Endoscopic band ligation for treatment of bleeding internal hemorrhoids in primary referral hospital: evidence-based case report

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ABSTRACT

Background and Aim. *It is preferred that the management of internal hemorrhoids necessitates minimally invasive modality, high efficacy, less complication and feasibility in hospital with availability of endoscopy. This study aimed to evaluate the efficacy and safety of endoscopic band ligation (EBL) for bleeding grade III internal hemorrhoids in an evidence-based case report.*

Methods. *A 50-year-old male patient with hematoschezia and anal pain was diagnosed as grade III bleeding internal hemorrhoid. Non-surgical management was preferred. The physician urged to provide the evidence regarding the safety and efficacy of endoscopic band ligation, compared to other modalities. A search was conducted on PubMed and Cochrane databases based on clinical query, with keywords "endoscopic band ligation AND internal hemorrhoids". The inclusion criteria were meta-analysis, systematic review and randomized clinical trial, and written in English. The critical appraisal was performed for validity, importance and applicability.*

Results*. Of 18 studies, only 2 studies suited the criteria. Compared to bipolar electrocoagulation (BPEC), EBL had significantly higher success rate in controlling bleeding and reducing the grade of hemorrhoids. In comparison with band ligation with rigid proctoscope (BL-RP), EBL was associated with higher success rate, lesser treatment sessions and earlier symptom control. Mild complications and symptomatic recurrence were comparable among EBL, BPEC and BL-RP.*

Conclusion*. Endoscopic band ligation is effective and safe for bleeding grade III internal hemorrhoids. It is feasible procedure in primary referral hospital.*

Keyword*: bleeding internal hemorrhoids, efficacy, endoscopic band ligation, safety*

ABSTRACT

Latar belakang dan tujuan. Tata laksana hemoroid interna yang lebih dipilih adalah modalitas yang minimal invasif dengan efektivitas tinggi, komplikasi lebih rendah, dan ketersediaan layanan endoskopi di rumah sakit. Studi ini bertujuan untuk menilai efektivitas dan keamanan endoskopi ligasi pada pasien dengan hemoroid internal berdarah derajat III dalam suatu laporan kasus berbasis bukti.

Metode. Seorang laki-laki berusia 50 tahun dengan hematoskezia dan nyeri anus didiagnosis sebagai hemoroid internal berdarah derajat III. Prosedur non-pembedahan merupakan tata laksana yang dipilih. Diperlukan bagi dokter yang merawat untuk menyampaikan bukti terkait profil keamanan dan efektivitas endoskopi ligasi bila dibandingkan dengan prosedur lainnya.

Pencarian bukti dilakukan melalui basis data Pubmed dan Cochrane berdasar pertanyaan klinis dengan kata kunci "endoskopi ligasi dan hemoroid internal". Kriteria inklusi meliputi meta-analisis, tinjauan sistematis, dan uji klinis terandomisasi yang tertulis dalam bahasa Inggris. Telaah kritis dilakukan dengan menilai validitas, kemaknaan, dan kemampulaksanaan.

Hasil. Dari 18 studi, hanya 2 studi yang sesuai dengan kriteria. Dibandingkan dengan endoskopi dengan bipolar coagulation, endoskopi ligasi menunjukkan keberhasilan yang lebih baik dalam mengendalikan perdarahan dan menurunkan derajat hemoroid dibandingkan dengan proktoskopi rigid ligasi, endoskopi ligasi berkaitan dengan keberhasilan yang lebih tinggi, sesi terapi yang lebih sedikit, dan pengendalian gejala yang lebih dini. Komplikasi ringan dan gejala terkait kekambuhan dilaporkan tidak berbeda bermakna antara endoskopi ligasi, endoskopi dengan bipolar electrocoagulation, dan proktoskopi rigid ligasi.

Simpulan. Endoskopi ligasi merupakan modalitas yang efektif dan aman dalam tata laksana hemoroid internal berdarah derajat III. Prosedur ini mampu laksana dilakukan di rumah sakit.

