

**A COMPARATIVE STUDY OF RUBBER BAND
LIGATION AND SCLEROTHERAPY IN PATIENTS
WITH SECOND DEGREE HAEMORRHOIDS**

Dissertation Submitted for

MS DEGREE (BRANCH I) GENERAL SURGERY

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CERTIFICATE

This is to certify that this dissertation titled “**A COMPARATIVE STUDY OF RUBBER BAND LIGATION AND SCLEROTHERAPY IN PATIENTS WITH SECOND DEGREE HAEMORRHOIDS**” submitted by **Dr.RAVIKUMAR. K** to the faculty of General Surgery, The TamilNadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirement for the award of MS degree Branch I General Surgery, is a bonafide research work carried out by him under our direct supervision and guidance from November 2010 to October 2011.

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DECLARATION

I, **Dr. RAVIKUMAR.K** solemnly declare that the dissertation titled “**A COMPARATIVE STUDY OF RUBBER BAND LIGATION AND SCLEROTHERAPY IN PATIENTS WITH SECOND DEGREE HAEMORRHOIDS**” has been prepared by me. This is submitted to **The TamilNadu Dr. M.G.R. Medical University, Chennai**, in partial fulfillment of the regulations for the award of MS degree (Branch I) General Surgery.

Place: Madurai

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CONTENTS

No.	TITLE	PAGE No.
1.	INTRODUCTION	1
2.	REVIEW OF LITERATURE	3
3.	AIM OF THE STUDY	37
4.	PATIENTS AND METHODS	38
5.	OBSERVATION	41
6.	TABLES AND FIGURES	48
7.	DISCUSSION	64
8.	CONCLUSIONS	72
	ANNEXURES	
	• BIBLIOGRAPHY	
	• PROFORMA	
	• MASTER CHART	

INTRODUCTION

Haemorrhoids are an extremely common surgical condition of anorectal area resulting in significant subjective discomfort and psychological stress. Very few people do not suffer from symptoms of haemorrhoids, and only few reports to their doctor before having resorted to self-medication with proprietary preparations¹. Hyams and Philpot² reported that about one in four of those over 30 years had some degree of haemorrhoids. Similar prevalence rates have been noticed by several authors in both western and Indian studies³⁻⁵.

The common ano-rectal complaints from the patients suffer from haemorrhoidal disease include bleeding, protrusion, discharge, discomfort. The pathogenesis of this condition is not well understood even after extreme hypothesis, but various theories like organic obstruction to the venous return from the superior haemorrhoidal veins, heredity factors, anatomical and physiological factors, bowel and dietary factors⁶⁻⁸, vascular cushions⁹, internal anal sphincter dysfunction^{10,11} and anal corpus cavernosum have been proposed. With the available non-surgical approaches for hemorrhoids like infrared coagulation, bipolar diathermy, direct current therapy, cryotherapy, etc. the number of haemorrhoidectomies performed has

decreased significantly over time¹². Rubber band ligation and injection sclerotherapy have become the mainstays of outpatient treatment for patients presenting with grade 1 to 2 haemorrhoids.

Both methods of treatment have been shown to be highly effective^{13,14}. Combination therapy of injection sclerotherapy plus rubber band ligation is a novel modality of treatment. Only few studies have been done so far to evaluate this treatment, two of them studying the effect of combination therapy on symptomatic hemorrhoids^{15,16}, one comparing it against rubber band ligation¹⁷ and one comparing it against sclerotherapy in addition to rubber band ligation¹⁸.

We planned to undertake a prospective randomized study comparing sclerotherapy and rubber band ligation in symptomatic second degree haemorrhoids.

REVIEW OF LITERATURE

Hemorrhoids have plagued the evolution of human race since they attained erect posture. Symptoms associated with this disease have caused the condition to be recorded in the ancient writings and documents extending as far back as the Babylonian, Egyptian, Hindu, Greek and Hebrew cultures¹⁹. During the time of Galen, Saint Fiacre²⁰ was given the “Patron saint” title for his role as healer of haemorrhoids, which the Galen followers propagated as “golden veins”, because of the large amounts of money saved by spontaneous letting of blood to avoid paying inordinate physician’s fees.

Many famous personalities in various fields had been victims of haemorrhoids, those include The Philistines, Napoleon Bonaparte²¹, Don Juan Demoranna and others. Maimonides, the most famous of ancient physicians, described soothing medications, ointments and suppositories for the treatment of hemorrhoids.

Though the terms “haemorrhoids” and “piles” are used quite interchangeably, etymologically the words have entirely different meanings. The term “haemorrhoids” is derived from the Greek adjective *haimrrhoides* meaning bleeding (haima = blood, rhoos = flowing) and emphasizes the

most prominent symptom in the majority of cases. But it cannot be applied accurately to all conditions diagnosed as haemorrhoids, for a number of them do not present with bleeding in many cases. The term 'Pile' on the other hand, derived from the Latin word '*Pila*', a ball, can be aptly used for all forms of haemorrhoids, or piles, for literally every such condition does produce a swelling of some kind, even though it may not show externally²³.

INCIDENCE AND PREVALENCE

According to Johansson et al. prevalence of haemorrhoids is quite common in Western World, with a reported 10 million people suffering from this affliction and a corresponding prevalence rate of 4.4% in USA³.

In both the gender, a peak in prevalence was noted from age 45-65 years, with a subsequent increase after age 65 years. The development of haemorrhoids before the age 20 years was unusual.

Hyams and Philpot et al. reported that about one in four of those over 30 years had some degree of haemorrhoids¹.

Anal Canal Anatomy:

The distal most portion of the alimentary canal extends for a distance of about 4cm from the Anorectal ring to the hairy skin of anal verge. The epithelium that lines the anal canal differs at various levels. The dentate line made up of anal valves anatomically demarcates the cranial pleated mucosa from the caudal smooth anoderm mucosa. The proximal mucosa corrugated into a series of 12- 14 columns of Morgagni with corresponding crypts between each fold.

Blood Supply:

From superior, middle and inferior haemorrhoidal artery which is a branch of the anterior portion of internal iliac artery.

The anal veins are distributed in similar fashion to the arterial supply. The superior and middle haemorrhoidal veins → superior rectal vein → inferior mesenteric vein → portal system

Inferior haemorrhoidal veins drain the lower half of the anal canal → join the external iliac vein on each side.

Physiology of the Anal Canal:

The physiology of the anal canal is highly complex mechanism which under normal situations allows the individual to control the retention and evacuation of gaseous, Liquid and solid fecal matter. When faecal materials enter the rectum there are three phases.

1. Accommodation:

Where the rectum slowly expands but both the internal and external sphincter retain their tone.

2. Sampling:

Rectal contents come in contact with the sensory lining of the anal canal after temporary relaxation of the internal sphincter.

3. Defecation:

Although this is under the voluntary control to a certain extent, when the volume of rectal contents reaches a critical point the urge to defecate becomes overpowering and the tone in the external sphincter is inhibited.

The tone of the internal sphincter at rest is about 90 cm of water. This called the resting Pressure.

Squeeze Pressure is generated by the contraction of the external anal sphincter and puborectalis muscle, more than double the intra anal canal resting Pressure.

The anorectal angle measures about 80 degrees produced by the anterior pull of the puborectalis muscle. Maneuvers that sharpen this angle augment continence were as those that straighten it favour defecation.

Anatomical Aspects:

Hemorrhoid is a condition of dilatation of the internal venous plexus within an enlarged displaced anal cushion.

Anal cushions are normal structures that have a rich arterial supply leading directly into distensible venous spaces. They help to seal the upper anal canal and contribute to continence of flatus.

Constipation and straining disrupt the supporting frame work of the cushions causing them to become displaced and congested. In some patients this is aggravated by tight internal sphincter, which leads to increased intra anal pressure during defecation.

Functions of Anal cushions:

Closure of the anus is mainly an activity of the muscles and nerves of the pelvic floor. However, a finetuning mechanism exists to close the final millimeter. The haemorrhoids bulge to affect this closure by rapid filling of veins. These haemorrhoidal veins are directly served by an arterial shunt, which can rapidly fill them under pressure. Arterial and venous pressure is evidenced by the squirting of bright red blood, from prolapsing hemorrhoids when the sphincter is relaxed. The sphincter normally keeps these veins tamponed, when the sphincter is closed as the basal pressure is exerted by the sphincter muscle.

CLASSIFICATION ²⁴:

Depending on the site of origin, external hemorrhoids appear at the perineum. They are situated below the dentate line and microscopically covered by modified squamous epithelium. They have variable coloration and are sometimes seen to swell and bulge with straining.

Internal hemorrhoids arrive above the dentate line and microscopically covered by transitional or columnar epithelium. At the time

of examination they often demonstrate considerable engorgement and sometimes ooze or spurt blood.

Sometimes the haemorrhoidal complex seem to go above as well as below the dentate line, such ones are called combined or mixed hemorrhoids.

Distribution is most commonly the right anterior, right posterior and left lateral positions; however, many variations can exist, especially if accessory hemorrhoids occupy the areas in between.

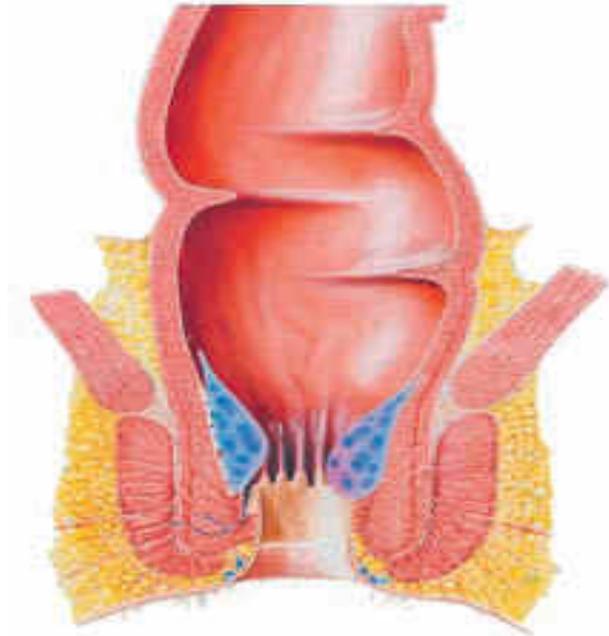
Classification- depending on the degree

First degree: Haemorrhoids leads to bleeding at the time of defecation and on physical examination are seen to bulge and sometimes actually bleed.

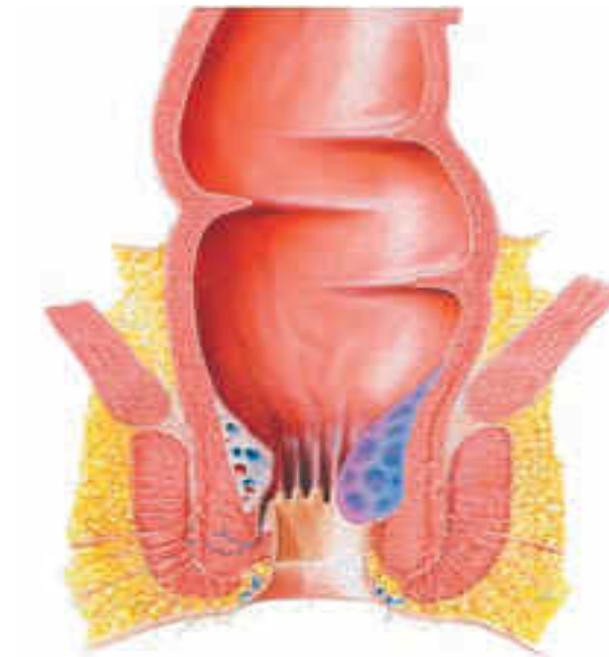
Second degree: Haemorrhoids protrude or bulge out of the anal canal during defecation and spontaneously return to their proper position.

Third degree: Haemorrhoids prolapse and require digital replacement.

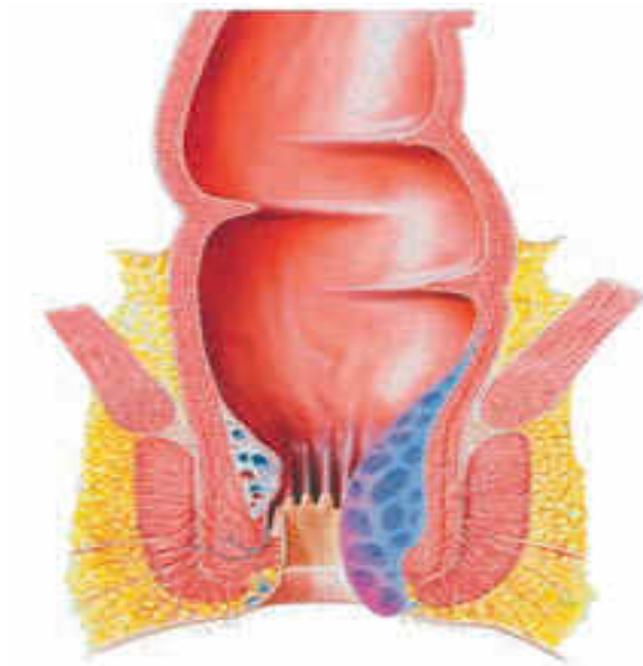
Fourth degree: hemorrhoids are incapable of digital reduction, they are permanently prolapsed.



