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A COMPARATIVE EXAMINATION OF BAND LIGATION, CRYOTHERAPY, STAPLER, AND OPEN HAEMORRHOIDECTOMY IN INTERNAL HEMORRHOIDS

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ABSTRACT

Background: Haemorrhoids are normal, vascular tissue within the submucosa located in the anal canal. They are typically located in the left lateral, right anterior, and right posterior quadrants of the canal. “Despite a long medical history of identification and treatment, haemorrhoids still pose a challenge to the medical fraternity in terms of finding satisfactory cure of the disease.” There are various modalities of treatment of haemorrhoids available at present. This study is intended to find out the overall best solution for the patient.

Objective: To study and compare cryosurgery, band ligation, Stapler and open haemorrhoidectomy in internal haemorrhoids in terms of:Cost effectiveness, Complication, Hospital stay, Patient comfort, Pain, Cosmesis.

Methods: The study group comprises of patients with complains of bleeding per rectum and on examination diagnosed to be having internal haemorrhoids, admitted in department of General surgery at SS Institute of Medical Sciences & Research Centre, Davangere from August 2022 to June 2024. Patients who are coming to Out Patient Department with complaints of bleeding per rectum or mass per rectum are subjected for detailed history taking which includes symptoms and duration of disease. According to severity and type of symptoms, patients are subjected for open haemorrhoidectomy, banding, stapler and cryosurgery based on simple random sampling. Cost effectiveness, Hospital stay, patient comfort, pain and cosmesis are considered. Complications like infection, excessive bleeding and stenosis are noted.

Results: Bleeding per rectum was the most common presenting complaint present in 66.25% of subjects followed by mass per rectum present in 47.5% of subjects.The duration of the stay in hospital was least for Cryo probe followed by band ligation. Patients with open haemorrhoidectomy stayed for longer duration.Complications were seen maximum in the open group with pain being the most common complication across other groups except in the cryo group where bleeding and discharge were more common than the pain. Stapler haemorrhoidopexy had least post op

complications among the four
Conclusions: Open Hemorrhoidectomy had post operative complications till post-op day 7 but were easily managed by analgesics and sitz bath and was most cost-effective with zero recurrence.Rubber band ligation and Cryotherapy had less postoperative complications by the end of day 7 and were cost-effective however recurrence is a complication seen higher than all other 2 groups.Stapler haemorrhoidopexy was costliest of all the four groups without significant improvement in post operative complications and recurrence as compared to other 3 groups.

Introduction

The word "haemorrhoid" is derived from the Greek haema (blood) and rhoos (flowing), and it was probably Hippocrates (460 BC) who was the first to apply the name to the flow of blood from the veins of the anus. The term "piles" is derived from the Latin “pila” (a ball) and was widely used by the public at the time of John of Arderne (born AD 1307), and in his treatise of 1370 he remarks that the "common people call them piles, the aristocracy call them haemorrhoids, the French call them figs (figer, to clot), what does it matter so long as you can cure them"[1]
Invasive Treatment Principles:Three broad methods have developed in parallel with each one relating to a hypothesis such as:

- Prevention of prolapse by mucosal fixation.
- Prevention of congestion or venous impedance by stretching or by sphincterotomy.
- Excision of the engorged vascular cushions. Some methods like cryosurgery combine mucosal fixation and tissue destruction.

OPEN HAEMORRHOIDECTOMY

It is practiced most frequently in UK as the Milligan-Morgan operation[2] usually under spinal or general anaesthesia in lithotomy position.
Technique-The skin covered component of each of the main piles is held with artery forceps and retracted outwards, the purple anal mucosal component is grasped and drawn down and out. V-shaped incision is put in the anal and perianal skin and dissection is carried out to free the cushions off the internal sphincter for 1.5-2cms and the pedicle is then transfixed and ligated with either absorbable or non-absorbable suture. The isolated haemorrhoids is then excised a few mm below the apical ligature, the transfixation suture is left long.Adequate bridge of skin and mucosa should be left in between. The final wound, “if it looks like a clover the trouble is over, if it looks like a dahlia, it is surely a failure.” Conventionally a three “quadrant” haemorrhoidectomy is done but additional piles may be removed in a similar way. The anal canal is packed with paraffin wax impregnated gauze and dressings applied [3].

