

Rubber band ligation of hemorrhoids: A guide for complications

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Abstract

Rubber band ligation is one of the most important, cost-effective and commonly used treatments for internal hemorrhoids. Different technical approaches were developed mainly to improve efficacy and safety. The technique can be employed using an endoscope with forward-

view or retroflexion or without an endoscope, using a suction elastic band ligator or a forceps ligator. Single or multiple ligations can be performed in a single session. Local anaesthetic after ligation can also be used to reduce the post-procedure pain. Mild bleeding, pain, vasovagal symptoms, slippage of bands, priapism, difficulty in urination, anal fissure, and chronic longitudinal ulcers are normally considered minor complications, more frequently encountered. Massive bleeding, thrombosed hemorrhoids, severe pain, urinary retention needing catheterization, pelvic sepsis and death are uncommon major complications. Mild pain after rubber band ligation is the most common complication with a high frequency in some studies. Secondary bleeding normally occurs 10 to 14 d after banding and patients taking anti-platelet and/or anti-coagulant medication have a higher risk, with some reports of massive life-threatening haemorrhage. Several infectious complications have also been reported including pelvic sepsis, Fournier's gangrene, liver abscesses, tetanus and bacterial endocarditis. To date, seven deaths due to these infectious complications were described. Early recognition and immediate treatment of complications are fundamental for a favourable prognosis.

Key words: Hemorrhoids; Rubber band ligation; Pain; Bleeding; Infection

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Core tip: Rubber band ligation of hemorrhoids is a very effective non-surgical treatment for internal hemorrhoids. Different techniques were developed mainly to improve efficacy and safety. This is an overall safe procedure, although severe complications can occur, such as infections. It is very important to know these possible complications to reduce their risk and to allow early recognition and successful treatment.

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GENERAL CONCEPTS OF HEMORRHOIDAL LIGATION

In the 1950s, Blaisdell^[1] described a new technique for the ligation of bleeding internal hemorrhoids which can be performed in the office without the need for hospitalization. This new concept was based on the fact that internal hemorrhoids are easily accessible, practically devoid of pain and thus, suitable for outpatient treatment. In addition, during this period, injection therapy was an alternative to surgery, but without any controlled destruction of hemorrhoidal tissue. The technique of office ligation of internal hemorrhoids was later modified and simplified using rubber bands by Barron^[2] in the 1960s. Since then, rubber band ligation (RBL) was established as one of the most important, cost-effective and commonly used treatments for first- to third-degree internal hemorrhoids, causing fibrosis, retraction, and fixation of the hemorrhoidal cushions^[3].

When compared to other non-surgical methods, like sclerotherapy and infrared coagulation, RBL has better long-term efficacy, requiring fewer sessions for treatment, although with a higher rate of post-treatment pain^[4,5]. Hemorrhoidectomy showed better response rates, but it was associated with more complications, time off work and pain than RBL^[4,6]. RBL should be considered as a first-line therapy for first- to third-degree internal hemorrhoids^[4] commonly indicated for bleeding and/or prolapsing. Surgical therapy can be considered in the presence of an important external component, thrombosis or recurrence after repeated banding^[6].

There are studies that evaluated the use of combined non-surgical therapies^[7-9]. A prospective randomized trial^[7] comparing the simultaneous application of sclerotherapy and RBL (sclerotherapy of the smaller non-prolapsing hemorrhoidal piles and RBL of the larger prolapsing piles), with sclerotherapy and RBL applied separately, showed that there was no significant difference between the combination and RBL alone groups.

RBL technique can be employed using an endoscope with forward-view or retroflexion or without an endoscope, using a suction elastic band ligator or a forceps ligator. Several patient positions can be used, without the need for bowel preparation or sedation^[3] and the ligations should be performed in the area above the dentate line that is devoid of sensory nerves.

The success rate of RBL ranges from 69% to 97%^[10]. A larger number of recurrences have been described with longer follow-up periods, but recurrences can be treated with repeat sessions and time to recurrence shortened with subsequent treatment courses^[10]. Recurrence rates are variable, with 6.6% to 18% of patients submitted to RBL requiring additional treatment sessions due to the recurrent symptoms^[10].