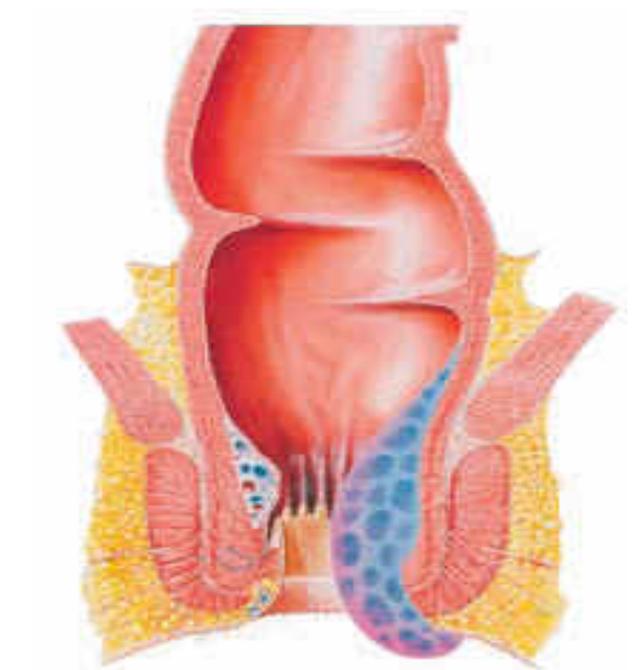
FIRST DEGREE HAEMORRHOID



SECOND DEGREE HAEMORRHOID



THIRD DEGREE HAEMORRHOID



FOURTH DEGREE HAEMORRHOID

Etiology

From the etiological point of view, internal piles may be divided into two main categories,

1. Internal haemorrhoids associated with a definite organic obstruction to the venous return from the superior haemorrhoidal veins e.g. Cirrhosis of liver, thrombosis of portal veins during pregnancy, carcinoma rectum²⁵.
2. Idiopathic haemorrhoids where no evident organic venous obstruction is present²⁶.

These cases represent the vast majority of patients encountered by the surgeon; a number of factors are incriminated as follows

1. Hereditary: Certain families appear to be specially predisposed to the development of hemorrhoids, so that many or all its members become affected, often at an early age, presumably as a result of some structural weakness of the wall of haemorrhoidal veins²⁷.

2. Anatomical and physiological factors: The valve less portal system of veins in erect position has blood in column from anal canal to liver bearing directly on the internal haemorrhoidal venous plexus. During defecation

when the anal canal is opened to atmosphere pressure, the pressure on portal system is greatly increased by straining and distension of haemorrhoidal veins is liable to occur. Additional factors like compression of superior haemorrhoidal vein by the descending mass of hard constipated faeces can compound this effect of recurring momentary haemorrhoidal enlargement and development of internal piles by middle age ²⁸.

3. Constipation, diarrhea associated with tenesmus and straining at Stools magnify the distending effect of normal defecation on the haemorrhoidal plexus as described above and predispose to development of hemorrhoids as proposed by Claeve et al. and Stewart et al.^{6,7}. Goligher on the other hand, blamed the retrograde flow of blood in the haemorrhoidal veins caused by intra-abdominal pressure resultant on straining at stool as the predisposing factor²⁹. Gibbons et al. investigated chronic constipation, bowel habits, anal pressure profiles and anal compliance and found that symptomatic hemorrhoids were associated with significantly longer anal pressure zones as well as greater maximum resting pressures at all levels of anal distension ³⁰.

4. Epidemiology and diet: Burkitt in his study comparing the American Negroes and rural African population postulated that the former suffered from the haemorrhoids more than the latter due to western eating habit of

low residue diet resulting in considerable delay in faecal transit time in the bowel and a high incidence of chronic constipation³¹. Prasad et al. after studying the dietary habits of haemorrhoid patients reported that least number of cases recorded in people having vegetarian dietary habit (3%) and greatest number of cases were in habit of taking non-vegetarian diet and were in the habit of over-eating (67%)⁵.

5. Internal anal sphincter dysfunction (IASD): Increased mean basal pressure in canal may lead to venous outflow obstruction and congestion, followed by engorgement of haemorrhoids and subsequent symptoms^{10, 11, 32}.

6. Thomson proposed the “vascular cushion” theory where normal haemorrhoidal tissues represent discrete masses of thickened submucosa which slide with straining efforts of defecation⁹. With passage of time, anatomic structures supporting the muscularis submucosae weakens and leads to slippage and prolapses with subsequent symptoms such as bleeding, engorgement, burning and discomfort.

7. Presence of an anal corpus cavernosum³³: Arterial pressure is directly transmitted to a shunt system at the haemorrhoidal level - the plexus enlarges, bulges and eventually prolapses.

The symptoms of haemorrhoids are bleeding, prolapse, discharge, anal irritation and Symptoms of secondary anemia.

COMPLICATIONS:

Prolapse and thrombosis are complications which may affect all the hemorrhoids present in a particular patient or may be confined to one or two³⁴.

TREATMENT

‘To tie; stab; to stretch; perchance to Freeze’³⁵

A wide range of treatment options starting from medical measures such as local medications, to ambulatory treatments such as sclerotherapy and banding, to surgical options in form of a variety of haemorrhoidectomies are available. Recent developments include cryotherapy and stapler haemorrhoidectomies.

Expectant or medical treatment³⁶:

Small piles which are discovered during the course of a routine examination and which have caused no symptoms are usually best left without treatment of any kind. But if the patient has any complaint referable to his piles, then active treatment by injections, rubber band ligation or other

measures should be advised. Injection treatment and rubber band ligation are very safe and disturb the patient very little and hence whatever may be the state of his general health, they can be safely given. There are few indications for medical measures alone:

- a. Patient who refuse any other kind of treatment except that of expectant or medical.
- b. In pregnant patients especially towards the last trimester because some surgeons believe that symptomatic internal hemorrhoids in pregnant patients improve enormously after parturition and because of risk of disturbing the course of pregnancy if the injections are given during its later stages.
- c. In the presence of coexisting ulcerative colitis or Crohn's disease of the large bowel, where the source of bleeding could be from inflamed mucosa itself and also that injection therapy might provoke an exacerbation of colitis or Crohn's disease.

Medical measures include aperients or advice regarding high roughage diet to overcome habitual constipation and local medical treatment with various kinds of ointments and suppositories. Preparations of unprocessed or processed bran, psyllium seed are available as commercial formulations like

Ispagol, Fybogel tablets and Metamucil. They are given to increase the bulk of the stool. Webster et al. in his trial found Fybogel to be significantly more successful than a placebo³⁷. Keighley et al. in his prospective trial of minor surgical procedures and high fiber diet for haemorrhoids, reported symptomatic relief in 37% of patients treated by high roughage diet alone at the end of 12 months³⁸.

LOCAL MEDICAL TREATMENT

INJECTION TREATMENT³⁹:

A variety of preparations are available like Vaseline, antithrombotic medications, gels, creams which are found to be of little value but give the patients great psychological support as they feel the medication reaches the site of botheration.

History:

Morgan of Dublin was the first person to practice injection of haemorrhoids in 1869 using persulfate of iron⁴⁰. Since then a number of surgeons namely Colles (1874), Mitchell (1871), Andrews (1879), popularized its use. In the beginning the usual practice was to make the

injection into the substance of the pile itself and the solution was often carbolic acid 10% mixed in equal parts of glycerol and water ⁴¹.

In 1928, Blanchard described the technique, originally suggested by Albright, of placing the injection not in the pile but above it, and using for the purpose much weaker solution of 5% phenol in almond oil in doses of 3-5 ml ⁴². Bacon (1949) and Turell (1959) introduced the method of injecting a quinine and urea hydrochloride solution directly into the piles ^{43,44}.

Rationale [45]: The injection when given into the submucous areolar tissue in which the haemorrhoidal veins lie produces an inflammatory reaction and fibrous tissue forms. This surrounds and constricts the veins (and arteries) in the submucosae. The fibrosis may also increase the fixation of the pile or to the underlying muscular coat and in that way it may reduce the amount of prolapse.

If the injection has been given below into the pile itself this fibrous tissue may provide a supporting and encasing layer protecting the veins from the trauma associated with passage of faeces.

If the injection has been given at a high level, above the pile mass, the fibrosis caused by it, will constrict and possibly completely obliterate the

radicals of superior haemorrhoidal vein and accompanying branches of superior haemorrhoidal artery in the pile pedicle. This in turn protects the veins of the pile itself from becoming distended by increased back pressure in the portal system during exertions of defecation and straining.

In summary the consequence of these changes will be to diminish venous congestion in the pile and to reduce the tendency to bleeding. In fact this devascularization is the main effect of injection treatment.

Indications⁴⁶:

1. For cases of first degree internal hemorrhoids injection treatment the best and usually gives prospect of complete cure or long freedom from symptoms.
2. Most second degree internal haemorrhoids which are relatively small, prolonged relief are seen before further injections are required. The larger they are and the more they approach third degree cases, the poorer becomes the prospects with injections.
3. Third degree haemorrhoids cannot be cured by injection treatment, but afford a very remarkable temporary palliation in patients whose

extreme age, poor general condition make it desirable to avoid or postpone operation.

Contraindication:

1. External piles or lower, skin covered components of large internal piles must never be injected as it produces severe pain.
2. In patients with some associated anal lesion, most frequently anal fissure where proctoscopy is necessary for both diagnosis, and for injection/rubber band ligation of the haemorrhoids themselves.
3. During the course of an attack of thrombosis of internal haemorrhoids for some three to four weeks after wards.
4. In treatment of internal haemorrhoids in pregnancy and coexisting ulcerative colitis or Crohn's disease as explained earlier under medical treatment.⁴⁷

Complications⁴⁸:

1. Necrosis and formation of injection ulcers. With 5% phenol solution being used now, necrosis is rare compared to earlier days when carbolic acid was used. To prevent this dose should be limited to 5 ml.

The effect of necrosis is to produce an injection ulcer which is often symptom less and takes 3 to 6 weeks to heal.

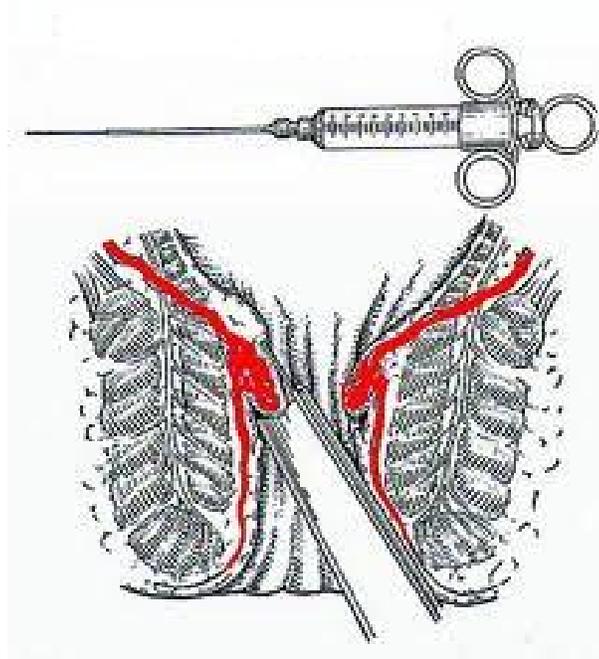
2. Submucous abscess, hematuria or prostatic abscess due to deep injection of right anterior haemorrhoid, stricture and encroachment of lumen, paraffinoma are all rarely encountered complications.

Results:

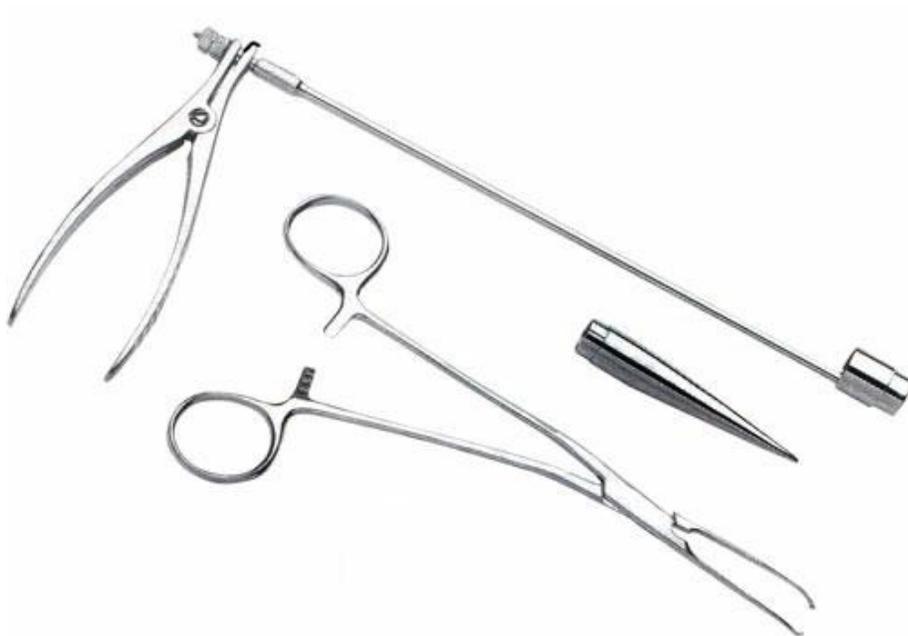
Earliest study was by Kilbourne et al. in his study of 26,262 cases of hemorrhoids treated by injections with an estimated recurrence rate of 15% within three years ⁴⁹.