Kata kunci: efektivitas, endoskopi ligasi, hemoroid internal berdarah, keamanan

INTRODUCTION

Hemorrhoids are very common anorectal condition defined as the symptomatic enlargement and distal displacement of the normal anal cushions.[1] It is benign condition affecting 4-55% of the population, frequently in ages 45 to 65.[1–3] It causes substantial discomfort, disability and decreased quality of life due to its sensitive symptoms such as anal bleeding, pain and itching sensation.[4–7] Compared to colon cancer, diverticular disease, irritable bowel syndrome and inflammatory bowel disease, hemorrhoids bring impacts on more frequent visits.[8] Hemorrhoids drive both economic and social impact on society, indicating major economic problem in health system regarding direct costs and working days lost.[9]

The managements for hemorrhoids encompass medical treatment, non-surgical procedures and surgery. The initial management includes dietary modification with adequate fluid and fiber intake, avoiding straining, limiting prolonged time on the toilet and regular exercise.[3,10,11] Further management encompassed non-surgical procedures and surgery. Non-surgical procedures, including infrared coagulation, sclerotherapy, cryotherapy, and rubber band ligation (RBL), are usually performed un-sedated in the office setting or endoscopy suite and do not require bowel preparation.[12–14] Among procedures, RBL is the most popular method in the treatment of low grade hemorrhoids. The RBL can be performed by endoscopy, known as endoscopic band ligation (EBL), or band ligation with rigid proctoscopy (BL-RP). Endoscopic band ligation is the most feasible procedure conducted in primary referral hospital providing the gastrointestinal endoscopy. This evidence-based case report (EBCR) is aimed to provide the clinical outcome of EBL in patients with grade III bleeding internal hemorrhoids.

CASE ILLUSTRATION

In this evidence-based case report, a 50-year-old male patient had hematoschezia and anal pain. Pale conjunctivae were identified. Rectal examination revealed palpable tender mass and proven bleeding spot on glove. Colonoscopy was performed. It showed internal hemorrhoid. The diagnosis of this patient was grade III bleeding internal hemorrhoid. The choices of management were then discussed. Beside surgical approaches, endoscopic band ligation was considered as minimally invasive treatment for this case. In order to provide the best clinical outcome and feasible procedure, this evidence-based case report was conducted to measure its efficacy and its safety.

CLINICAL QUESTION

The following clinical question arose: What is the clinical outcome of endoscopic band ligation in patients with internal hemorrhoids? The patients, intervention, comparison and outcome (PICO) format for this question was as follows:

- Patients (P): patients with internal hemorrhoids
- Intervention (I): endoscopic band ligation
- Comparison (C): no endoscopic band ligation or other modality
- Outcome (O): bleeding; complication

METHODS

Search Strategy

To answer the clinical question, a comprehensive literature search was conducted in October 2022 using the following databases: PubMed and Cochrane. The keywords used for the search are shown at Table 1.

Eligibility Criteria and Article Selection

The following inclusion criteria were applied in this study: 1) clinical studies among patients with internal hemorrhoids; 2) comparison between patients with and without EBL or other modalities; and 3) absence of hemorrhoids greater than grade 1 and controlled bleeding as primary outcome. Studies without a specific analysis for baseline patients with internal hemorrhoids were excluded. Studies with adjuvant therapy to combine with EBL were excluded. The types of studies included were meta-analysis, systematic reviews and randomized clinical trial (RCT). Inclusion was not restricted by year of publication. Only studies using English language were recruited. Review article, guidelines, animal or in-vitro studies, case series and case report were excluded.

Critical Appraisal

The quality of selected studies was assessed by critical appraisal tools developed by the Centre for Evidence-Based Medicine (CEBM), University of Oxford. Critical appraisal was conducted by authors independently. Any differences in judgement were discussed among authors before the final decision was made.

Data Extraction

The data extracted from each study encompassed the study population, details of intervention and outcomes measured. The authors conducted data extraction independently. Any disagreements were discussed among authors before the final decision was made.

RESULTS

Search Results

Sequential steps applied in the selection of studies were shown in a flowchart as presented in Figure 1. Two original articles were eligible for this EBCR. Both of them were RCTs.

Jutabha R, et al. conducted RCT among 55 patients with bleeding grade II or III internal hemorrhoids comparing EBL vs. bipolar electrocoagulation (BPEC). Subjects were followed up every 3 months for a total of 12 months.15 Study by Wehrmann T, et al. enrolled 100 patients with bleeding grade II or III internal hemorrhoids.16 The two-arms intervention in this RCT encompassed 50 subjects undergoing BL-RP and 50 subjects having EBL.16 The median follow-up in this study was 12 months (9-22 months).16 Both studies recruited subjects having internal hemorrhoids with unsuccessful conservative treatment, including dietary fiber supplementation and medical treatment.[15,16]

Critical Appraisal

The articles were critically appraised for validity, importance and applicability using tools developed by the CEBM for RCT. The validity of selected study is available in Table 2. Both studies conducted randomization by means of a computer-generated