STAPLED HAEMORRHOIDOPEXY

Recently a modified circular stapler approach has been proposed for surgical management of haemorrhoids. The procedure for prolapsed haemorrhoids (PPH) was described initially by Longo in1998. It is based on the concept of occlusion of the superior and middle haemorrhoidal vessels and lifting of the prolapsed anorectal mucosa upwards and repositioning of the vascular cushions back into the anal canal which in turn causes the haemorrhoidal tissue to atrophy[4]. A modified 33 mm circular stapler is used to perform the stapled haemorrhoidopexy. This operation is carried out by the use of the PPH procedural setconsisting of a circular stapler, a suture threader a circular anal dilator, with a purse string suture anoscope.[5] The single greatest advantage of stapled haemorrhoidopexy is reduction in postoperative pain. The pain after PPH is described as Vague and dull and similar to tenesmus. Mehigan and co-workers prospectively randomized 40 patients to undergo PPH haemorrhoidopexy versus Milligan Morgan haemorrhoidectomy.[6] The average postoperative pain score from day zero to day ten significantly lesser in PPH and also patients had shorter hospital stay and a faster recovery to normal activity.

RUBBER BAND LIGATION

Produces fixations of mucosa by causing ulceration instead of a simple submucosal inflammation. Equipment–A number of instruments have been devised. The original Barron ligator gives the smoothest operation and is sturdy enough for frequent use. It is the most commonly used. The rubber O rings are 2-3mm and are loaded onto the 11mm inner drum. The McGiveny ligator is simpler and cheaper but less sturdy. Van Hoorn‟s banding equipment makes it a one-handed procedure using a 1.8 cm proctoscope with a large rubber band stretched over its tip. Thomson‟s device is a modified McGiveny applicator used along with a proctoscope. Others include the Preston gun and a complex multi-action machine popular in France. Recently ligating device attached to the end of a video endoscope has been Described.

Technique – It is better suited for 2nd or 3rd degree haemorrhoids. The base of the cushion lies between 1.5 and 2cms from the pecten and here the mucosal tissue can be grasped with forceps and drawn into a preloaded inner drum. A rubber band is discharged by pressing the trigger.

LIGATION Barron[7] recommended that only one ligation should be performed at each session paced at 3 weeks interval. Subsequent authors recommend two or even all three ligations at the same sitting. Some recommend the use of two bands at each site. Additional procedures include phenol injection into the strangulated tissue or freezing it.

CRYOSURGERY

The use of freezing temperature for the therapeutic destruction of tissue began in England in 1845 when James Arnott described the use of iced salt solution (about - 200c) to freeze advanced cancers of breast and cervix. In 1898 Campbell White in New York introduced Cryosurgery for the treatment of skin lesions using liquid air(-190C). Cryosurgery for haemorrhoids was started by Fraser and Gill and popularized by Lewis and Lloyd Williams.[8] Cryosurgery is a technique of freezing live human tissue. The great advantage of this is that it is painless, particularly suited for outpatient with no need for anaesthesia, no bleeding, can be repeated easily, applicable on high-risk patients also. Equipment – The fundamental principal of cryodestruction is that the living cells are first injured and then killed from the effects of freezing. Cell death is induced by combination cryobiological effects. Freezing produces local dehydration of tissues, denaturation of lipid protein complex of cell membranes, extra cellular ice crystal formation, membrane alteration and enzyme inhibition. Essential item is cryoprobe which can be cooled by circulation through it in liquid nitrogen or nitrous oxide gas. Liquid nitrogen produces a reduction of temperature to -180 0C as compared with -70 0C with nitrous oxide.

CRYOGEN BOILING POINT (0C) at ATM PRESSURE

Liquid nitrogen (-195.8) ,Nitrous oxide (liquid) (-89.5) ,Carbon dioxide (solid) (-78.5) ,Argon liquid (-185.7) ,Freon 22 (-40.8) ,Freon 12 (-29.8) .

Application of cryoprobe- In cryosurgery, most widely used gas is Nitrous oxide which is allowed to expand through a small orifice. The effectiveness of cryoprobe depends upon rapid and sustained conduction of heat away from tissues. The probe tip can be autoclaved or sterilized with formation of vapor. In this method application of single probe is in the long axis of the pile while nitrous oxide is circulated. Immediate active portion of probe develops white frost on its surface and become adherent to part of haemorrhoid. Gradually margin of tissue becomes white reaching maximum width of 6-7mm after 2minutes. Freezing should be continued for 3 minutes in total. When the flow of nitrous oxide stops it takes 10-12 sec before the frost on the surface of active end of instrument thawed. The tissue no longer remains adherent to it. So, in this way until the probe is freezes one should not attempt to withdraw it. The slough usually takes 2-3wks to separate leaving behind the granulating area which heals in another 2-3wks [9].

Materials and Methods: The study group comprises of patients with complains of bleeding per rectum and on examination diagnosed to be having internal haemorrhoids, admitted in department

of General surgery at SS Institute of Medical Sciences & Research Centre, Davangere from August 2022 to June 2024.