Milligan et al. in his five-year follow up study reported that 98.3% of patients with first degree internal haemorrhoids were symptom free, 15% of them requiring further injections usually between one and three later. In second degree, 68% were asymptomatic, but 38% had recurrent symptoms⁵⁰. Third degree, 31% were 'cured', but 69% had further trouble.

Greca et al. compared rubber band ligation with sclerotherapy in 82 patients. 64% improved after rubber band ligation compared with 70% after sclerotherapy. Complications were recorded in 5 patients after rubber band



INJECTION SCLEROTHERAPY



BANDING INSTRUMENTS

ligation. Repeated treatment was necessary in 13 patients after sclerotherapy compared to 4 after rubber band ligation.

In a similar trial by Cheng et al. reported that out of 30 patients with grade 1-2 haemorrhoids who underwent treatment, 18 were completely asymptomatic, 5 greatly improved, 5 no better and 2 worse. 77% patients were satisfied with treatment ⁵¹.

RUBBER BAND LIGATION:

The operation was developed by Barron (1964) as a modification of an outpatient ligation method originally proposed and practiced by Blasdell (1958) ^{52,53}.

Rationale: The principle of the method is to apply a rubber ring ligation through a proctoscope, to the mucosal - covered part of the internal pile. Over a period of 7 to 10 days this elastic band gradually cuts through the tissue and the pile sloughs off immediately ⁵⁴.

The technical difficulty of the assistant holding the proctoscope, while the surgeon holds, the ligator and tissue forceps is overcome with Vanhoorn (1972) ligating proctoscope ⁵⁵. It is capable of applying the rubber band to the hemorrhoid without the need to introduce a separate ligator. The

proctoscope functions as the drum of a ligator and carries the rubber bands slipped onto the drum with aid of a loading cone.

Thomson in 1980 introduced another modification of conventional ligator in which instead of the proximal end being a forceps handle, is a fenestrated metal cylinder just a fraction smaller than the tube of the proctoscope being used, so that it fits accurately into the proximal half of the latter. It needs to be used in conjunction with a Naunton-Morgan proctoscope.

Disadvantages and complications:The main disadvantage of this method is that it does have play role in removal of the skin - covered component of the pile or an associated skin tag, which in patients with large piles, may be of considerable size and troublesome. This makes the procedure less than curative. However, Barron opines that the lower remaining portion of the pile may undergo some shrinkage once the mucosal-covered part is dealt with and if skin tag continues to bother, they can be subsequently removed under local anaesthesia ⁵⁶.

1. Immediate severe pain: When the band has been placed at an improper level, severe pain occurs immediately after application. This can be avoided

by using a suction band ligator, advising the patient to inform if pain is experienced soon after application of suction.

Incidence of pain has been reported as varying from 6.66% to 29.97% in the clinical trials of rubber band ligation ^{51,57}. Weiner (1977) in his large trial of 3244 patients found that 41% of patients suffered little pain and 14% of patients suffered severe pain after rubber band ligation ⁵⁸.

2.Delayed pain: A sensation of fullness and pressure follows banding and sometimes this sensation intensifies over 24 to 48 hours but settles soon after⁵⁹.

3.Bleeding: Early bleeding or passage of blood with the first bowel movement common after this procedure. Later delayed bleeding occurs in less than 1% about 7 to 14 days post operatively. This bleeding usually subsides with injection of local anesthetic and epinephrine along with pressure for few minutes ⁶⁰.

4. Thrombosis: It can occur at the internal or external haemorrhoidal level any time after banding. Examination of the area, determines the therapy required ⁶⁰.

5. Anal fissure: It occurs in less than 1% of patients which is due to ulceration that follows sloughing of tissue and it spreads to lower anal canal. Conservative treatment is prescribed initially and is followed by sphincterotomy if it does not heal ⁶¹.

6. Slippage: Slippage is unusual and rare if the technique is rightly used. It can be avoided by using double bands ¹⁶.

7. Sepsis: In 1978, a case of tetanus was reported by Murphy et al. following rubber band ligation. In 1980, O'Hara reported a fatal case of clostridial infection following banding ⁶³.

Results:

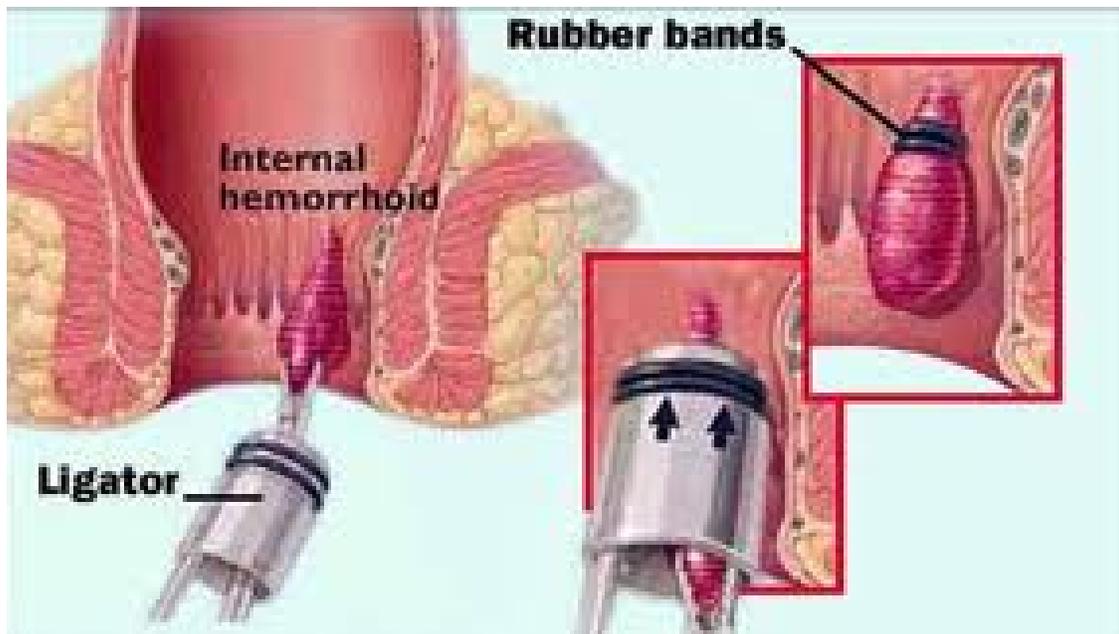
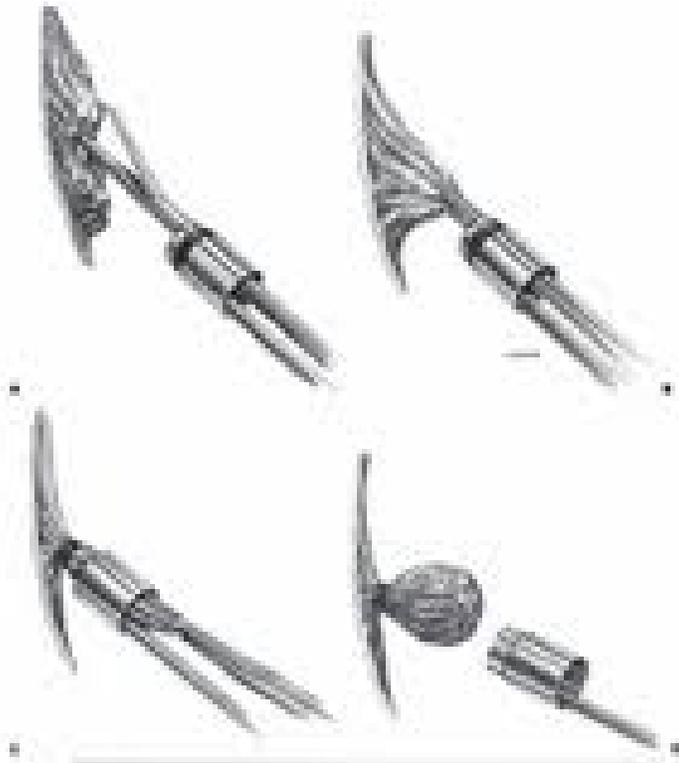
In controlled trials of rubber band ligation contrasted with other methods of treatment, Murie et al. and Greca et al. found on review at one year that 34 of 43 patients (79%) and 18 of 28 patients (64%) respectively were symptom free or greatly improved. A three to four year postal follow up by Steinberg et al. of 125 patients treated by rubber band ligation showed that 44% were entirely free of symptoms and another 45% were considerably improved ⁶⁵. A similar study by Wroblewski et al. of 266 patients 3 to 5 years after banding found that 69% were completely asymptomatic and a further 11% were improved ⁶⁶.

In a large trial done between 1979 and 1997 for first episode of second degree hemorrhoids by Savoiz et al. it was found that after a mean follow up of 5-6 years 88% were symptom free ⁶⁷. Gartell et al. in randomized controlled trial comparing rubber band ligation with phenol injection in 269 patients over 6 years reported successful outcome in 89% patients with rubber band ligation compared to 70% for injection treatment ⁶⁸. All symptoms responded more favorably to rubber band ligation.

Templeton et al. in a randomized controlled trial comparing rubber band ligation (N=71) with infrared coagulation (N=66) in 137 patients found that satisfactory outcome was obtained in 85% patients with infrared coagulation compared to 92% patients with rubber band ligation ⁶⁹. 33 patients were rendered asymptomatic and 24 improved.

Ambrose et al. in his prospective randomized trial comparing photocoagulation and rubber band ligation after 1 year follow up reported 77% satisfactory outcome ⁷⁰. Arabi et al. in his trial comparing rubber band ligation with lateral subcutaneous sphincterotomy found it satisfactory results in 88% at the end of 6 months and 84% at the end of 1 year follow up.

BANDING PROCEDURE





BANDING



AFTER BANDING

Manual dilatation of the anus and lower rectum:

Lord et al. had suggested this method of treatment ⁷¹. He suggested that internal haemorrhoids are caused by circular constricting bands in the wall of the lower rectum or of the anal canal, which interfere in some way with normal defecation, leading to abnormal rising of intrarectal pressure during the act and to consequent venous congestion leading to hemorrhoids.

Rationale ⁷²: If these constricting bands are broken down under general anaesthesia by vigorous stretching of anal canal and lower rectum by four fingers of both hands inserted as far as they can reach into the bowel and dilating in all directions, haemorrhoidal state can be corrected. After the operation the dilation achieved in surgery is preserved by regular use of bulk forming agent like Normacol (Sterculia) and an anal dilator of 4 cms diameter.

Complications⁷³:

1. Splitting of the anal and perianal skin, this usually heals quickly.
2. Mucosal prolapse.
3. Anal incontinence

Results: Sandilands et al. on a 4 to 7 year followup of 118 patients (Mean 5-6 years) in a randomized controlled trial found that 55% patients were cured, 22% improved, 11% unchanged, 2% worsened and 9% had other forms of treatment ⁷⁴.

Lateral subcutaneous sphincterotomy:

The aim of reducing the increased activity of internal sphincter could be achieved by a lesser maneuver than forcible dilation as described by Notaras et al.⁷⁵.

In subcutaneous sphincterotomy the internal sphincter is divided in the left lateral side of rectum either from within outwards (Notaras) or from the inter-sphincteric plane outside inwards (Goligher) ⁷⁶.

Side effects and complications ⁷⁷:

- a. Pain and bleeding
- b. Immediate prolapse of hemorrhoids.
- c. Inter sphincteric abscess formation.
- d. Incontinence to flatus and faecal soiling.

Results:

Arabi et al. in a randomized trial comparing lateral subcutaneous sphincterotomy to rubber band ligation in Grade 1-2 haemorrhoids in 100 patients, 49 with sphincterotomy, 51 with rubber band ligation found that 11 patients required haemorrhoidectomy later, 5 after lateral subcutaneous sphincterotomy and 6 after rubber band ligation ⁷⁸, Immediate complications of pain and bleeding were reported in 27% of patients treated by rubber band ligation compared to 14% after subcutaneous sphincterotomy.

CRYOSURGERY:

Cryosurgery is based on the concept of cellular destruction through rapid freezing followed by rapid thawing. Such treatment has been used increasingly in medicine. Its application in treatment of haemorrhoids was initiated by Lewis et al.⁷⁹ and later popularized by Lloyd - Williams ⁸⁰.

Rationale ⁸¹:

The tip of the cryoprobe is kept in contact with the pile until it is enveloped by an ice ball. The probe is then switched off, rewarmed and detached from the pile mass. Edema and swelling occurs within 24 hrs.

Areas of necrosis with superficial sloughing and ulceration occur after 10- 14 days. Healing of such ulcer is complete in 6 weeks.

Complications ⁸²:

1. Pain during the first few days or a week.
2. A discharge of serous or brown offensive fluid from the anal canal which is profuse in half the patients.

Results:

In a clinical trial of 68 patients treated by cryotherapy, John Golligher found that 38 patients were pleased, 8 patients were satisfied and 12 patients disappointed with the treatment on whom further treatment was necessary ⁸³.

INFRARED COAGULATION:

This technique was developed by Nath et al. for coagulating bleeding points ⁸⁴ and was adapted to elective treatment of hemorrhoids by Neiger et al. ⁸⁵.

