Original Research Article

Comparison of single versus double versus triple site band ligation for haemorrhoids in a single visit: a case-controlled double blind randomized study

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ABSTRACT

Background: Rubber band ligation is considered one of the most popular non-surgical procedures available, representing the most reasonable balance between efficacy, pain and potential of complication. The present study was a controlled double blinded randomized study to compare Single versus double versus triple site band ligation for haemorrhoids in single treatment visit with special regards to its safety and efficacy in our patient population.

Methods: There were 78 patients equally randomized in three groups by closed enveloped method. The number of patients in each group was 26, In Group A, a single, in Group B, two, and in Group C three major haemorrhoidal groups were rubber band ligated, in a single treatment visit on outpatient basis under topical anaesthesia with lignocaine 2% jelly.

Results: Rubber band ligation was effective with significant symptom improvement seen in all patients with 88% patient satisfaction at end of 30 days period. Post ligation pain score and number of analgesic requirement in immediate post band ligation period, at 12 hours, at 1,7,14, 21 and 30 days post band ligation were similar in all three groups with p value >0.05. Multiple site haemorrhoidal bandings was done safely at single session without severe discomfort, pain or bleeding or severe complications requiring hospitalization.

Conclusions: The study finding shows that triple site band ligation in a single session is a safe way of treating symptomatic haemorrhoids with similar post-procedure pain and patient satisfaction as conventional single or double site band ligation.

Keywords: Band Ligation, Haemorrhoids, Triple site ligation

INTRODUCTION

Haemorrhoid is one of the oldest diseases suffered by mankind well recorded in ancient texts of Greeks, Egyptians and Hindus.¹

A wide variety of treatment options are available and the choice of method depends on the severity and type of symptoms, degree of prolapse, expertise of the operator and the equipment available.¹

In 1954, Blaisdel invented the first automatic ligator of haemorrhoids, which was modified by Barron in 1963.² From that time, it is widely used for the treatment of haemorrhoids and has replaced haemorrhoidectomy in 45% of cases.³

The main principal of rubber band ligation is production of tissue necrosis and subsequent fibrosis above the base of the cushion.¹ A number of prospective studies have found rubber band ligation to be a simple, safe, and

effective method for treating symptomatic first, second, and third degree haemorrhoids as an outpatient procedure with significant improvement in quality of life. Its success rate is between 60% and 90%.⁴⁻⁸ Controversies exist about the number of piles that can be banded in any one session.

In general, only one or two quadrants are banded per visit because multiple bandings may lead to excessive discomfort and the potential for greater complication.⁹⁻¹¹

In contrast, many authors have advocated multiple site ligations.¹²⁻¹⁵

The present case-controlled double blinded randomized study was conducted with the aim and objective of comparing single versus double versus triple site band ligation for haemorrhoids in a single treatment visit with special regards to its safety, efficacy and the satisfaction of the patients in our patient population.

METHODS

The study was a prospective randomized double blinded case controlled study conducted from June 2013 to December 2014 in Department of Surgery at Medical college Kota after the approval of the institutional ethical committee.

All patients presenting with symptomatic haemorrhoids to the out-patient department were evaluated and selected for the study after applying the inclusion and exclusion criteria.

Inclusion criteria

Patients with symptomatic first, second and third degree haemorrhoids, aged 18 years and older were included.

Exclusion criteria

Patients having fourth degree haemorrhoids, immunocompromised status, bleeding disorders or on anticoagulant therapy, deranged liver function tests, allergy to lignocaine jelly, having infectious, inflammatory or other anorectal diseases, not willing for inclusion in study or younger than 18 years age were excluded.

A detailed history of each patient was taken along with personal, family and dietary history and systemic and local examination including proctoscopy was done. Routine blood investigations were done in all patients and sigmoidoscopy or colonoscopy was done in selected patients.

The patients were explained in detail about their disease and the various modalities of treatment available, with the advantages and disadvantages of each.

All patients enrolled in the study signed the consent form and randomly allocated to one of the three arms of the study, A, B, C, by closed envelope method.

