures. It can and often does result in death – surely too high a price to pay for hemorrhoid treatment. It has followed all other hemorrhoid procedures. The symptoms are: severe pain, urinary retention, fevers, usually within 24 hours in a young man whose problem is often missed by a doctor. We are always conscious of this risk, and so far have not had this complication. We suspect this is due to the instrument itself, which sucks up the hemorrhoid but not the muscle coat and also to the care in having mobility at the band site on rectal exam (the nudge[®]). There are many reports of this complication in the literature following surgery or any anal procedure[8, 12, 13, 21]. There have been other unusual infections following different procedures: Barron's ligation - tetanus[15], and cryosurgery - meningitis[66].

There has been urinary hesitancy in three patients but no urinary retention. All these resolved within 12 hours. Urinary retention is a very common problem after any hemorrhoid procedure. After hemorrhoidectomy Chik reported 31/204 with urinary retention; 7/90 with stapled hemorrhoidectomy and 24/114 with standard

hemorrhoidectomy for a net percentage of 15.2%[7]. There is even a problem with rubber band ligation, but only if multiple bands are applied at the same time[9]. We ascribe the absence of this complication to the same 7 factors related under pain prevention plus the eighth point that no band is intentionally deployed close to the anterior wall of the lower rectum because of the important plexus of parasympathetic nerves located there and important too for the male in preventing impotence. A rare report of impotence following sclerotherapy is described by Bullock[6]. The anatomy of this plexus and the ease with which this can be involved in surgery or even a band are clear from Pilkington's paper[19].

Unanswered Questions:

1. Is the relationship discovered between colo-rectal cancer, polyps and hemorrhoids related to a common cause of lack of fiber?
2. A policy of using the presence of hemorrhoids as a marker for colo-rectal cancer and polyps can improve early detection and reduction in mortality with the use of annual FOBT, and appropriate flexible sigmoidoscopy and colonoscopy?
3. Can the techniques described and the use of the CRH O'Regan ligator lead to the same results in the hands of other gastroenterologists and surgeons?

CONCLUSION

- We recommend the use of the CRH O'Regan ligator as a significant improvement on Mr. Barron's original device that has really performed very well since its introduction.
- We have carefully described the device and recounted our experience in 6,690 patients followed for a mean of 42 months).
- The overall recurrence rate is low (Table 1). Our recurrence rate is 8% for complete recurrence with time and 5% for partial recurrence.
- Our complications are 0.6% for each patient and 0.20% for each band.
- The safety profile is exceptional. There were no deaths and no urinary retentions and no sepsis in our series.
- As time progressed there were a large number of patients who developed colo-rectal cancer and or polyps and some were brought to attention because of first degree relatives with colo-rectal cancer and or polyps over the period of the study.

STUDY HIGHLIGHTS

What is Current Knowledge?

- Hemorrhoids are painful, chronic, cause bleeding and pain.
- They are often inadequately treated.
- When treated there are a wide variety of treatments available some with alarming results.
- The anatomy and types and causes have conflicting explanations and descriptions.
- Bleeding from hemorrhoids may be a red herring and hide a cancer higher up.

What is New Here?

- We present a simple and safe and painless treatment with a device that improves on the original Barron ligator.
- We present low recurrence and complications.
- The absence of urinary retention in this large series is ascribed to our technique particularly in avoiding banding close to the anterior wall.
- We have clarified the causes and issues in hemorrhoidal disease.
- We attribute the high pressure to the hemorrhoidal mass.
- We suggest that the removal of tissue by banding is important.
- We have discovered a high risk of polyps and cancers with time.
- We suggest that hemorrhoids are a marker for colo-rectal cancer and polyp because of a common cause, possibly lack of dietary fiber.

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