Principle ⁸⁶: Infrared photocoagulation causes localized tissue destruction by rapidly increasing the temperature. The light source is directed end on to the base of the hemorrhoid and the effect is immediately visible as white coagulum. Each haemorrhoidal column is dotted four to five times and all

three hemorrhoids can be dotted in one session. An ulcerated surface develops and subsequently heals with scarring. It is best used for treating bleeding without prolapse or minimal prolapse.

Complication ⁸⁷:

1. Pain is the most common complaint which is usually immediate and can last for several days.
2. Some surgeons find the light source unpleasant with accompanying headaches and visual disturbances after prolonged use.

Results:

Ambrose et al. in randomized trial comparing photocoagulation with injection sclerotherapy in 135 patients, 73 with photocoagulation and 62 with injection sclerotherapy were assessed at 1, 4, 12 month intervals ⁸⁸. There was no clinical difference between the groups at 12 months; however the proportion of patients who were symptomatic improved 59% after photocoagulation compared to 50% with sclerotherapy.

BIPOLAR DIATHERMY⁸⁹⁻⁹¹:

This technology was developed to treat bleeding peptic ulcers endoscopically, was later used successfully in treatment of obstructing lesions of esophagus and rectum.

Bipolar diathermy utilizes an electric current to generate a coagulum of tissue at the end of a cautery tip applicator.

Dennison et al. in his randomized controlled trial comparing bipolar diathermy and infra-red coagulation found that no significant difference in complications or number of treatment sessions required ⁹³.

Complications ⁹³:

Pain is the only complication reported which is often short term.

DIRECT CURRENT THERAPY⁹²:

Popularly known as Ultroid therapy. This is monopolar low voltage instrument that includes a generator unit and a disposable probe.

Using a nonconductive proctoscope, the probe is applied to the apex of the hemorrhoid and then 16 milliamperes current is passed through the probe for up to 10 minutes for each hemorrhoid after which the current is reduced to

zero before withdrawing. No anesthetic is required and only one hemorrhoid is treated per session.

Disadvantage:

The probe has to be held for a long time, which is very tiring for both the patient and surgeon and only one hemorrhoid can be treated at a time.

Results:

Hinton et al. in his randomized controlled trial comparing monopolar to bipolar diathermy in 50 patients of third degree haemorrhoids reported satisfactory outcome in 76.9% and 83.3% respectively ⁹⁴.

TRANSANAL HAEMORRHOIDAL DEARTERIALIZATION:

This latest treatment modality was introduced by Morinaga et al. who used a specially designed proctoscope coupled with Doppler transducer ⁹⁵

Rationale ⁹⁶: Under conscious sedation and local anaesthesia Doppler modified proctoscope is introduced, rotating circumferentially six haemorrhoidal arteries which are the branches of superior haemorrhoidal artery are identified at 1,3,5,7,9 and 11'o clock positions. 2.0 vicryl figure of eight sutures are placed around the vessels 2-3 cms proximal to dentate line with a depth, adequate enough to obliterate the doppler arterial sound.

Complications: As observed in the study by Norman Sohn et al.

- Mild pain resulting in loss of work >2 days observed in few patients (8%)
- Prolapse with thrombosis in 4%.
- Anal fissure in 1%.

Results:

In a prospective trial of 60 patients treated by this method by Sohn et al. excellent results have been achieved as tabulated.

S.No	Symptom	Fully resolved	Improved
1	Recurrent thrombosis	100%	-
2	Pain	71%	14%
3	Bleeding	88%	8%
4	Protrusion	92%	4%

Combination of rubber band ligation with injection sclerotherapy¹⁸.

This is a new and novel method of treatment where the two conventional methods of rubber band ligation and injection sclerotherapy are combined.

Rationale: After rubber band ligation of the hemorrhoid, injection is given around the base of hemorrhoid into the submucosae. The addition of injection sclerotherapy to rubber band ligation has the theoretical advantage of exciting a greater inflammatory reaction between the mucosa and submucosa and preventing premature slipping of the band, thus reducing the chances of rebleeding. It has also been postulated that injection combined with rubber band ligation reduces after pain.

Results:

Choi et al. between periods of 1978 to 1983 treated 111 patients with this form of concomitant therapy. Only 94 patients were subsequently available for follow up which ranged between 2 to 60 months (mean 18 months). Results were excellent in 51 patients (54%) good in 20 (21%) and poor in 9(10%). Fourteen (15%) patients had unsatisfactory results. Only 4

of these required haemorrhoidectomies. The other 10 had residual symptoms but did not require further treatment.

Ackroyd et al. used the same method against rubber band ligation alone in his randomized trial with 30 patients in each group and found that symptomatic relief was same at the end of 6 weeks but amount of bleeding was less in the group of rubber band ligation plus injection sclerotherapy¹⁷.

Prabhakar et al (2001) in their prospective randomized comparative study of injection sclerotherapy, rubber band ligation and a combination of two therapies in the treatment of symptomatic haemorrhoids reported satisfactory outcome in 71.42%, 74.28% and 76.66% respectively with number of sessions required to obliterate haemorrhoids and number of patients requiring additional treatment during follow up same in all 3 groups.

OPERATIVE HAEMORRHOIDECTOMY⁹⁷:

The surgical treatment of haemorrhoids was one of earliest exercise in operative surgery and was practiced in ancient Greece and Rome. The methods used were excision and ligation and the use of cautery, the same maneuvers have been passed down through the ages and represent in essence

the main types of operations available for the treatment of haemorrhoids at the present day.

- a. Ligation and excision
- b. Sub mucosalhaemorrhoidectomy
- c. Excision of individual piles with suture over a clamp and excision of individual piles and immediate suture without a clamp
- d. Excision of the entire pile bearing area with suture
- e. Excision with clamp and cautery
- f. Laser sub mucosalhaemorrhoidectomy⁹⁸
- g. Harmonic scalpel haemorrhoidectomy⁹⁹

STAPLER HAEMORRHOIDECTOMY¹⁰⁰:

In 1990, Staplers were first used in the treatment of hemorrhoids. The technique was successively developed and slightly modified by Longo.

After gentle anal dilation, a circular non absorbable single filament pursestring suture is placed in the submucosal layer at the edge of the dentate line or 2 to 3 cm above the line. Circular stapler is then inserted (open) into the anal canal and the suture tied on the rod. The EEA instrument is tightened and the central ring of tissue is incised by the circular knife, with staples applied in an encircling anastomosis.

Using the stapler, haemorrhoids can be completely transected or partially transected and pulled up in the original position as described by Longo called “high transaction” or “lifting of the anal canal”. It does not damage the anal mucosa which is lifted higher up in the anal canal by resection of a variable ring of insensitive mucosa at the anorectal junction.

Complications:

Although no complications have been reported, there has been one case of life threatening pelvic sepsis and one case of rectovaginal fistula after stapler haemorrhoidectomy, Ho et al. (2001) reported mild stenosis in 6 patients who underwent surgery out of 29 patients at the end of 6 weeks¹⁰¹.

Results: Shalaby et al. in their randomized trial comparing stapled haemorrhoidectomy to Milligan Morgan haemorrhoidectomy with 100 patients in each group, reported lesser operating time, postoperative pain, earlier bowel movement and hospital stay¹⁰². Patient satisfaction was 92% in staplerhaemorrhoidectomy compared to 80% in Milligan – Morgan, haemorrhoidectomy.

Stapler has also produced good results in the treatment of thrombosed prolapsed circumferential haemorrhoids.

AIM OF THE STUDY

To compare the efficiency of sclerotherapy and rubber band ligation in the treatment of second degree haemorrhoids in our institution .

PATIENTS AND METHODS

PATIENTS

The study was carried out between November 2010 and October 2011 over a period of twelve months. A total of 142 patients with second degree haemorrhoids who consented to participate in the study and who did not have any other associated anorectal lesions were included in the study. Seven patients developed thrombosed haemorrhoids and five patients subsequently lost to follow up, hence they were excluded from the study leaving 130 patients who formed the study groups.

METHOD

A detailed history was obtained with emphasis on symptoms occupation and dietary habits. All patients underwent digital rectal examination and proctoscopy. Patients were then assigned to two treatment groups i.e. sclerotherapy or rubber band ligation group consecutively by block randomization.

In sclerotherapy group, with the patient in left lateral position, 3 to 5 ml of 5% phenol in groundnut oil was injected into a point above the main mass of hemorrhoid into the sub mucosa, till elevation and pallor of the

mucosa was seen. Similarly in rubber band ligation group one rubber band was applied on each haemorrhoidal bundle on rectal mucosa.

Patients were followed up at intervals of 3 weeks, 6 weeks and 9 weeks. At each followup symptoms of bleeding, prolapse, discomfort, discharge, pruritus / irritation were assessed. Proctoscopic findings with regard to grade of haemorrhoids and any treatment associated complications were also noted. Their response to treatment on follow up visits was assessed and termed 'complete' when all haemorrhoids disappeared or incomplete when any residual haemorrhoids were found.

Patients were asked to assess degree of symptomatic relief on a 4 point scale as follows:

Excellent: Patients who became completely asymptomatic.

Better: Patients who had improvement of symptoms.

Same: Patients who had persistence of symptoms without any improvement

Worse: Patients whose symptoms worsened after treatment.

Intraoperative pain during the treatment was assessed on a visual analogue scale (VAS) ranging from 1 to 10 with 1 indicating no pain and 10 the worst pain.

If the patient was still symptomatic, further treatment given up to a maximum of three times. Patients failing to respond after these three visits for treatment were considered as treatment failure and surgery advised.

STATISTICAL METHODS:

Data was entered in SPSS -10 Software and Statistical analysis of the results were done by Chi Square test with Yates correction, Fishers exact test, ANOVA and Kruskal Wallis test.

OBSERVATION

Out of 130 patients in our study, 65 patients were randomized to sclerotherapy and 65 patients to rubber band ligation (Table 1, Fig.1).

Patients in this study had age ranging between 18 years to 73 years with a mean age of 46.86 ± 14.57 . The highest frequency of haemorrhoids occurred between 41-50 years of age. Age distribution was comparable in both the groups (Table 2, Fig.2).

There were 102 men (78.46%) and 28 women (21.54%) in this study (Fig.1). The sex distribution was also comparable between the groups.

Fifty three patients (40.77%) were manual laborers, 40 (30.77%) patients had occupation involving predominantly sitting throughout the day and 37 (28.46%) worked mainly standing (Table 3, Fig.3).

88 patients (67.69%) were in the habit of taking predominantly vegetarian diet, 55 (42.31%) with low fiber content and 23 (17.69%) with high fiber. 42 (32.30%) of patients were taking predominantly non-vegetarian diet, 28 (21.54%) with high fiber and 12 (11.53%) with low fibre.

In the study groups 86 (66.16%) patients had constipation and 44 (33.84%) of patients had normal bowel habit (Table 4, Fig.4).

In the study group bleeding per rectum was the predominant symptom (86.15%) followed by prolapse(71.53%). Discomfort(20%), discharge (13.84%) and pruritus/irritation(23.38%) were the other presenting symptoms. The distribution of presenting symptoms among the patients in individual treatment groups was comparable (Table 5, Fig.5).

On proctoscopy, most common site of main haemorrhoid was 11 O' clock position (93 patients) followed by 3 O' clock (58 patients) and 7 O' clock (47 patients) (Table 6, Fig.6).

Symptomatic responses at 3 weeks follow up (Tables 7&7A and Fig.7)

Fastest symptomatic improvement of bleeding was seen in rubber band ligation group compared to sclerotherapy group.13.11% of patients in sclerotherapy still had persistent bleeding at the end of 3 weeks follow up. Whereas it was found in5.88% patients in rubber band ligation group. The difference was statistically significant ('p' value = 0.02). Fastest improvement of prolapse was noticed in rubber band ligation group compared to the sclerotherapy group ('p' value = 0.015).There was significant difference in improvement of other symptoms like discharge, discomfort and pruritus / irritation in the two treatment groups. ('p' value = 0.017).

Patient assessment at 3 weeks follow up (Table 8 and Fig.8)

16.92% of patients in sclerotherapy group, and 7.69% in rubber band ligation group felt no relief from symptoms. However, 66.15% in sclerotherapy group and 78.46% in rubber band ligation group felt “better” . There were 7.69% in sclerotherapy group and 13.84% in rubber band ligation group who expressed their relief as “excellent”and required no further treatment. The number of patients who experienced ‘excellent’ symptomatic relief was significantly higher in rubber band ligation group compared to sclerotherapy (‘p’ value 0.04).

Proctoscopic assessment at 3 weeks follow up (Table 9 and Fig.9)

After completion of 3 weeks follow up, incomplete clinical response was seen in 92.30% patients in sclerotherapy and 83.07% patients in rubber band ligation group. Complete response was seen in 7.70% of patients in sclerotherapy and 16.93% patients in rubber band ligation group. Rubber band ligation shows significantly better clinical response as compared to sclerotherapy (‘p’ value = 0.026).

Symptomatic responses at 6 weeks follow up (Table 10,10A and Fig.10)

At 6 weeks post treatment, bleeding persisted in 11.47% of patients in sclerotherapy group & 1.96% patients in rubber band ligation group. Persistent prolapse was present in a significant number of patients in both groups. Other symptoms like discomfort discharge and pruritus / irritation persisted in 13.51% patients in the sclerotherapy group and 2.5% of patients in rubber band ligation group. There was statistically significant difference in improvement of symptoms between the treatment groups at 6 weeks follow up for all the symptoms.