SAMPLE SIZE: Sample size is calculated by using the formula:

$$n = \frac{\{z1\sqrt{[2P(1-P)]} + z2\sqrt{[P1(1-P1) + P2(1-P2)]}\}^2}{(P1-P2)^2}$$

P1	Probability of variable in sample-1 (Value <1.0)	0.2*
P2	Probability of variable in sample-2 (Value <1.0)	0.04*
P	Arithmetic average of P1 & P2	0.12
AH	Alternate hypothesis ONE sided (1), or TWO sided? (2)	1
1-α	Set level of confidence (value<1.0). Usual values 0.95;0.99	0.9
1-β	Set level of power of test (value<1.0). Usual values 0.8;0.9	0.8
Z1	Z value associated with set level of alpha (One sided)	1.64
Z2	Z value associated with set level of beta	0.84
n1	Minimum sample size	4+0

Substituting the above values in the formula, sample size obtained is 40(20 per group).
Since there are 4 groups, total sample size is 20*4= 80
*Source: Shukla S et al. Randomised trial of open haemorrhoidectomy verses stapled haemorrhoidectomy for grade II, III haemorrhoids

INCLUSION CRITERIA:
Only internal haemorrhoids are included

EXCLUSIONCRITERIA:
- External haemorrhoids
- Recurrent haemorrhoids
- Secondary haemorrhoids.
- Haemorrhoids in pregnancy
- Haemorrhoids due to portal hypertension

Among the 100 patients who are diagnosed to be having internal haemorrhoids are randomly grouped into four categories of 25 patients each.
Group 1 Patients are subjected to open haemorrhoidectomy.
Group 2 Patients are subjected to banding.
Group 3 Patients are subjected to cryosurgery.
Group 4 Patients are subjected to stapler haemorrhoidectomy.

METHODOLOGY FOR DATA COLLECTION:
Patients who are coming to Out Patient Department with complaints of bleeding per rectum or mass per rectum are subjected for detailed history taking which includes symptoms and duration of disease. Then they are subjected to per rectal digital examination. Proctoscopy is done to find out the internal haemorrhoids and its degree and position. Systemic examination and basic investigation done. According to severity and type of symptoms, patients are subjected for open haemorrhoidectomy, banding, stapler and cryosurgery based on simple random sampling. Follow up of patients after treatment is done by history, per rectal examination and proctoscopy. Cost effectiveness, Hospital stays, patient comfort, pain and cosmesis were considered. Complications like infection, excessive bleeding and stenosis are noted.

Statistical Analysis:
SPSS (Statistical Package For Social Sciences) version 20. (IBM SPASS statistics [IBM corp. released 2011] will be used to perform the statistical analysis.Data will be entered in the excel spread sheet.
Descriptive statistics of the explanatory and outcome variables will be calculated by mean, standard deviation, median and IQR (based on data distribution) for quantitative variables, frequency and proportions for qualitative variables..
Inferential statistics like:
 Chi-square test will be applied for qualitative variables.
 ANOVA / Kruskal-Wallis test will be applied to compare the quantitative variables among the groups with post-hoc Bonferroni /Mann-Whitney test for inter group comparison.
The level of significance is set at 5%
 Any other necessary tests found appropriate will be dealt at the time of analysis based on data distribution.
Result: A total of 80 cases were enrolled in the department of general surgery across all different units at SS Institute of Medical Sciences during the study period. The age of the patient ranged from 26 to 67 years of which predominant age group was 41 to 50 years. Demographics of the study population are as follows:

TABLE 1. AGE DISTRIBUTION

Age in years	No. of Cases	Percentage
18-20	0	0
21-30	7	8.75
31-40	22	27.5
41-50	30	37.5
51-60	18	22.5
61-70	4	5
Average	45.175	100

GRAPH.1. AGE DISTRIBUTION
37.5% of the subjects were in the range of 41-50 years followed by 31 to 40 years who made up 27.5% of the total study population then 22.5% people were between 51-60 years. 5% people were in the range of 61-70 years and none of them were below 20 years. Average age of the subjects in our study is 45.17 years.