The number of patients in each group was 26 with a total of 78 patients. In Group A, a single, in Group B, two, and in Group C, three major haemorrhoidal groups were rubber band ligated, in a single treatment visit on outpatient basis under topical anaesthesia with lignocaine 2% jelly.

Pre procedure preparation

No special pre-procedure preparation was done. The patients were evaluated by proctoscope and given proctoclysis enema if the rectum was found to be loaded.

Post-procedure advice and follow up

As the study was a case-controlled double blinded randomized study, the patients were not told about their allocated group and the follow up assessment was done by the member of the surgical team who was not involved in the intervention and was not aware of the patient group.

After the session of band ligation, patients were given a chart containing a Faces pain rating scale (Wong & Baker) from 0 to 10 (0=no hurt, 10=hurt worst), to record pain at fixed intervals: immediately after band ligation and at 12 hour, 24 hour, 7 days, 14 days, 21 days and 30 days post band ligation.¹⁶ All the patients were given tablet Paracetamol (500 mg) for pain relief and the number of pills consumed in 1st, 2nd, 3rd and 4th week post ligation was noted.

Twice a day warm sitz baths, oral intake of bulk forming agents (Isabgol Husk 2 TSF BD) along with high fiber diet and plenty of oral fluids was advised to all patients and also to avoid any per rectal cream in the post procedure period. The patients were followed up for thirty days post ligation at 7, 14 and 30 days and asked to report SOS to hospital in case of any complication.

Complications occurring after band ligation in immediate period, and at 7 days, at 14 days, 21 days and at 30 days were noted in each group. The number of days of occupational absenteeism, the symptomatic relief and the satisfaction of the patient categorized as excellent, good, fair, poor or terrible, at the end of thirty days was noted in each group. The data was entered in a computerised database and appropriate statistical analysis (ANOVA) was done on MS Excel 2013® with statistical pack installed, A *P* value of <0.05 was considered significant.

RESULTS

A total of 78 cases were enrolled during the study period. The demographic and clinical parameters are given in Table 1.

Table 1: Demographic and clinical parameters.

Parameter	No. of patients Group-A (%)	No. of patients Group-B (%)	No. of patients Group-C (%)	Total (%)	P value
Sex					0.375
Male	22 (84.6)	24 (92.3)	22 (84.6)	68 (87.2)	
Female	04 (15.4)	02 (7.7)	04 (15.4)	10 (12.8)	
Age (in years)					0.257
<20	01 (3.8)	0	0	01 (1.28)	
20-30	05 (19.2)	04 (15.4)	09 (34.6)	18 (23.07)	
31-40	11 (42.3)	07 (26.9)	05 (19.2)	23 (29.48)	
41-50	05 (19.2)	07 (26.9)	05 (19.2)	17 (21.79)	
51-60	02 (7.7)	06 (23.1)	02 (7.7)	10 (12.82)	
>60	02 (7.7)	02 (7.7)	05 (19.2)	09 (11.53)	
Religion					0.239
Hindu	24 (92.3)	19 (73.1)	22 (84.6)	65 (83.3)	
Muslims	02 (7.7)	06 (23.1)	02 (7.7)	10 (12.8)	
Others	0	01 (3.8)	02 (7.7)	03 (3.9)	
Occupation					0.857
Sedentary	12 (46.1)	13 (50)	11 (42.3)	36 (46.1)	
Manual	14 (53.9)	13 (50)	15 (57.7)	42 (53.9)	
Degree of haemorrhoids					0.324
First	04 (15.38)	03 (11.53)	03 (11.53)	10 (12.82)	
Second	16 (61.53)	11 (42.30)	13 (50)	40 (51.28)	
Third	06 (23.07)	12 (46.15)	10 (38.46)	28 (35.89)	
History of hypertension					0.252
Present	06 (23.07)	02 (7.69)	03 (11.53)	11 (14.11)	
Absent	20 (76.92)	24 (92.30)	23 (88.46)	67 (85.89)	
History of diabetes mellitus					0.854
Present	02 (7.69)	02 (7.69)	03 (11.53)	07 (8.97)	
Absent	24 (92.30)	24 (92.30)	23 (88.46)	71 (91.03)	
Presence of acid peptic ulcer disease					0.641
Present	17 (65.38)	20 (76.92)	19 (73.07)	56 (71.79)	
Absent	09 (34.61)	06 (76.92)	07 (26.92)	22 (28.20)	
Family history of haemorrhoids					0.764
Present	06 (23.07)	08 (30.76)	06 (23.07)	20 (25.64)	
Absent	20 (76.92)	18 (69.23)	20 (76.92)	58 (74.36)	
Bowel habits					0.956
Normal	06 (23.07)	08 (30.76)	07 (26.92)	21 (26.92)	
Straining	03 (11.53)	03 (11.533)	04 (15.38)	10 (12.82)	
Constipation	17 (65.38)	15 (57.69)	15 (57.69)	47 (60.25)	
Diarrhoea	0	0	0	0	
Pallor					0.822
Present	18 (69.2)	19 (73.1)	20 (76.9)	57 (73.1)	
Absent	08 (30.8)	07 (26.9)	06 (23.1)	21 (26.9)	
Haemoglobin (g/dl)					0.252
<10	23 (88.5)	20 (77)	24 (92.3)	67 (85.8)	
>10	03 (11.5)	06 (23)	02 (7.7)	11 (14.2)	
Haemoglobin (g/dl) Mean ($\pm$ S.D.)	7.67 ($\pm$ 1.81)	8.11 ($\pm$ 1.81)	7.31 ($\pm$ 1.49)	7.69 ($\pm$ 1.73)	0.243
Treatment taken in past					0.514
Nil	10 (38.46)	06 (23.07)	08 (30.76)	24 (30.76)	
Conservative	16 (61.53)	19 (73.07)	18 (69.23)	53 (67.94)	
Surgical	0	01 (3.84)	0	01 (1.28)	

