



A PROSPECTIVE STUDY TO ASSESS THE EFFICACY OF LIGATION OF INTERNAL HEMORRHOIDS WITH VICRYL 1-0 AND LORD'S DILATATION

Bharat Chaudhary*

PG Resident, Department of General Surgery, Pacific Medical College and Hospital, Udaipur, Rajasthan, India. *Corresponding Author

Arpit Oberoi

PG Resident, Department of General Surgery, Pacific Medical College and Hospital, Udaipur, Rajasthan, India.

Saurav Dey

PG Resident, Department of General Surgery, Pacific Medical College and Hospital, Udaipur, Rajasthan, India.

Om Kant Sharma

Associate Professor, , Department of General Surgery, Pacific Medical College and Hospital, Udaipur, Rajasthan, India.

ABSTRACT

The treatment of hemorrhoids has been widely discussed in the various literatures. The various methods are being employed by majority of surgeons throughout the world. However optimal choice of surgical method for treating such a wide disease require that the approach should be so simple so as to suite the caliber of all surgeons with varying experience and be so convenient so as to be readily acceptable to all patients and yet be effective in a large number of patients, and should be cost effective. Also there should be no/minimal post-operative complications. The present study has been undertaken to assess the efficacy of ligation of internal hemorrhoids with 1-0 vicryl and Lord's dilatation in Pacific Medical College and Hospital, Udaipur since January 2021 to July 2022. This study consists of 50 cases of hemorrhoids which were then further divided into 2 groups, Group 1 consists of patients who had ligation with 1-0 vicryl and Group 2 consists of patients who had Lord's dilatation. In this series most of the patients were in the age group 35-65 and the disease was found be predominantly more in males than in females. The main presenting symptom was pain during defecation, bleeding per rectum and constipation. Among males and females, males in group 1 are the highest number with 1st grade while most of the 2nd grade hemorrhoids were found in group 2 males. The basic characteristics were collected before the surgical intervention and the outcome assessment was done during the follow up at 3 months and 6 months of the intervention.

Following conclusions merits the attention:

- The Lord's procedure is simple, easy to perform and less time consuming.
- It can be performed as a day care procedure.
- It does not require any costly equipment. It is a cost effective procedure.
- The procedure which we did in our study are characterized by absence of incision, dissection and excision.
- It obviates any raw area or suture line.
- The outstanding feature of the procedure was painless postoperative course.
- The amount of blood loss during operation and in postoperative period was almost nil. This fact is quite clear as the procedure does not include any cutting, dissection or excision.
- There is early post-operative recovery.
- Long term results were good because there is no recurrence.
- In this study Lord's procedure appears to be more efficient when compared to ligation with 1-0 vicryl.

KEYWORDS :

INTRODUCTION

Hemorrhoid is derived from Greek terms haem (blood) and rhoos (flow), which refer to the flow of blood. Pile refers to a ball or a pill. Therefore, we should refer to this condition on clinical examination as hemorrhoids when the patient reports bleeding and piles when the patient complains of swelling^[1]. Hemorrhoids, which are characterized by the symptomatic expansion and distal dislocation of the typical anal cushions, are a fairly prevalent anorectal disease. Hemorrhoidal development has allegedly been caused by a number of conditions, including constipation and extensive straining. Hemorrhoidal disease is characterized by vascular channel dilatation and distortion, as well as degenerative alterations in the connective tissue that supports the anal cushion. Hemorrhoids may show signs of vascular hyperplasia and inflammatory response^[2].

The actual epidemiology of hemorrhoids is unknown since people frequently self-medicate rather than seek appropriate medical care, despite the fact that they are known to be a highly common source of rectal hemorrhage and anal discomfort. Hemorrhoids rarely develop before the age of 20, and their highest prevalence in both sexes occurs between the ages of 45 and 65. Whites and people with higher socioeconomic status were more frequently impacted than

black people and people with lower socioeconomic status^[3].