COMPLICATIONS OF RBL

There are several complications associated with this technique, which can be classified as minor or major (severe)^[11]. Mild bleeding, pain, vaso-vagal symptoms, slippage of bands, priapism, difficulty in urination, anal fissure, and chronic longitudinal ulcers are more common and normally considered minor complications. Massive bleeding, thrombosed hemorrhoids, severe pain, urinary retention needing catheterization, pelvic sepsis, fistula and death are major complications that have been less commonly reported.

Several studies described different rates of complications following RBL, ranging from 3%^[12] to 18.8%^[13]. The most common complications are pain and bleeding.

A review of 39 studies including 8060 patients submitted to RBL revealed post-banding complications in 14% of the patients, in the form of severe pain in 5.8%, haemorrhage in 1.7%, infection in 0.05%, anal fissure and fistula in 0.4%^[14].

In a prospective study by Bat *et al*^[11], including 512 patients submitted to RBL, 37 (7.2%) patients had complications. In this study RBL was performed using the Barron applicator, with a single ligation per session, with a total of one to seven ligations per person at four-week intervals. Minor complications were reported in 4.7% (thrombosed prolapsed hemorrhoids, slippage of bands, minor rectal bleeding, chronic longitudinal ulcer, priapism, difficulty in urination, and tender induration) and severe complications, requiring admission were described in 2.5% of the patients (massive bleeding, severe thrombosis of hemorrhoids, severe pain, perianal abscess, and fistula). Severe complications were more common in right anterior hemorrhoid RBL and in patients with previous hemorrhoidectomy. Most complications occurred following the first session.

Studies do not show any significant manometric change after RBL^[15-17], namely, in the maximum resting pressure and squeeze pressure.

Bleeding

Bleeding after RBL normally occurs after 10-14 d, probably due to the sloughing of the ligated hemorrhoids^[11,18,19].

Patients taking anti-platelet and/or anti-coagulant medication have a higher risk of secondary bleeding. There are cases of massive life-threatening haemorrhage following hemorrhoidal RBL in patients on acetylsalicylic acid (ASA)^[18,20,21] and clopidogrel^[19].

In a study by Bat *et al*^[11], including 512 patients submitted to RBL, five of the six patients who had massive bleeding, developed symptoms 10 d or more after the procedure. Three patients that were transfused were taking ASA regularly.

In a retrospective study^[10] including 805 patients who had undergone RBL aiming to evaluate the efficacy and safety of this procedure, higher bleeding rates were encountered with the use of ASA /nonsteroidal anti-inflammatory drugs (NSAIDs) and warfarin. Two (25%) of eight patients taking warfarin bled, whereas three

(7.5%) of 40 patients taking ASA or other NSAIDs bled.

Marshman *et al*^[22] conducted a study, including 241 patients undergoing RBL over a five-year period and focused on complications. Three (1.2%) patients required hospitalization for complications, of these patients, two on oral anticoagulants were admitted for significant bleeding.

In a retrospective study^[23], including 364 patients submitted to RBL while on antithrombotic therapy, holding antithrombotic medication 7-10 d following the procedure, appeared to equalize the risk of bleeding to that of patients not taking antithrombotic medications. There were 23 bleeding complications, and patients on clopidogrel experienced 50% of the significant bleeding episodes and 18% of the insignificant bleeding episodes, having a higher risk for bleeding complications, but due to the small sample size, this difference did not reach statistical significance. These authors defend that not stopping the drug before the procedure reduces the risk of ischemic events and allows ligation in the first consultation. Also, the greatest risk for bleeding typically occurs from 5 to 10 d after ligation.

It is routinely recommended that patients should stop this medication for at least 1 wk prior to, and 2 wk post RBL^[18]. The risk of the hemorrhoidal bleeding against the risk of thrombotic events must be balanced.

Concerning liver cirrhosis few data are published. In a prospective study including 500 patients submitted to RBL of symptomatic internal hemorrhoids, this procedure proved to be safe in 16 patients with coagulation disorders due to liver cirrhosis^[13].