Table 2: Presenting Complaints.

Parameter	No. of patients Group-A (%)	No. of patients Group-B (%)	No. of patients Group-C (%)	Total (%)	P value
Bleeding per rectum	26 (100)	26 (100)	26 (100)	78 (100)	0.999
Prolapse					0.854
Present	11 (42.3)	12 (46.15)	10 (38.46)	33 (42.3)	
Absent	15 (57.7)	14 (53.84)	16 (61.53)	45 (57.7)	
Painful defecation					0.740
Present	05 (19.23)	05 (19.23)	07 (26.92)	17 (21.80)	
Absent	21 (80.76)	21 (80.76)	19 (73.08)	61 (78.20)	
Discharge per rectum					0.363
Present	06 (23.07)	10 (38.46)	06 (23.07)	22 (28.20)	
Absent	20 (76.92)	16 (61.53)	20 (76.92)	56 (71.79)	
Mucus in stool					0.476
Present	02 (7.69)	04 (15.38)	05 (19.23)	11 (14.10)	
Absent	24 (92.30)	22 (84.61)	21 (80.76)	67 (85.89)	

Table 3: Post band ligation parameters.

Parameter	Group - A	Group - B	Group - C	P value
Post band ligation pain score (mean±SD)				
Immediate post procedure	2.81±0.85	2.58±0.86	2.77±1.10	0.643
At 12 hours	2.0±1.06	1.92±0.79	1.85±0.92	0.838
At 24 hours	0.92±0.69	1.23±0.99	1.12±0.91	0.442
7, 14, 21, 30 days post band ligation	0	0	0	
Analgesic tablets taken (mean±SD)				
0-7 days	11.42±2.91	10.89±2.21	11.31±2.36	0.719
8-14 days	0.96±0.95	0.96±0.99	1.0±1.09	0.988
15-21 days	0.07±0.3	0	0	0.372
22-30 days	0	0	0	
Absence from work (in days) (Mean±SD)	0.92±0.56	0.80±0.49	0.92±0.56	0.672
Absence from work (in days)				0.860
Nil	05 (19.23%)	06 (23.08%)	05 (19.23%)	
1 day	18 (69.23%)	19 (73.08%)	18 (69.23%)	
2 days	03 (11.54%)	01 (3.85%)	03 (11.54%)	
Symptoms control at the end of 30 days				0.241
Complete relief	13 (50%)	09 (34.61%)	14 (53.84%)	
Improvement with diet and medicines	13 (50%)	17 (65.38%)	12 (46.15%)	
No improvement or Worsening of symptoms	0	0	0	
Patient's assessment at the end of 30 days				0.419
Excellent	6 (23.07%)	03 (11.53%)	06 (23.07%)	
Good	17 (65.38%)	19 (73.07%)	18 (69.23%)	
Fair	03 (11.53%)	04 (15.38%)	02 (7.69%)	
Poor & terrible	0	0	0	