Patient assessment at 6 weeks (Table 11 and Fig.11)

After completion of 6 weeks followup 9.23% of patients in sclerotherapy group and 4.67% patients in rubber band ligation group felt no relief from symptoms. 40% of patients in rubber band ligation group and 60% of patients in sclerotherapy group felt symptomatically better. Similarly, 30.77% patients of sclerotherapy group, and 55.33% patients of rubber band ligation group had excellent symptomatic relief. The difference in symptomatic relief experienced between these two groups was significant with rubber band ligation faring better than sclerotherapy group ('p' value = 0.04).

Proctoscopic assessment at 6 weeks follow up (Table 12 and Fig.12)

After completion of 6 weeks follow up, incomplete clinical response was seen in 53.85% patients in sclerotherapy and 35.38% patients in rubber band ligation group. Complete response was seen in 46.15% of patients in sclerotherapy and 64.62% patients in rubber band ligation group. Rubber band ligation shows significantly better clinical response as compared to sclerotherapy ('p' value = 0.022).

Symptomatic responses at 9 weeks follow up (Table 13,13A and Fig.13)

At 9 weeks post treatment, bleeding persisted in 8.19% patients in sclerotherapy group and 1.96% patients in Rubber band ligation group. Persistent prolapse was present in a significant number in sclerotherapy group. Other symptoms like discomfort, discharge and pruritus / irritation persisted in 8.11% and 2.50% of patients in the sclerotherapy and rubber band ligation group respectively. There was statistically significant difference in improvement of symptoms between the two treatments groups at 9 weeks follow up.

Patient assessment at 9 weeks (Table 14 and Fig.14)

After completion of 9 weeks follow up 7.69% of patients in sclerotherapy group and 1.53% patients in rubber band ligation group felt no relief from symptoms. 33.85% of patients in rubber band ligation group and 50.76% of patients in sclerotherapy group felt symptomatically better. Similarly 41.55% of sclerotherapy and 64.61% of rubber band ligation group had excellent symptomatic relief. The difference in symptomatic relief experienced between the two groups was significant ('p' value = 0.032).

Proctoscopic assessment at 9 weeks follow up (Table 15 and Fig.15)

After completion of 9 weeks follow up, incomplete clinical response was seen in 38.46% and 18.46% of patients in sclerotherapy and rubber band ligation groups respectively. Complete response was seen in 61.54% patients in sclerotherapy and 81.54% in rubber band groups. Rubber band ligation shows significantly better clinical response as compared to sclerotherapy ('p' value = 0.023).

Improvement in symptoms over time:

It was found that all symptoms improved with time on follow up. Symptoms of discomfort, discharge, pruritus / irritation were the earliest to disappear and showed best response to treatment. Bleeding was slow to disappear in sclerotherapy group. Prolapse showed maximum improvement in Rubber band ligation group ('p' value = 0.03), but persisted in both groups even at 9 weeks follow up.

Intraoperative pain (Table 16):

All patients experienced some amount of pain during treatment which was expressed as a visual analogue scale (VAS) from 1 to 10. The mean VAS score was 4.45 ± 1.38 in the sclerotherapy and 5.29 ± 1.90 in the rubber band ligation group respectively. The difference between the two groups was not significant.

Number of treatment sessions (Table 17):

The mean number of treatment session was 1.172 ± 0.38 for sclerotherapy and 1.0312 ± 0.18 for rubber band ligation group.

The difference between the two groups was less significant ('p' values = 0.126).

Table 1: Distribution of patients in treatment Groups

Group	No. of Patients	Percentage %
Sclerotherapy	65	50.00
Rubber band ligation	65	50.00
Total	130	100.00

Fig.1 Distribution of patients in treatment Groups

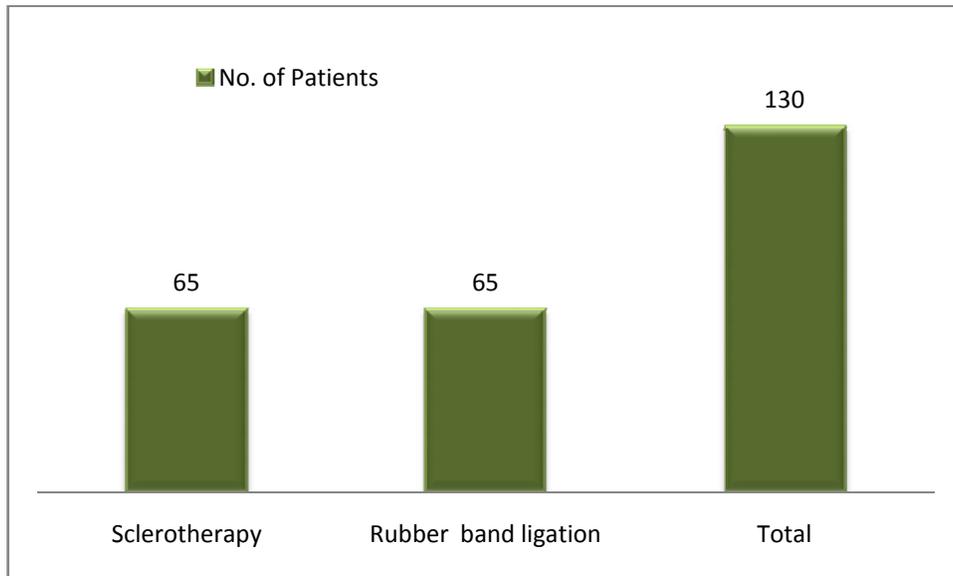


Table 2: Age Distribution among patients (years)

Age (years)	Frequency	Percentage %
21-30	20	15.38
31-40	21	16.15
41-50	40	30.76
51-60	26	20.00
61-70	21	16.18
71-80	2	1.53
Total	130	100.00

Fig.2 Age Distribution among patients (years)

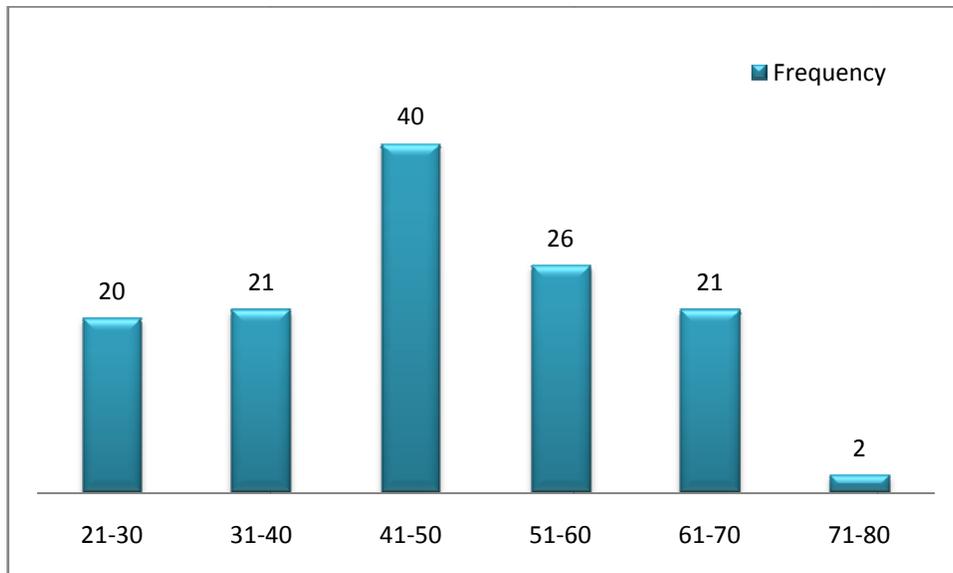


Table 3: Occupation

Occupation	Total no.of Patients	Percentage %
Manual labourers	53	40.77
Predominantly standing	37	28.46
Predominantly sitting	40	30.77
Total	130	100.00

Fig.3 Occupation

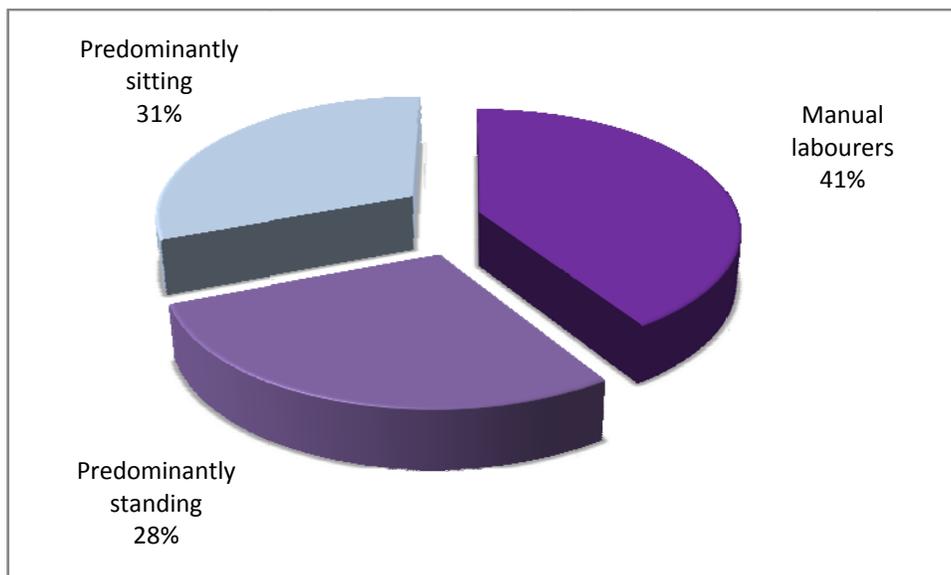


Table 4: Bowel Habits

Bowel Habits	Total no.of Patients	Percentage %
Normal	44	33.84
Diarrhoea	0	0
Constipation	86	66.16
Total	130	100.00

Fig.4 Bowel Habits

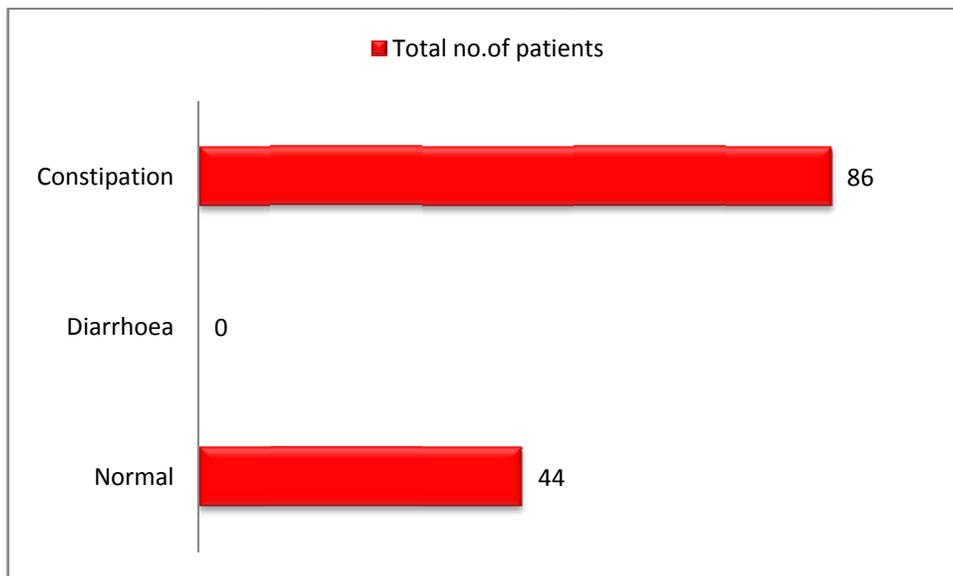


Table 5: Presenting Symptoms

Presenting symptoms	Total no.of Patients	Percentage %
Bleeding	112	86.15
Prolapse	93	71.53
Discomfort	26	20.00
Discharge	18	13.84
Pruritus / irritation	33	25.38

Fig.5 Presenting symptoms

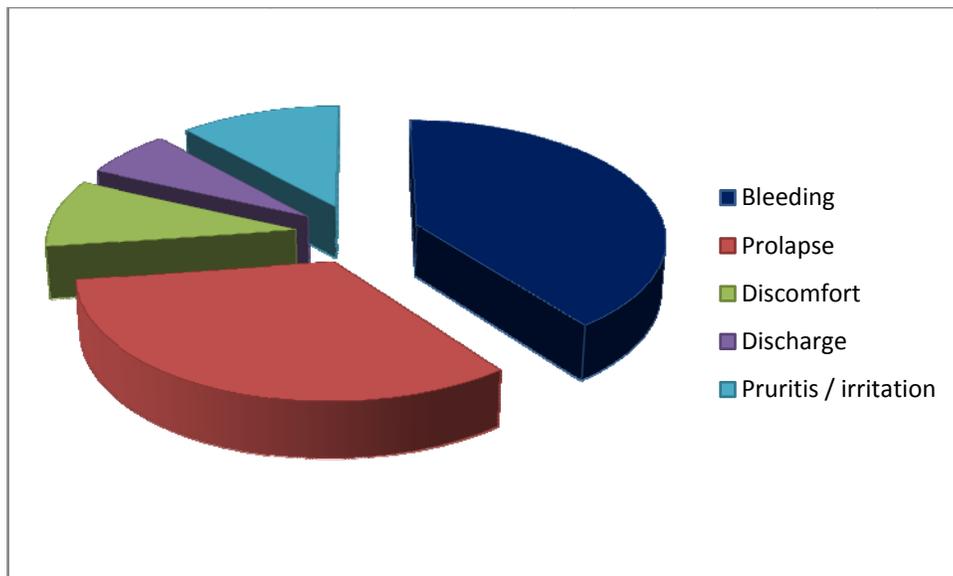


Table 6: Site of Haemorrhoids

Site Haemorrhoids	Total no.of Patients	%
11 O'clock	93	71.53
3 O'clock	58	44.61
7 O'clock	47	36.15