Pain

Pain is one of the most common complications of RBL. Some studies reported mild anal pain in at least 25%-50% of patients, for the first 48 h after banding^[24,25], sometimes associated with nausea, shaking, light headedness, and urinary retention^[25].

In a prospective study^[26] specifically evaluating pain and patient satisfaction following RBL of hemorrhoids, pain was the most common symptom occurring in almost 90% of patients, with the pain scores higher 4 h following the procedure. At 1 wk, 75% of patients reported themselves as being pain-free; however, 7% were still experiencing moderate-to-severe pain. A total of 65% required oral analgesia during the week following RBL, most frequently on the day of the procedure. Vaso-vagal symptoms (dizziness or fainting) occurred in 30%, more commonly at the time of the procedure and in the evening of that day. Patients requiring oral analgesia and those experiencing bleeding or vaso-vagal symptoms were significantly less likely to be satisfied with RBL.

To minimize complications, before application, the tissue should be tested and if the patient complains of discomfort following the ligation, the band should be removed immediately and reapplied^[27].

Infectious complications

Septic complications have been described after hemo-

rrhoid treatments, namely, after injection sclerotherapy, RBL, cryotherapy, hemorrhoidectomy and stapled hemorrhoidopexy^[28,29].

Several infectious complications have been reported following RBL including pelvic sepsis, Fournier's gangrene, liver abscesses, tetanus and bacterial endocarditis. Deaths due to these infectious complications were also reported.

One of hypotheses is related to the transmural necrosis or slough following banding that facilitates the development of deep infection by migration of the bowel bacterial flora, which can spread to adjacent tissues^[30-32]. Transient bacteraemias have been described following digital rectal examination, protoscopy, colonoscopy, injection sclerotherapy and hemorrhoidectomy^[33-37].

One of the most serious complications is pelvic sepsis, with several reports in the literature^[14,30,31,38-41]. Suspicion should arise in patients with pain, fever, edema and urinary retention^[28-31], normally 3-10 d following banding. To our knowledge, only one case that developed septic complications was human immunodeficiency virus (HIV) positive^[40].

A case of Fournier's gangrene in an elderly patient with diabetes following RBL was described. The patient recovered after surgical debridement and antibiotherapy^[42].

Liver abscesses associated with the treatment of hemorrhoids were first described related to hemorrhoidectomy^[43,44] and sclerotherapy^[45]. To our knowledge, there are six case reports of liver abscesses due to RBL of hemorrhoids^[20,46-50]. Most cases were male (5/6 patients), more frequently due to *Klebsiella* (4/6 patients) and multiple abscesses (5/6 patients) were normally present. All patients recovered and only in one case a right hepatectomy was necessary (Table 1).

Tetanus due to RBL was described in two patients^[51,52], both of whom survived.

There is a only a case report of patient with a ventricular septal defect that developed endocarditis leading to septic pulmonary and renal emboli following single-quadrant banding of hemorrhoids^[53]. The patient recovered after cardiac surgery.

The literature shows that all seven deaths linked to RBL were due to septic complications^[32,38,54,55]. Most cases were male (six patients) and no predisposing factors have been established. Time until symptom onset was between 3 to 10 d after banding, and the most common initial symptoms were pain and urinary retention (Table 2).

Early recognition and immediate treatment of infectious complications are fundamental. There are several authors recommending enemas, application of povidone-iodine solution and oral antibiotics before the procedure to reduce the risk, but studies supporting these recommendations are lacking.

SPECIAL SITUATIONS

There are certain conditions that have been considered a contraindication for RBL of hemorrhoids due to a higher risk of complications, namely, HIV and Crohn's disease.