Age, sex, religion, occupation were similar in all three study groups. Nine (11.53 %) patients were more than 60 years of age. The male: female (M:F) ratio was 87:13.

Most (n=40) (51.28%) of the patients were having second degree of haemorrhoids. History of constipation was common and was present in 47 (60.25%) of the patients.

The Mean ($\pm$ S.D.) haemoglobin (g/dl) level was 7.69 ($\pm$ 1.73).

The main presenting complaints are summarized in Table 2. Bleeding per rectum was predominant presenting symptom and was present in all 78 (100%) patients. Prolapse was the next common symptom and was present in 33 (42.3%) patients and was equally distributed in all three groups ($p=0.854$). Many of the patients had more than one complaint.

The immediate Post Band Ligation Pain Score (Mean $\pm$ S.D.) was 2.81 ± 0.85 , 2.58 ± 0.86 , 2.77 ± 1.10 in Group A, B and C respectively, which was similar in all three groups ($P=0.643$). All patients were pain free at the end of 7 days. Most ($n=55$, 70.51%) of the patients were absent for just one day from work and 16 (20.51%) did not take any leave from work, which was similar in all three groups ($p=0.86$). At the end of 30 days, overall improvement in symptoms was seen in all patients and the results were similar in all three groups with complete relief seen in 36 (46.15 %) patients. No further procedure was required in our study ($p=0.241$). Most ($n=54$, 69.23 %) assessed the treatment as good at the end of 30 days. None assessed the treatment as poor or terrible. The results were similar in all three groups ($p=0.419$) (Table 3).

Post procedure complications such as severe bleeding requiring admission or blood transfusion, severe pain requiring admission or removal of band, urinary retention, sepsis etc., were not seen in any patient in any of the three groups.

DISCUSSION

Rubber band ligation (RBL) is considered one of the most popular non-surgical procedures available for haemorrhoids, representing the most reasonable balance between efficacy, pain and potential of complication.^{17,18}

The main highlights of our study were: age, sex, religion, occupation, hypertension, diabetes mellitus, haemoglobin level, degree of haemorrhoids, bowel habit were similar in all three study groups (Table 1) This shows that the results were not influenced by the distribution of these factors among the three study groups.

The main presenting complaints were bleeding per rectum, constipation, prolapse, painful defecation, discharge per rectum and presence of mucus in stool. Many of the patients had more than one complaint (Table 2).

Around three fourth of our patients ($n=57$, 73.1%) had clinically pallor. History of Hypertension was present in 11 (14.11%) patients and history of Diabetes Mellitus was present in 7 (8.97%) patients. Rubber band ligation was safely performed in all of these patients without any complication. Nine patients were more than 60 years of

age. This demonstrates that rubber band ligation can be easily and safely performed in older age group.

A review of 39 studies incorporating 8060 patients undergoing banding revealed complications in 14%, the most common being pain (5.8%) and haemorrhage (1.7%). (Wechter et al).¹⁹

Post procedure complications such as severe pain, severe bleeding requiring admission, blood transfusion, urinary retention, sepsis etc., were not seen in any patient of all three groups although the sample size was small.

Similar to our study, Lee et al, Khubchandani et al and Poon et al in separate studies found triple site band ligation in single session equally effective, safe, acceptable and more cost effective.^{15,20,21}

Post ligation pain score was recorded immediately after ligation, at 12 hours and 24 hours and at seven, 14, 21 and 30 days post band ligation period.