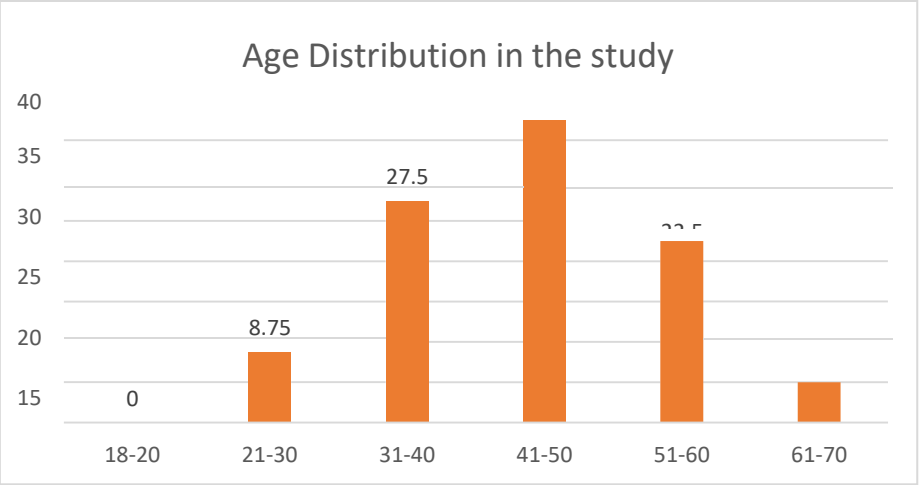


TABLE 2. GENDER DISTRIBUTIONS IN PRESENT STUDY:

Gender	No. of Cases	Percentage
Male	62	77.5
Female	18	22.5
Total	80	100

TABLE 3. GENDER DISTRIBUTION IN DIFFERENT TREATMENTMODALITIES:

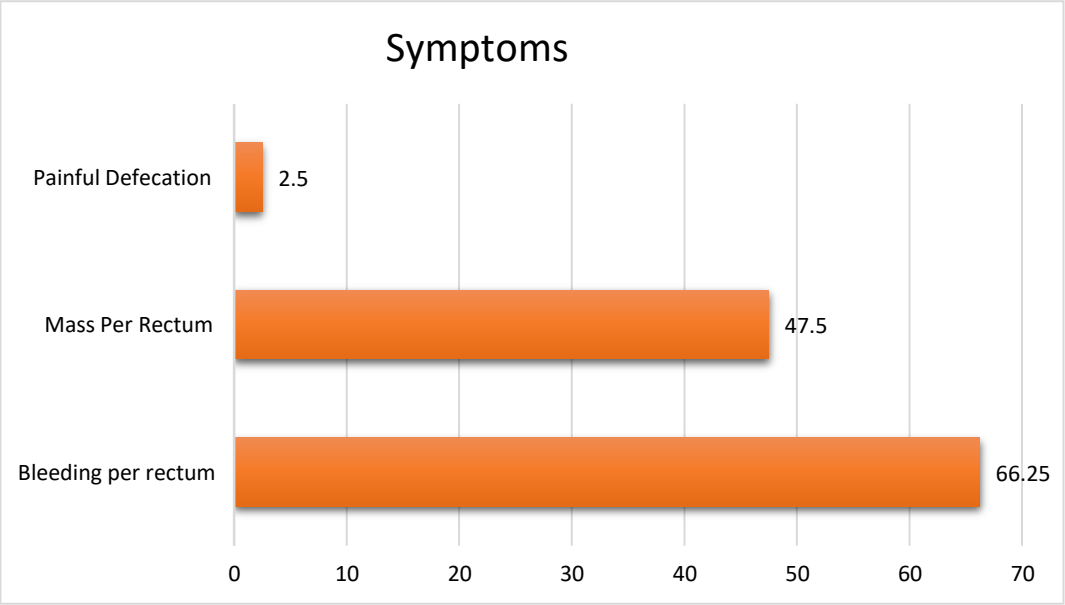
Gender		SURG				Total
		B	C	O	S	
Females	Count	8	5	1	4	18
	%	40.0%	25.0%	5.0%	20.0%	22.5%
Males	Count	12	15	19	16	62
	%	60.0%	75.0%	95.0%	80.0%	77.5%
Total	Count	20	20	20	20	80
	%	100.0%	100.0%	100.0%	100.0%	100.0%
Chi-square value- 7.16						
p value- 0.06						

Out of 80 patients 62 were males and 18 were females. The p-value was again 0.06 and hencewas insignificant in outcome of the study.

PRESENTING COMPLAINTS:

The chief complaints the study groups are given in the table below.