Table 1. Terminology used in two databases

Database	Terminology	Hit
Pubmed	(((((endoscopic band ligation[Title/Abstract]) OR (endoscopic hemorrhoid ligation[Title/Abstract])) OR (endoscopic hemorrhoidal ligation[Title/Abstract])) OR (endoscopic haemorrhoidal ligation[Title/Abstract])) OR (endoscopic haemorrhoid ligation[Title/Abstract])) AND ((((internal hemorrhoids[Title/Abstract]) OR (internal haemorrhoids[Title/Abstract])) OR (hemorrhoidal disease[Title/Abstract])) OR (haemorrhoidal disease[Title/Abstract]))	9
Cochrane	"endoscopic band ligation" OR "endoscopic hemorrhoid ligation" OR "endoscopic hemorrhoidal ligation" OR "endoscopic haemorrhoid ligation" OR "endoscopic haemorrhoidal ligation" in Title, Abstract, Keywords AND "internal hemorrhoids" OR "internal haemorrhoids" in Title, Abstract, Keywords	15

method. The investigators and subjects were blinded to group allocation in both studies. All subjects in both studies completed the intervention and the follow-up.

In accordance with the CEBM critical appraisal tools for RCTs, the importance of each study encompassed the size and precision of treatment effects, which is denoted by a relative risk (RR), absolute risk reduction (ARR), relative risk reduction (RRR) and number needed to treat (NNT). This information is revealed in the Data Extraction section.

All two studies are applicable to the patient described in this case report, as both studies only recruited patients with confirmed bleeding grade II-III internal hemorrhoids. The age of patient in this case report also suited the age range of subjects in the studies. The EBL is feasible in the primary referral hospital with endoscopy unit. This procedure is also a relatively low cost for management of bleeding internal hemorrhoids.

Data Extraction

Data from each study regarding study design, population, intervention and outcome measure were extracted. The data are revealed in Table 3.

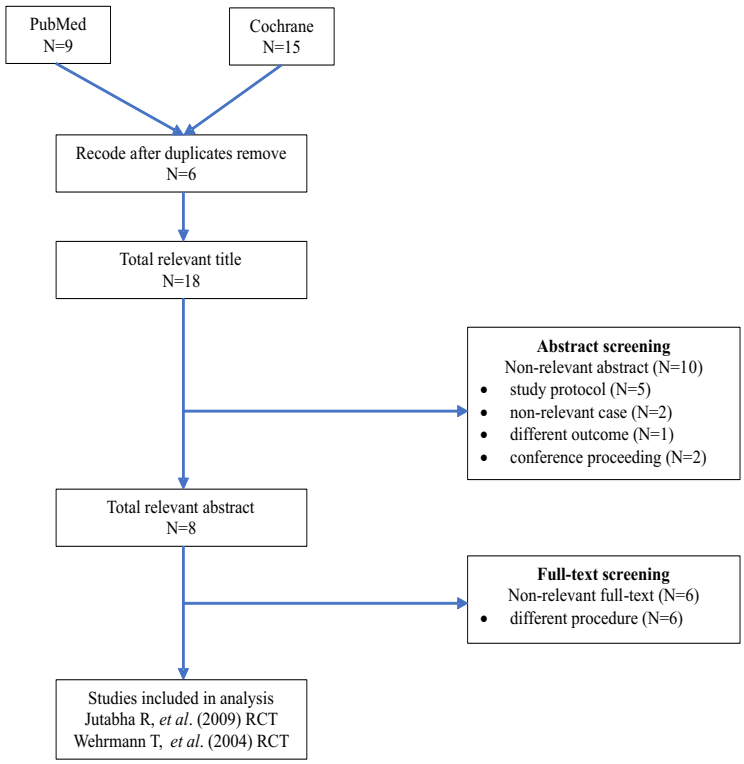

Figure 1. The result of electronic database searches and study selection

Table 2. Validity of selected studies

	Jutabha R, et al.15	Wehrmann T, et al.16
Was the assignment of patients to treatments randomised?	Yes	Yes
Were the groups similar at the start of the trial?	Yes	Yes
Aside from the allocated treatment, were groups treated equally?	Yes	Yes
Were all patients who entered trial accounted for? And were they analysed in the groups to which they were randomised?	Yes	Unclear
Were measure objective or were the patients and clinicians kept "blind" to which treatment was being received?	Yes	Yes