Mild discomfort was experienced by most patients after rubber band ligation which lasted for 1-2 days (Table 3). All the patients in all the groups were pain free after 7 days post band ligation. The results were similar in all three groups with P value >0.05 . None had severe discomfort in the present study.

Lee et al. 1994 reported that patients with multiple haemorrhoidal banding in a single session compared with patients with single banding had greater discomfort and pain (29 vs. 4.5%).¹⁵ Also, Gehamy et al reported that pain was much more frequent with multiple ligations than after single ligation.²²

On the contrary, Hardwick and Durdey failed to show any relationship between the number of bands applied and the degree of pain.²³

This study demonstrates that pain or discomforts is similar after single, double or triple band ligation if adequate precautions are taken. Authors undertook precautions such as applying the bands above dentate line and at different levels and the use of sitz baths, high fibre diet and laxative in post procedure period. Therefore, fear of pain should not be a contraindication for triple band ligation.

In this study, none of the patient in any group had severe haemorrhage requiring hospital admission or blood transfusion as we had excluded patients with coagulopathy from the study to avoid haemorrhage. A review of nine papers published in 2003, had described in detail, 18 cases of severe septic complication following banding including six deaths.²⁴

In this study, none of the patient had sepsis and the results were similar in all three groups. Authors took

precautions of excluding immunocompromised patients from the study to minimize the complications.

Absence from work

Post Barron band ligation absence from work ranged from zero to two days (Table 3). 16 patients didn't take any leave from work whereas seven patients took two days off and remaining 55 patients took leave of one day.

Mean ($\pm$ S.D.) days absence from work was similar in all three groups with p value 0.672 (Table 3). Therefore triple band ligation is similar to single and double band ligation regarding absence from work.

In a study by Groves et al 68% of patients had one day off from work and 6% had >4 days of work off whereas no patient in present study was more than 2 days absent from work.²⁵

Symptoms at end of 30 days

At the end of 30 days, overall improvement in symptoms was seen in all patients and the results were similar in all three groups. No further procedure was required in our study (Table 3) (p value 0.24).

Along with band ligation, warm sitz baths, high fibre diet, plenty of oral fluids and laxatives were advised. We tried to band the largest or the most actively bleeding haemorrhoid in single band ligation. Also, symptoms of haemorrhoids are episodic with symptom free intervals. This may explain the improvement in symptoms even after single band ligation.

With careful technique and supportive medical treatment, symptom control may be achieved even after a single site band ligation.

Patient assessment of treatment

The self-assessment by patients at the end of 30 days was important in knowing patient acceptance, which was high, as 88% patients assessed the treatment as excellent or good (Table 3).

Because improvement in symptoms was seen in all patients and post band ligation pain and complications was similar in all three groups, the results were similar in all three groups with p value 0.419.

This result were similar to study by Poon et al, who reported results as either excellent or good in over 90% in both conventional and triple band ligation groups.²¹

This shows that Barron band ligation has wide acceptance with more than 90% patients finding it excellent or good.

Limitations of present study was that, follow up was done only for one month. Since the haemorrhoids are chronic

disease with long symptomatic and symptom free intervals, a longer follow up of 5-10 years duration is necessary before any conclusions can be drawn regarding long-term effectiveness of single, double or triple site Barron band ligation in haemorrhoids.

CONCLUSION

From the above done prospective study the following conclusions are drawn: Rubber band ligation is a simple outpatient treatment not needing much expertise to perform, does not necessitate the need for expensive equipment and can be done with minimal infrastructure on out-patient basis without anaesthesia.

It can be done safely in elderly, anaemic and patients with hypertension and diabetes mellitus.

Multiple site haemorrhoidal bandings can be done safely at single session without severe discomfort, pain or bleeding or severe complications requiring hospitalization. Rubber band ligation is effective with significant symptom improvement with overall improvement in symptoms was seen in all patients with 88% patient satisfaction at end of 30 days period.

The study finding showed that Triple site rubber band ligation in a single session is a safe way of treating symptomatic haemorrhoids and can be done when required with similar post-procedure pain and patient satisfaction as conventional single or double site band ligation.

Based on these conclusions, triple site rubber band ligation can be recommended as an effective outpatient treatment for haemorrhoids.

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