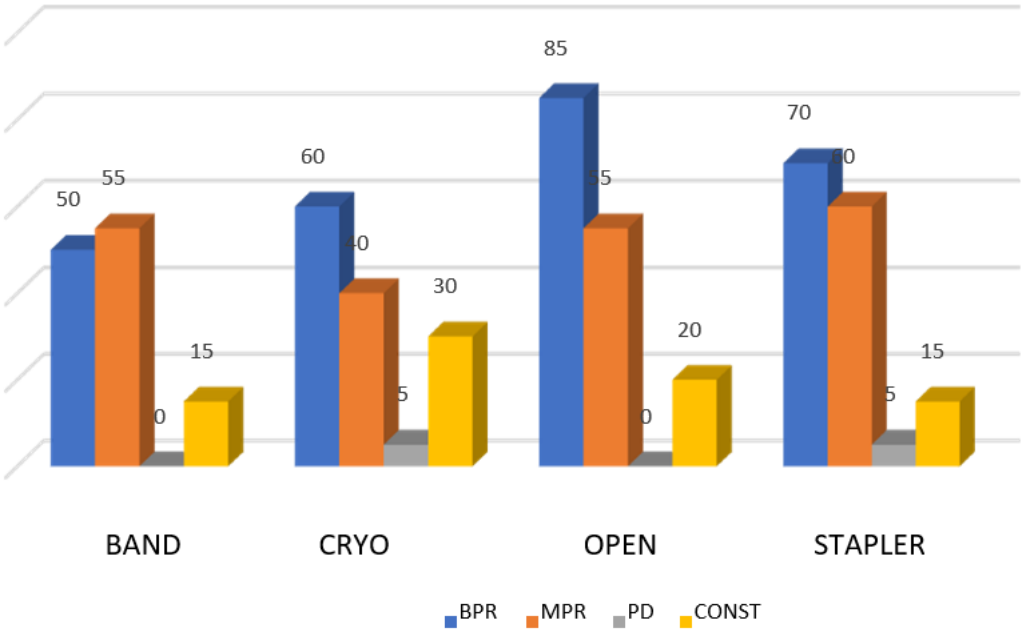
GRAPH. 2. CHIEF COMPLAINTS.



STUDY GROUPS.

In our study groups, bleeding per rectum was the most common presenting complaint present in 66.25% of subjects followed by mass per rectum present in 47.5% of subjects. Constipation was present in 20% of the subjects and lastly only 2.5% subjects had painful defecation.

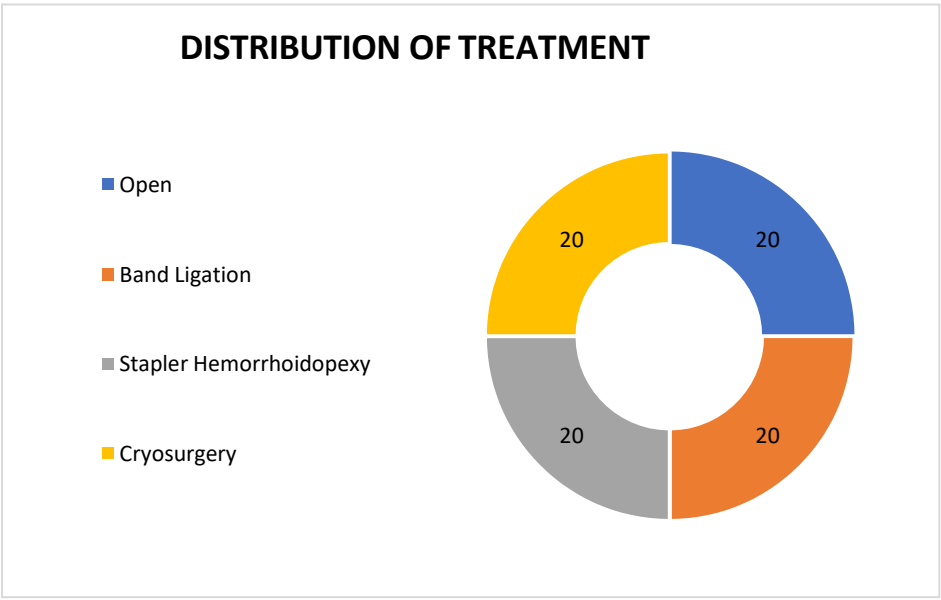
GRAPH. 3. DISTRIBUTION OF PRESENTING COMPLAINTS IN DIFFERENTSTUDY GROUPS.



TYPE OF TREATMENT:

Once the diagnosis was made, patients were randomly selected for the different treatment modalities. Accordingly, 20 underwent open haemorrhoidectomy, 20 underwent Rubber band ligation, 20 underwent stapler haemorrhoidopexy and 20 underwent cryo-probe application.