In 1989, there was a case report of a 45-year-old

Table 1 Case reports of liver abscesses due to rubber band ligation of hemorrhoids

Age (yr)	Sex	Bacteria	Comorbidities	No.	Treatment	Outcome	Ref.
58	Male	Klebsiella aerogenes	Diabetes	Multiple	Antibiotics, drainage	Resolution	[20]
58	Male	Klebsiella pneumoniae	Previous pulmonary tuberculosis	Multiple	Antibiotics, drainage, right hepatectomy	Resolution	[46]
40	Male	Citrobacter freundii		Single	Antibiotics, drainage	Resolution	[47]
64	Male	Fusobacterium necrophorum	Asthma	Multiple	Antibiotics, drainage	Resolution	[48]
49	Male	Klebsiella pneumoniae	Diabetes, hypertension, dyslipidaemia, stroke, previously treated pulmonary tuberculosis	Multiple	Antibiotics	Resolution	[49]
61	Female	Klebsiella pneumoniae	Peptic ulcer, dyslipidemia	Multiple	Antibiotics, drainage	Resolution	[50]

Table 2 Deaths related to rubber band ligation

Age (yr)	Sex	Comorbidities	Time until symptom onset (d)	Symptoms	Bacteria	Ref.
38	Male	None	4	Pain, urinary retention	None	[32]
54	Male	None	10	Vomiting, urinary retention, fever	None	[32]
34	Male	None		Pain, urinary retention, fever	<i>Enterobacteriaceae</i> (abdomen fluid) <i>Escherichia coli</i> (retroperitoneum and blood)	[32]
37	Male	None	5	Pain, urinary retention	<i>Escherichia coli</i> (urine and rectal cultures)	[32]
73	Male	Not described	3	Pain, fever, urinary retention,		[38]
27	Male	Schizophrenia	4	Fever, pain, difficulty passing urine	<i>Clostridia perfringens</i> , <i>Clostridia sporogenes</i> , <i>Bacteroids</i> (pelvic muscles), <i>Escherichia coli</i> (rectal cultures)	[54]
68	Female	None	7	Anal pain, difficulty passing urine, vomiting	<i>Enterococcus</i> (perianal fluid)	[55]

HIV positive male patient who developed a supraleator abscess after RBL^[40]. The authors concluded that this procedure is potentially dangerous in HIV patients and it should be abandoned. Although this complication was also described in HIV negative patients following RBL^[38] and, to our knowledge, this is the only infectious complication described in an HIV positive patient. In a retrospective review^[56] of asymptomatic HIV positive patients that were submitted to RBL of symptomatic hemorrhoids, this technique proved to be safe and effective. It was performed in 11 HIV positive patients and no complications were reported. Median CD4 cell count was 450 (range, 200-1000) cells/ μ L and there was a median of two (range, 1-4) bands per patient.

In a retrospective study^[57], including 42 patients with ulcerative colitis and 20 with Crohn's disease, treated both surgically and conservatively for hemorrhoids over a 41 year period, patients with ulcerative colitis had a low complication rate (4 complications after 58 courses of treatment) and Crohn's disease had a high complication rate (11 complications after 26 courses of treatment). No reference was made to RBL treatment in this study. Thus, concerning Crohn's disease and RBL very few data are published. D'Ugo *et al*^[58] published a 9-year retrospective study of 45 Crohn's disease patients treated for hemorrhoids either medically or surgically. In this series RBL was considered a surgical treatment, and in total two patients submitted to it reported no complications.

DIFFERENT TECHNICAL APPROACHES

Suction vs forceps ligation

A prospective randomized clinical trial including 100

patients with second- and third-degree hemorrhoids compared suction and forceps ligation concerning pain after the procedure, intra-procedure bleeding and other complications. The forceps group had higher pain scores immediately after ligation and at 24 h post-banding, needed higher amount of analgesia and had higher intra-procedure bleeding^[59]. Authors hypothesized that this is due to poorer visualization and forceps-induced physical trauma of the friable hemorrhoids.

Single vs multiple ligations

Initially, single ligation per session was recommended due to the belief that a higher complication rate is associated with multiple banding, namely, pain and tenesmus after the procedure^[2].

A retrospective study^[60] comparing patients with multiple banding in a single session ($n = 155$) and single banding ($n = 22$) showed that patients with multiple hemorrhoidal banding did experience more discomfort and pain (29% vs 4.5%), but that this was well tolerated and manageable with oral analgesia of limited duration. Vasovagal reactions, limited bleeding, urinary symptoms, and local swelling and oedema were also more common. There were no cases of massive bleeding or sepsis.