Fig.6 Site of Haemorrhoids

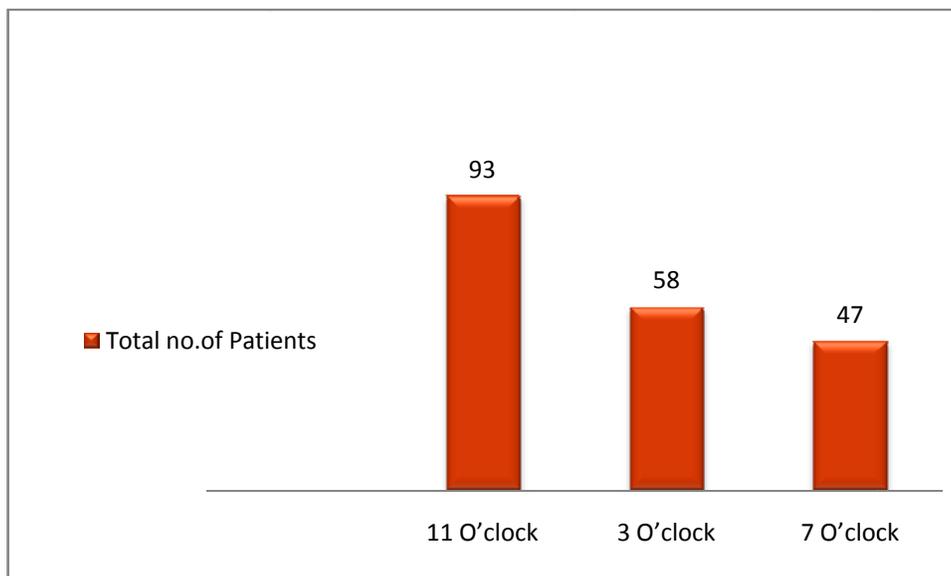


Table 7: Persistence of symptoms at 3weeks follow up

symptoms	Sclerotherapy		Rubber band ligation	
	No	%	No	%
Bleeding	8/61	13.11%	3/51	5.88%
Prolapse	28/49	57.14%	13/44	29.54%
Others	6/37	16.21%	2/40	5%

Others – Discomfort, Discharge, Pruritus / Irritation

Fig.7 Persistence of symptoms at 3weeks follow up

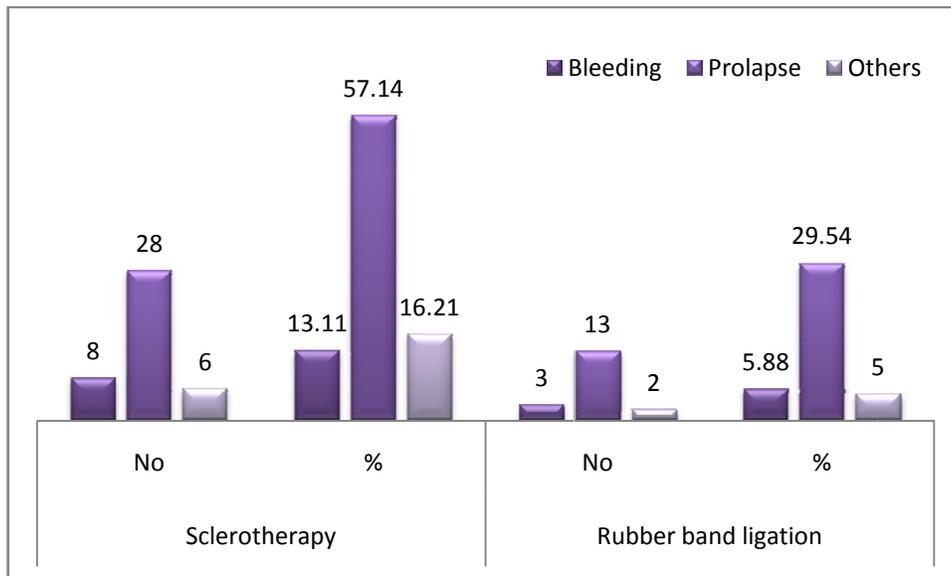


Table 7A: Test of significance between the study groups

Symptoms	'p' Value
Bleeding	0.02
Prolapse	0.015
Others	0.017

Table 8: Patients Assessment of symptomatic relief at the end of 3 weeks

Symptomatic relief	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Same	17	26.15%	5	7.69%	22	16.95%
Better	43	66.15%	51	78.46%	94	72.31%
Excellent	5	7.69%	9	13.84%	14	10.77%
Total	65	100%	65	100%	130	100%

Test of significance 'p' Value = 0.04

Better: Patients who had improvement of symptoms

Excellent: Patients who were completely asymptomatic

Same: Patients who had persistence of symptoms without any improvement

Fig.8 Patients Assessment of symptomatic relief at the end of 3 weeks

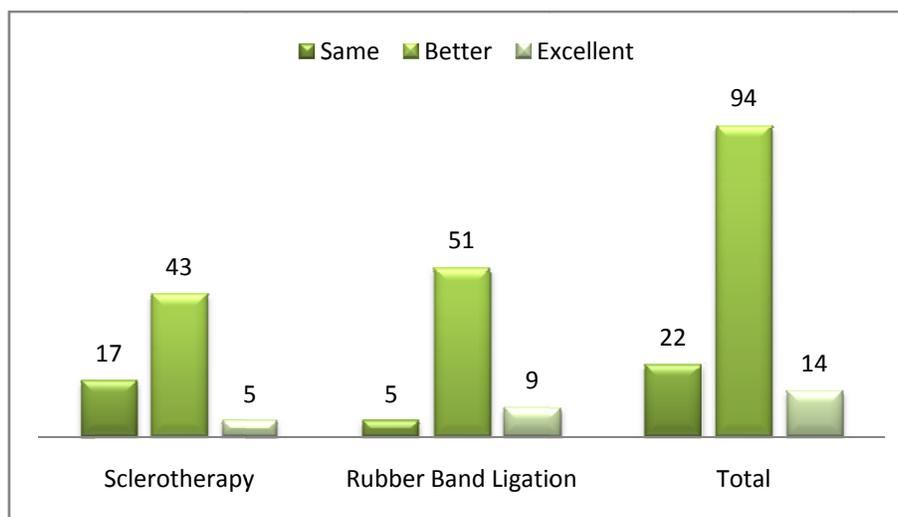


Table 9: Clinical Response in patients at the end of 3 weeks follow up

Observed response	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Incomplete	60	92.30	54	83.07	114	87.69
Complete	5	7.70	11	16.93	16	12.31
Total	65	100	65	100	130	100

Test of significance 'p'Value =0.026

Incomplete response: Any haemorrhoids persisting after the treatment.

Complete response: All haemorrhoids disappeared after treatment.

Fig.9 Clinical Response in patients at the end of 3 weeks follow up

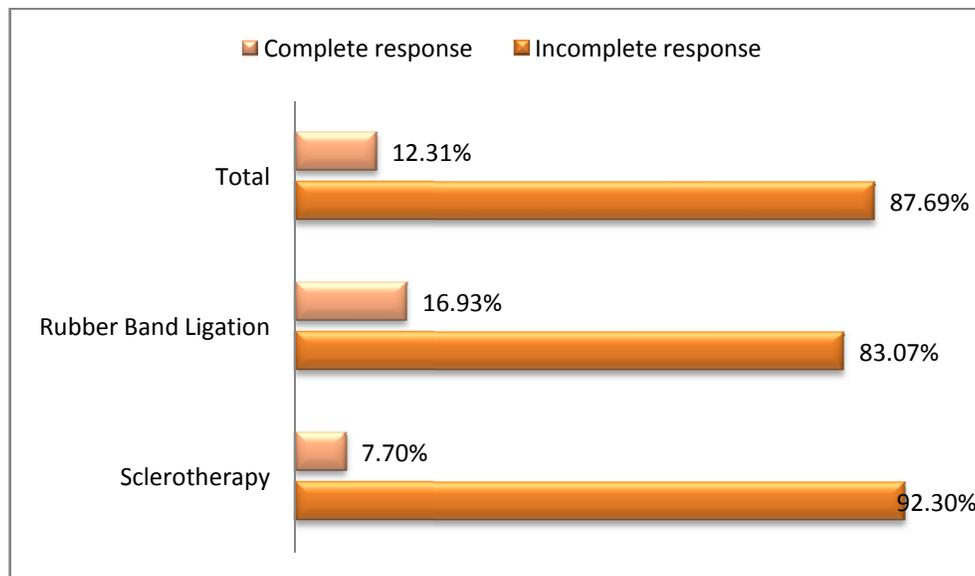


Table 10: Persistence of Symptoms at 6 weeks follow up

Symptoms	Sclerotherapy		Rubber band ligation	
	No	%	No	%
Bleeding	7/61	11.47	1/51	1.96
Prolapse	25/49	51.02	6/44	13.63
Others	5/37	13.51	1/40	2.50

Others – Discomfort, Discharge, Pruritus / Irritation

Fig.10 Persistence of Symptoms at 6 weeks follow up

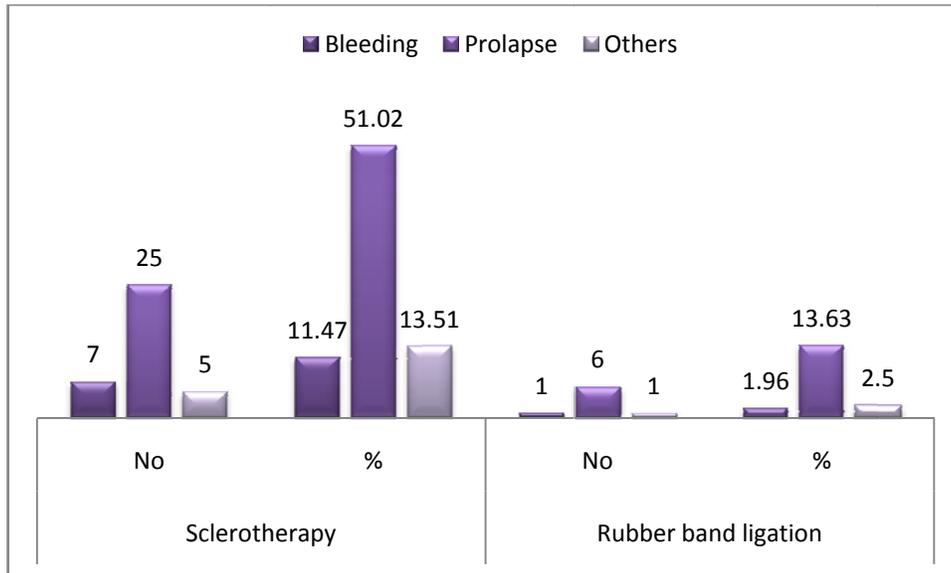


Table 10A: Test of significance of improvement of symptoms at the end of 6 weeks of followup between the two study groups

Symptoms	'p' Value
Bleeding	0.02
Prolapse	0.015
Others	0.02

Table 11: Patients assessment of symptomatic relief at the end of 6 weeks follow up

Symptomatic relief	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Same	6	9.23	3	4.67	9	6.93
Better	39	60	26	40	65	50
Excellent	20	30.77	36	55.33	56	43.07
Total	65	100	65	100	130	100

Test of significance 'p' Value = 0.04

Better: Patients who had improvement of symptoms

Excellent: Patients who were completely asymptomatic

Same: Patients who had persistence of symptoms without any improvement

Fig.11 Patients assessment of symptomatic relief at the end of 6 weeks

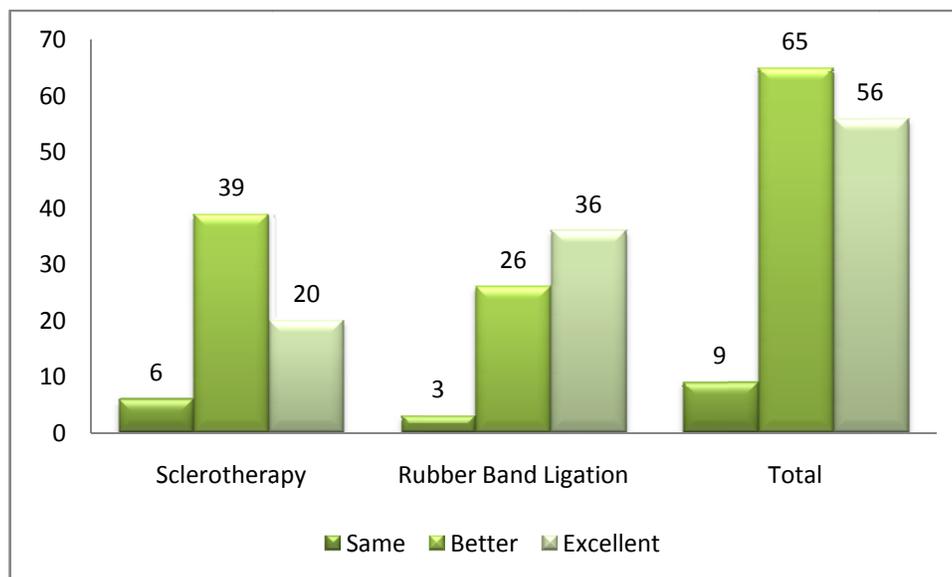


Table 12: Clinical response in patients at the end of 6 weeks follow up

Observed Response	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Incomplete	35	53.85	23	35.38	58	44.61
complete	30	46.15	42	64.62	72	55.39
Total	65	100	65	100	130	100

Test of significance 'p' Value = 0.022

Incomplete response: Any haemorrhoids persisting after the treatment.