Table 3. Main findings of the studies

Study	Study Population	Intervention	Outcome	Study Reslt
Jutabha R, et al.15 (RCT)	45 patients with bleeding grade II-III internal hemorrhoids (Goligher's classification) Mean age 51.5 years	EBL vs. BPEC	Control of rectal bleeding Reduction of all internal hemorrhoid segments (grade 0 or I)	RR 0.21 ARR 30% RRR 0.79 NNT 3.33
Wehrmann T, et al.16 (RCT)	100 patients with bleeding grade II-III internal hemorrhoids (Goligher's classification) Mean age 48 years	EBL vs. BL-RP	Absence of all hemorrhoids greater than grade I Absence of recurrent bleeding	RR 0.74 ARR 20% RRR 0.26 NNT 0.01

Abbreviations: ARR=absolute risk ratio; BL-RP=band ligation with rigid proctoscope; BPEC=bipolar electrocoagulation; EBL=endoscopic band ligation; NNT=number needed to treat; RR=relative risk; RRR=relative risk ratio

DISCUSSION

Endoscopic band ligation is known as simple, quick, and effective methods in managing grade I-III symptomatic internal hemorrhoids.[1–3,14,17] This procedure utilizes devices comprise a transparent plastic cap with preloaded bands that fits on the tip of an endoscope.[13] Band placement leads to ischemic necrosis, ulceration and scarring resulting in fixation of the connective tissue of the rectum.[13] There were limited studies investigating the efficacy and safety of EBL. Two RCTs recruited in this EBCR demonstrated the efficacy of EBL compared with other methods.

In accordance with the validity components, all two studies were well-designed and sufficiently valid. The assignment of randomization was conducted in both studies by means of computer-generated randomization. The difference between groups in each study was statistically not significant. Both studies enrolled subjects in each group equally regarding treatment and follow-up schedule. There was no loss to follow-up in both studies. The limitation of study by Wehrmann T, et al. is the uncertainty of blinding process. It may lead to potential treatment bias.

The EBL is non-invasive treatment using suction to elevate the cushions and placing one or more rubber bands around the base of each cushion while taking care to avoid impinging any muscle tissue.[17] Ligation ultimately necroses the trapped connective tissue and the scar is affixed to the rectum.[13,14,17] The resultant fibrosis leads to fixation of the remaining hemorrhoidal tissues, implicating prevention of prolapse and bleeding.[14] This procedure is appropriate for patient with grade I or II internal hemorrhoids and certain grade III internal hemorrhoids.[2,3,13,14,17]

Study by Jutabha R, et al. showed that compared to BPEC, EBL had higher success rate in lowering the risk of rectal bleeding and in promoting the reduction of hemorrhoidal stage among patients with bleeding grade II-III internal hemorrhoids and having failed at least 8 weeks on intensive medical treatment.[15] Further, EBL significantly required lesser treatment sessions in comparison with BPEC (2.3+0.2 vs. 3.8+0,4 sessions, $p<0.005$).[15] Study by Wehrmann T, et al. demonstrated that EBL was significantly associated with higher success rate, lesser treatment sessions required and earlier symptom control than BL-RP.[16] Cazemier M, et al. further reported that EBL was easier to perform more ligations than BL-RP.[18] Japanese Practice Guidelines also stated that EBL may be considered first in grade III internal hemorrhoids cases.3 These results may emphasize that the efficacy of EBL among patients with bleeding grade III internal hemorrhoids is considerable.

The safety issue is also reported in both studies. Mild complications were similar between EBL and BPEC (4% vs. 5%, $p>0,05$). Symptomatic recurrence at 1 year follow-up for EBL was lower than BPEC, but it was statistically not significant. Both procedures, BL-RP and EBL, were comparable in rectal pain post-procedure and recurrent rectal bleeding during median 12 months follow-up. No blood transfusion was needed after EBL in both studies. Hall JF also stated that increased bleeding after ligation, if any, is usually self-limited.[14] These evidence-based findings may perform EBL as safe procedure in managing patients with bleeding grade III internal hemorrhoids.

Regarding our case, we should explain to our

patient that the evidence is still limited. Yet, there is a tendency that EBL is effective and safe for grade III bleeding internal hemorrhoids, compared to BPEC and BL-RP. Patient should be informed that rectal pain after EBL and recurrent symptoms may exist and it needs further evaluation, management and follow-up.

CONCLUSION

We concluded that EBL is associated with better clinical outcomes and comparable mild complications in management of bleeding grade III internal hemorrhoids in primary referral hospital providing gastrointestinal endoscopy, compared to other non-invasive treatments including BPEC and BL-RP. Further studies with better trial designs are highly needed to provide high-quality evidence for clinical practice guidelines.

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