GRAPH. 4. TREATMENT MODALITIES



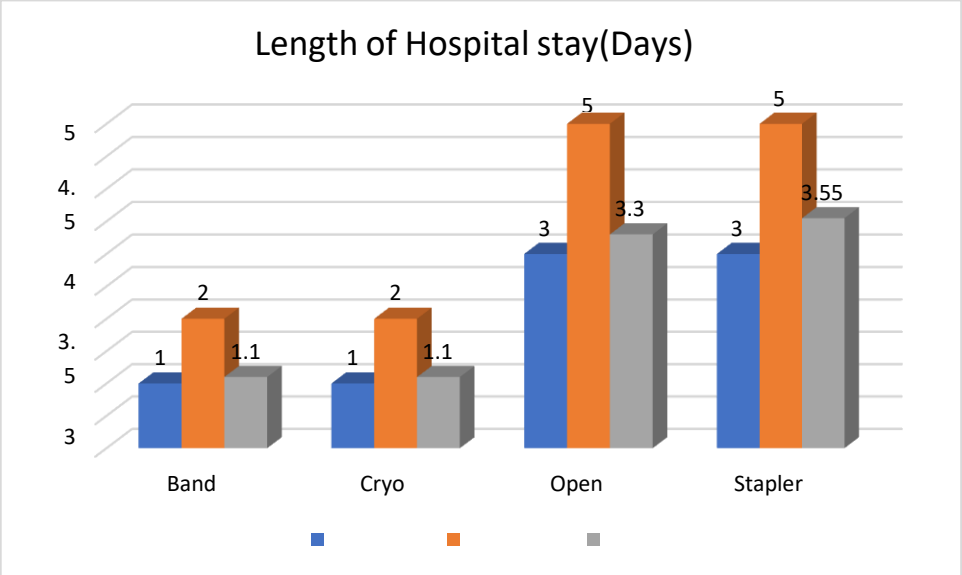
POST-OPERATIVE STAY:

The duration of the stay in hospital was least for Cryo probe followed by band ligation. Patients with open haemorrhoidectomy stayed for longer duration.

Out of 20 patients who underwent stapler haemorrhoidopexy, the mean duration of stay averaged at 3.55 days, which was highest in whole population and higher than average stay of population combined. The band ligation and Cryo-probe application had least length of stay averaging 1.1days both. The average length of stay of whole population was: 2.66. These were similar to findings in

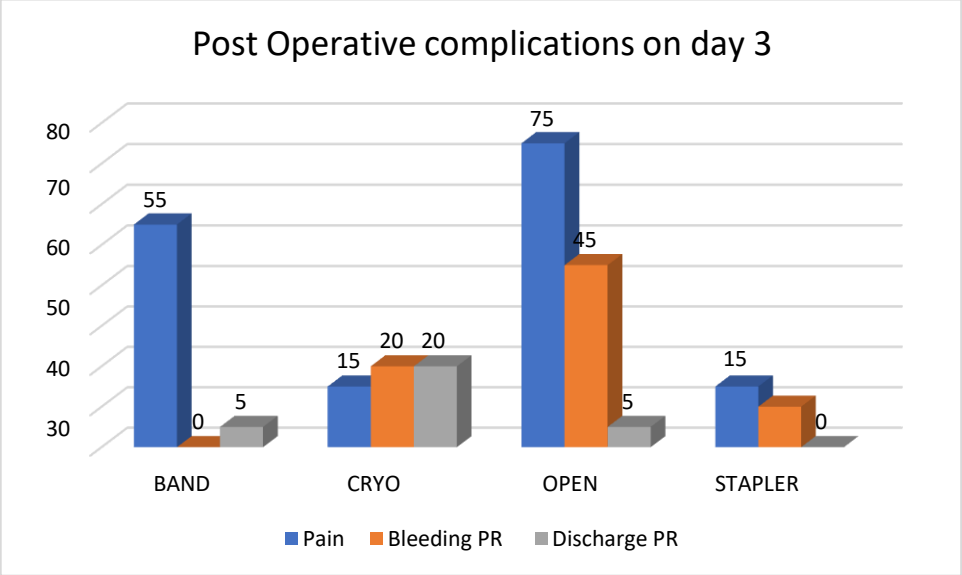
other studies done by Dr Shailesh et al[10] and Dr. Ammanagi et al.[11]

GRAPH.5. LENGTH OF HOSPITAL STAY:



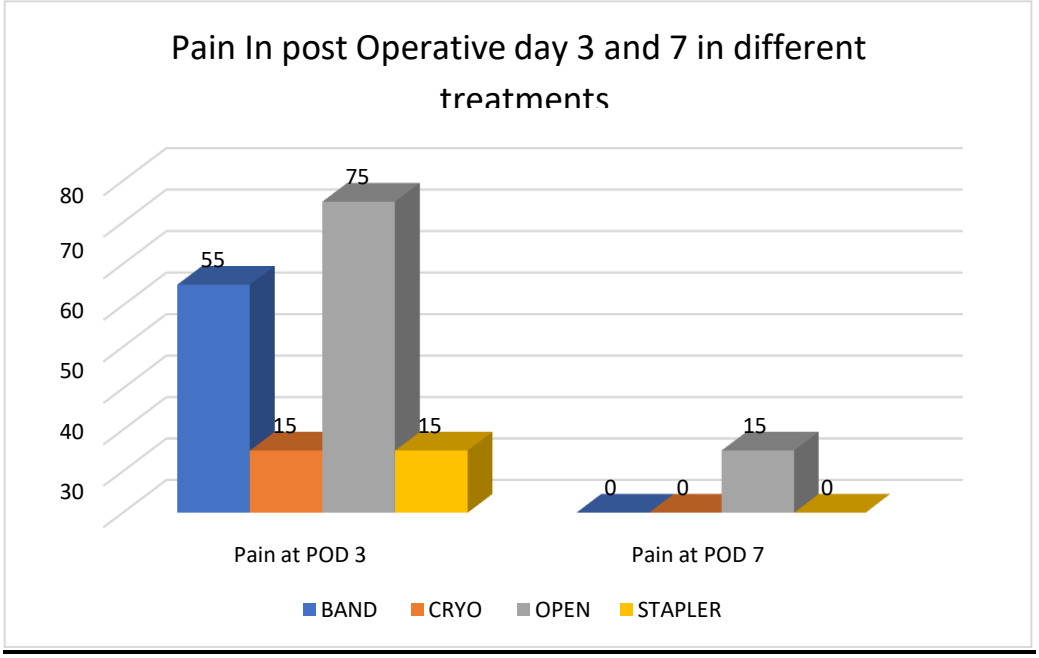
Patients were followed on third post-operative day and seventh post-operative day.Then weekly for first four weeks after surgery.

GRAPH.6. POST OPERATIVE COMPLICATIONS ON DAY 3.



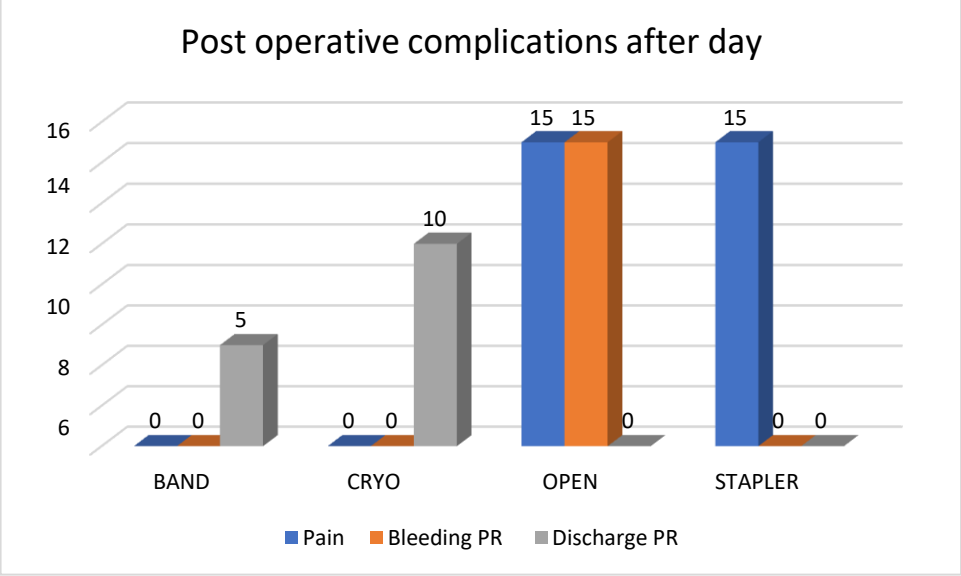
As seen in above graph the post operative complications were seen maximum in the open group with pain being the most common complications across other groups except in the cryogroup where bleeding and discharge were more common than the pain. Stapler haemorrhoidopexy had least post op complications among the four.