Randomized controlled trials comparing single and triple band ligation^[27,61] showed that triple RBL is an equally safe and effective procedure for managing internal hemorrhoid disease. Fewer treatment sessions are required for triple RBL, so this strategy is more cost-effective^[61]. Furthermore, there is a risk of possible bleeding from untreated hemorrhoids after an initial RBL for other hemorrhoids^[2].

Endoscopic vs non-endoscopic ligation

The endoscopic hemorrhoidal ligation was initially described in 1998, in the forward-view^[62] and then in retroflexion^[63,64]. Some authors favoured the retroflexed position due to easy assessment and treatment^[63].

Endoscopic ligation proved to be an effective and safe technique for treating internal hemorrhoids. In a study by Berkelhammer *et al*^[63], retroflexed endoscopic band ligation of second- and third-degree bleeding internal hemorrhoids, with a mean of three bands (range 1-6) placed in a single session, showed an excellent result in 80% of patients with second-degree hemorrhoids (better than third-degree hemorrhoids with an excellent result in 54%). Major, nonfatal complications were detected in 4% (severe pain, delayed haemorrhage requiring transfusion, urinary retention, and severe thrombosis of external hemorrhoids) of patients. In a study by Fukuda *et al*^[64], retroflexed endoscopic multiple band ligation was performed on patients with symptomatic first- to fourth-degree internal hemorrhoids, with a mean of 8 bands (range 4-14) placed per treatment session. The long-term response was excellent for 89% of the patients, without any major complications in the 82 patients included (severe pain, late-onset haemorrhage requiring transfusion, or severe thrombosis of external hemorrhoids).

Endoscopic ligation has some advantages over rigid instruments that are more difficult to manoeuvre and have limited visualization, allowing for more band placement and photographic documentation of the procedure^[62,63]. There are randomized studies comparing ligation with flexible videoendoscopes (retrograde or antegrade) and the conventional technique with rigid proctoscopes^[65,66]. These trials showed that the long-term efficacy and safety were similar, but with videoendoscopes fewer treatment sessions were needed and a higher proportion of patients treated with a single session^[65].

Local anaesthetic vs no-local anaesthetic in hemorrhoidal ligation

The use of local anaesthesia after hemorrhoidal banding in order to reduce post-procedural pain was studied. In 2015, a meta-analysis^[24] including four randomized controlled trials (387 patients in total), comparing pain and other associated symptoms in patients who received a local injection after hemorrhoidal banding and patients who did not, showed that the post-procedure pain score was significantly lower in the group of patients with local anaesthetic injection. These studies included different anaesthetic treatment protocols. Hooker *et al*^[25] randomized patients to receive a local injection of 0.5 mL of 0.5% bupivacaine with 1:200000 epinephrine, an injection of normal saline, or no injection, immediately superior to each band. In patients receiving bupivacaine within 30 min post-banding, there was a significant reduction in pain, nausea and shaking, which may be useful in the immediate period. However, bupivacaine injection did not reduce pain at 6 h or more post-banding, and did not have other benefits. In a study by

Law *et al*^[67] patients received 1-2 mL of 2% lignocaine injected into the banded hemorrhoidal segment, but no post-ligation pain reduction was reported. Kwok *et al*^[68] randomized patients to an anesthetic injection of 1 mL of 0.5% bupivacaine without adrenaline in the submucosa proximally to the rubber band site and showed that this reduced discomfort compared with no local anaesthetic by the time patients left the clinic (30 min after the procedure). Benefit beyond this period was not obtained. Authors hypothesized that local anaesthetic injection deep to the banded tissue, until a bleb large enough to encompass the "base" of the hemorrhoid was raised, would be more effective than injection into the devitalized banded tissue.

Bupivacaine effect lasts for 4 to 6 h^[25], so this could help in the short-term period following banding, but no study has thus far showed that this can be helpful beyond this period.

CONCLUSION

RBL of hemorrhoids is a very effective and safe procedure, with severe complications being uncommon. Before applying the bands, it is very important to know the patient's medical history, namely, comorbidities and medication. After RBL, patient education is mandatory, including analgesia, softening of the stools, warm sitz baths and information concerning early and late complications. If complications occur, early recognition and immediate treatment are fundamental for a successful outcome.

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