Complete response: All haemorrhoids disappeared after treatment.

Fig.12 Clinical response in patients at the end of 6 weeks follow up

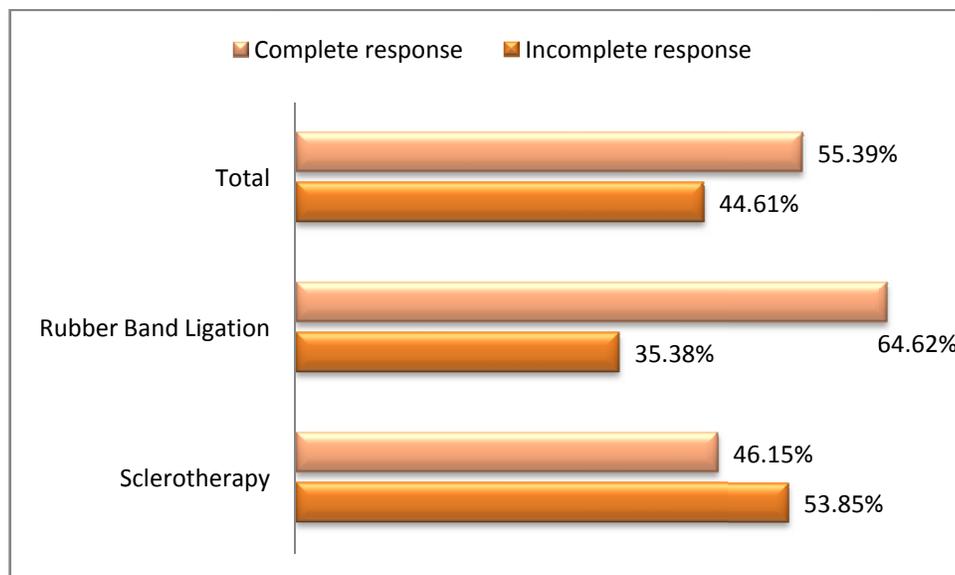


Table 13: Persistence of symptoms at 9 weeks follow up

Response	Sclerotherapy		Rubber Band Ligation	
	No.	%	No.	%
Bleeding	5/61	8.19	1/51	1.96
Prolapse	16/49	32.65	4/44	9.09
Others	3/37	8.11	1/40	2.50

Fig .13 Persistence of symptoms at 9 weeks follow up

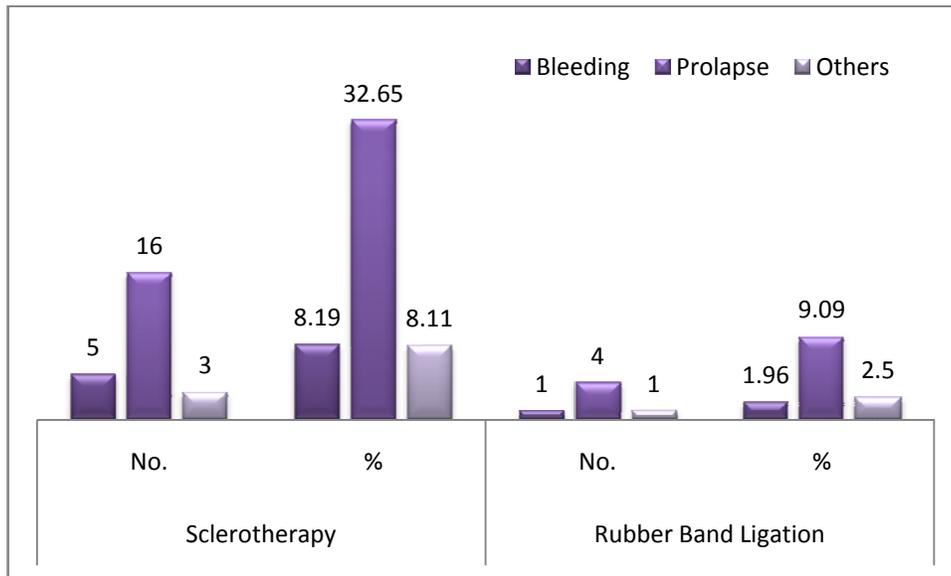


Table 13A: Test of significance of improvement of symptoms at the end of 9 weeks of followup between the two study groups

Symptoms	'p'Value
Bleeding	0.01
Prolapse	0.043
Others	0.02

Table14: Patient assessment of symptomatic relief at the end of 9 weeks follow up

Symptomatic relief	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Same	5	7.69	1	1.53	6	4.61
Better	33	50.76	22	33.85	55	42.31
Excellent	27	41.55	42	64.61	69	53.08
Total	65	100	65	100	130	100

Test of significance 'p'Value = 0.032

Better: Patients who had improvement of symptoms

Excellent : Patients who were completely asymptomatic

Same : Patients who had persistence of symptoms without any improvement

Fig.14 Patient assessment of symptomatic relief at the end of 9 weeks follow up

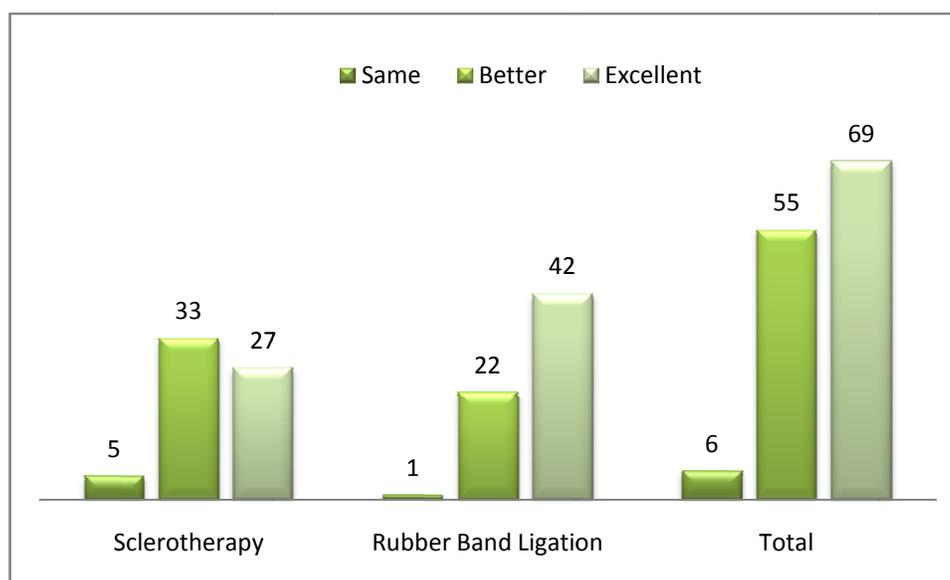


Table 15: Clinical response in patients at the end of 9 weeks follow up

Observed response	Sclerotherapy		Rubber band ligation		Total	
	No	%	No	%	No	%
Incomplete	25	38.46	12	18.46	37	28.46
Complete	40	61.54	53	81.54	93	71.54
Total	65	100	65	100	130	100

Test of significance 'p' Value = 0.023

Incomplete response : Any haemorrhoids persisting after the treatment

Complete response : All haemorrhoids disappeared after treatment

Fig.15 Clinical response in patients at the end of 9 weeks followup

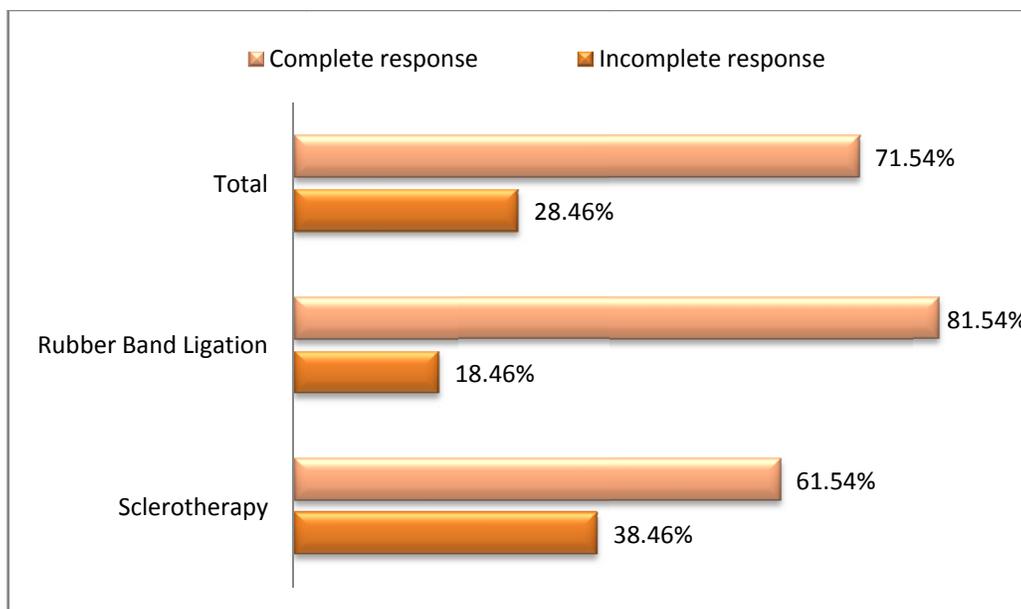


Table 16: Intra operative Pain – Visual Analogue Scores

Patient Group	No. of Patients	Minimum	Maximum	Mean±SD
Sclerotherapy	65	2	9	4.45±1.90
Rubber band ligation	65	1	10	5.29±1.90
Total	130	1	10	4.88±1.95

Test of significance 'p' Value = 0.124

Table 17: No. of treatment sessions

Treatment group	Mean no. of sessions±SD
Sclerotherapy	1.172±0.38
Rubber band ligation	1.0312±0.18

Test of significance 'p' Value = 0.126

DISCUSSION

Our study had patients with age ranging from 18 years to 73 years with the highest frequency between 41-50 years. Johansson et al. reported a similar pattern of age distribution in their study of prevalence of haemorrhoids ³. Presence of haemorrhoids in patients aged less than 20years was unusual and highest frequency was reported between 45-65years by them (Table 2).

Hyams and Philpot found that prevalence rate increased with age but tapered off over 70². Haas et al. in their study of 594 patients with symptomatic haemorrhoids found that prevalence of haemorrhoids was higher only after 30 years of age but no significant difference was found between age groups⁴.

There were 102 men (78.46%) and 28 women (21.54%) in our study (Fig.1). Keighley et al. found similar sex distribution with 154 men and 62 women in his study ²⁹.

30.77% patients in our study had occupation involving predominantly sitting throughout the day, 28.46% worked mainly standing and 40.77% were manual labourers (Table 3, Fig.3).

Prasad et al. reported highest frequency of haemorrhoids in two classes of people, those who perform hard physical work and those doing clerical jobs (28%). This is comparable with our study.

In our study, 67.69% of patients were in the habit of taking predominantly vegetarian diet, 42.31% with low fibre content and 17.69% with high fibre content. Another 32.30% were taking predominantly nonvegetarian diet, 21.54% with high fibre and 11.53% with low fibre.

Burkitt et al. reported a higher prevalence of hemorrhoids in American Negroes compared to native African population who ate predominantly cereal-based high fibre diet ²⁵.

Another study comparing various ethnic populations eating diets consisting of varied dietary fibre reported less intestinal transit time and more stool weight in patients taking more dietary fibre, which they felt leads to less constipation and hence lesser risk of developing haemorrhoids ⁸.

In the present study of ours, there was evidence of 66.16% of patients having constipation and 33.84% of patients had normal bowel habits (Table 4, Fig.4).

Johansson et al. had questioned the role of constipation in pathogenesis of haemorrhoids because the age distribution pattern for occurrence of haemorrhoids and constipation were dissimilar³.

We found that bleeding per rectum was the predominant symptom (86.15%) followed by prolapse (71.53%)pruritus/irritation (23.38%), discomfort (20%) and discharge (13.84%) (Table 5, Fig.5).

Prabhakar et al. reported incidence of complaints as follows, Bleeding (70%), prolapse (27%), itching (25%), mucus discharge (23%) and pain (23%)¹⁸.

Greca et al. reported symptoms of bleeding (87.80%), prolapse (75.60%), discharge (48.78%) and discomfort (57.3%) in 82 patients¹³.

Responses at 3 weeks follow up:

Patients who received sclerotherapy were found to have significantly higher persistence of bleeding and prolapse at 3 weeks when compared to rubber band ligation group 'p' value for bleeding was 0.02 andfor prolapse was 0.015 respectively. (Table 7,7A and Fig.7).

Significantly more number of patients in the Rubber band ligation group had excellent symptomatic relief on patient assessment when compared to sclerotherapy group ('p' = 0.04)(Table 8, Fig.8).