GRAPH.6. POSTOPERATIVE COMPLICATIONS ON DAY 7:



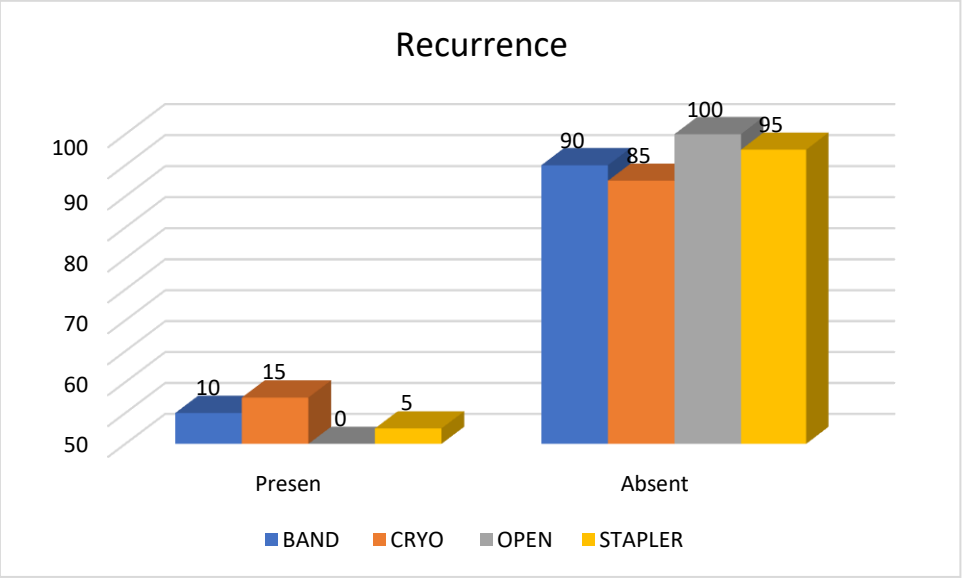
On post-op day 7 pain and bleeding PR was still the most common complication among theopen and stapler group followed by discharge which was seen more in cryo and band ligation.

GRAPH.7. PAIN IN POST-OP DAY 3 AND 7 IN ALL 4 GROUPS.



In this graph the pain is compared in post-op day 3 and 7 in all four groups: Pain was present in 75% of the patients in open group and they needed additional analgesics. But by post-op day 7 the pain had reduced and seen only in 15% of the patients. Pain was also higher in Band with 55% patients and by the end of post-op day 7 all the patients had been relieved of the pain. Both Cryo and stapler groups reported pain in 15% population which was relieved totally by post op day 7. This was supported by similar findings in a study done by Shumi et al.[12]

GRAPH.8. DISTRIBUTION OF THE SUBJECTS BASED ON RECURRENCE



The long term complication: Recurrence was seen highest in cryo group followed by band and lastly stapler. It was not at all seen in the open group.

DISCUSSION:

In our study following findings were noted:

- Incidence of haemorrhoids increases with age and occurrence is highest in 4th to 6th decade of life.
- It is predominantly seen in males. Whether this was because of gender preference or due to stigma in females to seek medical attention has to be evaluated seperately.
- This study also concluded that bleeding is commonest presenting complaint followedby mass per rectum.
- Length of stay in hospital was least in both Rubber band ligation and Cryotherapy.
- Post-operative complications were least in Stapler haemorrhoidopexy followed by Cryosurgery. Open Hemorrhoidectomy had higher post operative complications among all 4 groups however they were easily managed.

All the procedures were done under strict aseptic precautions under either spinal or general anaesthesia. Patients were followed up to assess postoperative complications and to compare between banding, cryosurgery and open haemorrhoidectomy and stapler haemorrhoidopexy.

- In a study done in 1997 by Mac Rae HM et al[13] they concluded that, Open haemorrhoidectomy had slightly more postoperative complications than rubber band ligation and our study too show similar findings.
- Our study also concluded that band ligation was safe, quick, economical and also effective in 2nd grade internal haemorrhoids which is similar to study done in 2009 by Dr. Mohamad Dilawaiz et al[14], which was further supported by another study done by Gagloo[15].

The cost of treatment was highest in the stapler group due to the instrumentation cost followed by Rubber band ligation and cryotherapy which had identical cost.Open haemorrhoidectomy had least cost. In terms of cost effectiveness open Haemorrhoidectomy ranked highest followed by Rubber band Ligation and Cryotherapy.

Least cost effectiveness is seen in stapler haemorrhoidopexy however the post operative complications were least and patients had early return to their usual activities and the conclusion was similar to the study done by Solanki et al.[16]

CONCLUSION:

- In our study we compared Band ligation, Cryosurgery, Open haemorrhoidectomy and Stapler haemorrhoidopexy for the treatment of internal haemorrhoids we found that:
- Open haemorrhoidectomy had post operative complications till post-op day 7 but were easily managed by analgesics and sitz bath and was most cost-effective withzero recurrence.
- Rubber band ligation and Cryotherapy had less postoperative complications by theend of day 7 and were cost-effective however recurrence is a complication seen higher than all other 3 groups.
- Stapler haemorrhoidopexy was costliest of all the four groups without significant improvement in post operative complications and recurrence.

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