Shrinkage of haemorrhoids was also significantly less in sclerotherapy group as compared to rubber band ligation group (p= 0.026)(Table 9, Fig.9).

It was therefore seen that sclerotherapy is slower to give symptomatic relief of bleeding and prolapse compared to rubber band ligation.

The persistence of symptoms in patients at 3 weeks follow up seemed to correlate well with the observed clinical response at the same interval and with the patient assessment of symptomatic relief.

These results were comparable with Gartell et al. randomized clinical trial comparing rubber band ligation with injection sclerotherapy at 6 weeks interval which reported higher success rate for rubber band ligation compared to sclerotherapy with symptoms of bleeding and prolapse being significantly higher in sclerotherapy treatment group ⁴⁷.

Responses at end of 6 weeks follow up:

At 6 weeks post treatment, bleeding and prolapse persisted in 11.47% and 51.02% of patients in sclerotherapy group, other symptoms like discomfort, discharge and pruritus / irritation persisted in 13.51% patients in the sclerotherapy group. There was statistically significant difference in improvement of symptoms between the treatment groups ($p=0.02$) (Table 10,10A and Fig.10)

About 30.77% patients of sclerotherapy group and 55.33% patients of rubber band ligation group had excellent symptomatic relief. The difference in symptomatic relief experienced between these two groups was significant with rubber band ligation faring better than sclerotherapy group ('p' value = 0.04) (Table 11, Fig.11)

After completion of 6 weeks follow up, complete response was seen in 46.15% of patients in sclerotherapy and 64.62% patients in rubber band ligation group. Rubber band ligation shows significantly better clinical response as compared to sclerotherapy ('p' value = 0.022) (Table 12, Fig.12)

Responses at end of 9 weeks follow up:

At the end of 9 weeks follow up, Only one patient in rubber band ligation had persistence of bleeding and other symptoms like discharge, discomfort, pruritus/irritation, compared to 5 patient in sclerotherapy group. Prolapse however persisted in 16 in sclerotherapy and 4 in rubber band ligation group. There was a significant difference in persistence of symptoms in the two groups at 9 weeks (Table 13,13A and Fig.13).

Patient assessment of treatment showed that significantly more patients felt better relief with rubber band ligation compared to sclerotherapy (p=0.032)

Choi et al. in their long-term follow up trial of combination treatment alone for internal haemorrhoids reported patient response as excellent in 54%, good in 21% and fair in 10% ¹⁶. Another 15% of patients had unsatisfactory results.

The observed clinical response was complete in only 61.54% and 81.54% in sclerotherapy and rubber band ligation group respectively. This response was significantly lower in sclerotherapy group compared to rubber band ligation group (p = 0.023)(Table 15, Fig.15)

It is therefore clear that disappearance of haemorrhoids is not necessary for symptomatic relief except perhaps in case of prolapse. Predominantly prolapsing haemorrhoids may therefore be better treated by surgery.

Prabhakar et al.¹⁸ in their prospective randomized comparative study of injection sclerotherapy and rubber band ligation and in 30 patients of second degree internal haemorrhoids at 6 months follow up tabulated as:

	Change	Better	Relieved
Sclerotherapy	30%	20%	50%
Rubber band ligation	9%	27%	64%

The number of patients who had shown improvement or who were asymptomatic at the end of follow up in two treatment groups in both studies were comparable.

Intraoperative pain:

Both the modalities of treatments were associated with some amount of intraoperative pain as measured on visual analogue scale. However, no significant difference in the VAS scores between treatment groups (4.45 ± 1.38 and 5.29 ± 1.90) (Table 16).

Prabhakar et al. too reported incidence of pain 28.5% and 34.5% in patients belonging to sclerotherapy and rubber band ligation groups respectively¹⁸.

Number of treatment sessions:

The number of treatment needed for sclerotherapy (1.172 ± 0.38) was less significant compared to rubber band ligation (1.0312 ± 0.18)(Table 17). In contrast, number of treatment sessions was significantly higher in the trial by Prabhakar et al.¹⁸ where the average number of sessions ranged from one to four with a median of 2.5.

Greca et al. had a mean of 1.121 sessions for rubber band ligation and 1.05 for sclerotherapy respectively¹³.

CONCLUSIONS

In comparison of rubber band ligation and sclerotherapy, we found out that all the symptoms of haemorrhoids showed improvement over the course of 9 weeks in both treatment groups. Due to the slower improvement of bleeding in patients with sclerotherapy group compared to rubber band ligation, patients with significant bleeding due to haemorrhoids maybe better treated by rubber band ligation to give quicker relief. However patients in both groups had excellent symptomatic relief even in the presence of prolapse, hence complete disappearance of prolapse is not a prerequisite for symptomatic relief. Both the modalities were not found to have significant effect on treating prolapse, hence patients with prolapse as the main presenting symptom may have surgery as an initial treatment option.

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PROFORMA

Name :

Age :

Sex :

OP No. :

Complaints

Bleeding

Relation to motion

Duration

Prolapse

Discomfort

Irritation

Bowel habits

Dietary habits

DIGITAL RECTAL EXAMINATION & PROCTOSCOPY

Pile mass

Fistula/ Fissure

Investigations

Hb %

Blood Urea

Tc

Sugar

DC

Serum creatinine

FOLLOW UP

After 3 weeks

After 6 weeks

After 9 weeks

MASTER CHART

S. No	Name	Age	Sex	Symptoms	Treatment Given	Symptomatic relief Attained At (Weeks)	Complete Response Attained At (weeks)
1	Chinna samy	24	M	P,O	SCL	-	-
2	Saravanan	52	M	B,P	RBL	6	6
3	Subbiah	35	M	B,P	SCL	6	6
4	Palaniammal	67	F	B,P,O	RBL	3	3
5	Ramasamy	26	M	P,O	SCL	3	3
6	Mariammal	43	F	B,P	RBL	-	-
7	Ibrahim	25	M	B,P	SCL	-	-
8	Rajkanna	44	M	B,O	RBL	6	6
9	Vellaiyammal	54	M	B,O	SCL	-	-
10	Sathyaraj	46	M	B,O	RBL	9	9
11	Rajapalani	47	M	B,P	SCL	-	-
12	Rajammal	21	F	P,O	RBL	6	3
13	Rasappa	38	M	B,P	SCL	-	-
14	Karuppan	41	M	B,O	RBL	6	6
15	Noorammal	27	F	B,P	SCL	-	-
16	Surya	62	M	B,O	RBL	9	9
17	Kavitha	29	F	B,P	SCL	6	6
18	Vivek	43	M	B,O	RBL	3	3
19	Palpandi	47	M	B,P,O	SCL	-	-
20	Sudha	54	F	B,P,O	RBL	6	6
21	Kutty	32	M	B,P	SCL	-	-
22	Radha	24	F	B,O	RBL	6	6
23	Magesh	63	M	B,P	SCL	-	-

24	Velammal	55	F	B,P	RBL	6	6
25	Lakshmi	22	F	P,O	SCL	-	-
26	Kannan	34	M	B,O	RBL	-	-
27	Abdulla	48	M	B,O	SCL	3	3
28	Durai	39	M	B,P	RBL	9	6
29	Rangammal	69	F	B,P,O	SCL	9	6
30	Karupayee	56	F	B,P,O	RBL	6	6
31	Sivakumar	49	M	P,O	SCL	9	6
32	Rajeshwari	34	F	B,P	RBL	6	6
33	Vijay	41	M	B,O	SCL	-	-
34	Selvaraj	64	M	B,P	RBL	9	9
35	Rajan	43	M	B,P,O	SCL	-	-
36	Muthu lakshmi	34	F	B,O	RBL	6	6
37	Nirmal	42	M	B,O	SCL	-	-
38	Vinoth	33	M	B,P	RBL	3	3
39	Marimuthu	57	M	B,P,O	SCL	6	6
40	Murugesan	65	M	B,P	RBL	6	6
41	Seemaisamy	66	M	P,O	SCL	-	-
42	Paulsamy	46	M	B,P,O	RBL	6	6
43	Ganesan	56	M	B,O	SCL	6	6
44	Manoharan	28	M	B,O	RBL	3	3
45	Ayyavu	67	M	P,O	SCL	-	-
46	Govindhasamy	47	M	B,O	RBL	6	6
47	Salamon	27	M	B,P	SCL	-	6
48	Mookiah	74	M	B,P	RBL	3	3
49	Ismail	62	M	B,P	SCL	-	-
50	Muthusamy	51	M	B,P	RBL	6	6
51	Syed	61	M	P,O	SCL	6	6
52	Saroja	54	F	B,P	RBL	3	3

53	Kumar	48	M	B,O	SCL	6	6
54	Murugan	21	M	B,O	RBL	6	6
55	Karuppan	31	M	P,O	SCL	9	9
56	Muthukumar	68	M	B,P	RBL	-	-
57	Menaha	23	F	B,O	SCL	3	3
58	Siva	46	M	B,P,O	RBL	-	-
59	Ravi	47	M	B,P	SCL	6	6
60	Ramnath	55	M	B,P	RBL	-	-
61	Nallasamy	61	M	B,P	SCL	-	-
62	Rajathy	58	F	B,P,O	RBL	6	6
63	Unellamuthu	32	M	B,P,O	SCL	9	6
64	Nachiappan	44	M	B,O	RBL	9	9
65	Muthu	28	M	B,P	SCL	6	6
66	Seetha lakshmi	54	F	P,O	RBL	3	3
67	Muthuiah	67	M	B,O	SCL	-	-
68	Selvakumar	46	M	B,O	RBL	6	6
69	Vimal	47	M	B,P	SCL	6	6
70	Prem	44	M	B,P	RBL	9	9
71	Maheswari	68	F	B,P	SCL	-	-
72	Rani	39	F	B,O	RBL	6	6
73	Karthikeyan	41	M	B,P	SCL	9	6
74	Rajendran	32	M	B,O	RBL	6	6
75	Rajesh	51	M	B,O	SCL	-	-
76	Sageetha	42	F	P,O	RBL	9	9
77	Mohan	24	M	B,P	SCL	6	6
78	Samuels	35	M	B,P,O	RBL	6	6
79	Chandran	44	M	B,P,O	SCL	-	-
80	Sundhar	49	M	B,P	RBL	6	6

81	Pandi	21	M	P,O	SCL	6	6
82	Valli	62	F	B,O	RBL	6	6
83	Periyasamy	55	M	B,P	SCL	-	-
84	Rajkumar	22	M	B,O	RBL	9	9
85	Balamurugan	65	M	P,O	SCL	-	-
86	Nisha	41	F	B,P,O	RBL	3	3
87	Mariappan	56	M	B,P,O	SCL	-	-
88	Ravikanna	24	M	B,P	RBL	6	6
89	Sarath Babu	63	M	B,P	SCL	6	6
90	Nagaraj	42	M	B,P	RBL	9	9
91	Chinnasamy	44	M	P,O	SCL	3	3
92	Manonmani	72	F	B,P	RBL	9	9
93	Ponnan	25	M	B,P	SCL	-	-
94	Karthik	39	M	B,O	RBL	3	3
95	Backiaraj	57	M	P,O	SCL	6	6
96	Rajangam	64	M	B,P	RBL	6	6
97	Akila	41	F	B,P,O	SCL	-	-
98	Rajendran	49	M	B,P,O	RBL	6	6
99	Tamilselvan	21	M	B,P	SCL	3	3
100	Raja	49	M	B,P	RBL	9	-
101	Raghavan	46	M	B,P	SCL	-	-
102	Babu	67	M	B,P,O	RBL	6	6
103	Krishnan	21	M	B,O	SCL	6	6
104	Saritha	52	F	B,P	RBL	6	6
105	Vinayagam	31	M	P,O	SCL	-	9
106	Vijayan	45	M	B,P	RBL	6	-
107	Gururaj	60	M	B,P,O	SCL	6	6
108	Devendran	33	M	B,P	RBL	9	6
109	Baskaran	54	M	B,O	SCL	-	-

110	Parthiban	58	M	B,O	RBL	6	6
111	Meena	57	F	B,P	SCL	9	6
112	Balan	37	M	B,O	RBL	6	3
113	Mani	52	M	B,O	SCL	6	6
114	Rakkan	44	M	P,O	RBL	9	9
115	Meenakshi	38	F	B,P	SCL	-	-
116	Manoj	45	M	B,O	RBL	6	6
117	Subramani	61	M	B,P,O	SCL	6	6
118	Sharath	46	M	B,P	RBL	9	9
119	Rathinam	56	M	B,P,O	SCL	-	-
120	Ravindran	31	M	B,P	RBL	9	9
121	Moorthi	47	M	B,P	SCL	9	6

122	Mahendran	54	M	B,O	RBL	6	6
123	Ahamed	48	M	P,O	SCL	-	-
124	Murali	34	M	B,P	RBL	6	9
125	Alex	54	M	B,P	SCL	-	-
126	Boopathy	49	M	B,O	RBL	9	9
127	Senthil	49	M	B,O	SCL	-	-
128	Sandeep	33	M	B,P,O	RBL	6	9
129	Shankar	51	M	B,P,O	SCL	-	-
130	Tamilselvan	55	M	B,P	RBL	-	-

B - Bleeding
P - Prolapse
O - Others

SCL - Sclerotherapy
RBL - Rubber Band Ligation

M - Male
F - Female