Hemorrhoids are more common as people age, but lesions can appear at any age, especially in children. Men appear to experience symptoms twice as commonly as women. Numerous contributing variables have been put up, including inheritance, age, constipation, sex, climate, pregnancy, laxative misuse, mucosal irritation, recurrent enema, obesity, sedentary lifestyle, use of suppositories, cirrhosis, and pessary use. Except for military aircraft pilots exposed to high gravitational pressures, no profession appears to be particularly susceptible to hemorrhoids^[4].

Hemorrhoids are often categorized according to where they are located and how much they prolapse. While external hemorrhoids are caused by dilated venules of this plexus that are positioned just below the dentate line and are coated with squamous epithelium, internal hemorrhoids are caused by the inferior hemorrhoidal venous plexus that is placed above the dentate line and are coated by mucosa. Hemorrhoids that are mixed (internal-external) can appear both above and beneath the dentate line^[5].

Normally, there are three large anal cushions in the anal canal's right anterior, right posterior, and left lateral areas, with a number of smaller cushions positioned in between.

Hemorrhoid sufferers' anal cushions have severe pathological alterations. These alterations include vascular thrombosis, aberrant venous dilatation, fibroelastic tissue degeneration, rupture, and anal subepithelial muscle deformation. Additionally, hemorrhoidal specimens have shown a strong inflammatory response that affects the vascular wall and connective tissue nearby, along with related mucosal ulcers, ischemia, and thrombosis^[2, 6].

Increasing fiber intake or including more bulk in the diet may help prevent straining during defecation since passing hard stool through the anal mucosa might damage the anal cushions and result in symptomatic hemorrhoids. Fiber supplements did not alleviate the symptoms of prolapse, discomfort, or itching in clinical studies of hemorrhoids, but they did reduce the chance of persistent symptoms and bleeding by almost 50%. Therefore, fiber supplements are seen to be a successful treatment for non-prolapsing hemorrhoids; however, it may take up to 6 weeks for a noticeable improvement to show^[7]. Fiber supplements continue to be a crucial component of both initial treatment and a regimen used after other therapeutic methods for hemorrhoids since they are affordable and safe^[8].

Any patient with hemorrhoids of any severity should be counseled to modify their lifestyle as a part of their therapy and as a preventative strategy. These adjustments include increasing dietary fiber and oral fluid intake, lowering fat intake, exercising frequently, improving anal hygiene, refraining from reading or straining while using the restroom, and avoiding drugs that cause constipation or diarrhea^[6].

But still when patient does not get relief, we have to go for its management as follows:

(A) Non-operative or conservative management

1. Improve defecation habits
2. Local hygiene improvement
3. High fibre diet
4. Hot sitz bath and warm soaks
5. Ice packs
6. Topical agents

(B) Minor surgical procedure

1. Lord's dilatation
2. Suture ligation
3. Sclerotherapy
4. Infrared coagulation
5. Rubber band ligation
6. Plication
7. Cryosurgery

© Hemorrhoidectomy

1. Stapler assisted
2. Surgical
3. Laser

Ligation of internal hemorrhoids with vicryl 1-0 and Lord's dilatation aims at answering a simple, safe but an effective method of surgical treatment of hemorrhoidal disease that suits first, second and third degree of symptomatic hemorrhoids; in addition to establish a non-expensive method.

Ligation of internal hemorrhoids with vicryl 1-0 is simple procedure like ligating a bleeder, whereas in lord's dilatation no vessel is ligated, however this is also mentioned as a procedure for 1st and 2nd degree hemorrhoid.

Therefore, I have chosen this subject to compare and find out which procedure is better one. Both the procedures are minor surgical procedures. There are plenty of cases of hemorrhoids

coming to surgical outdoor at Pacific Medical College and Hospital, Udaipur, Rajasthan.

AIMS AND OBJECTIVES

1. To evaluate the efficacy of ligation of internal hemorrhoids with vicryl 1-0 and Lord's dilatation in the patients admitted in surgical ward at PMCH, Udaipur.

2. To compare the above treatment modalities and to evaluate the complications, including post-operative complications (day 0 to 3 of surgery) and long-term complications (at 3 months).

3. To assess the patient's response, level of satisfaction and patient's compliance up to 6 months of surgery

MATERIALS AND METHODS

STUDY DESIGN:

- Type of study: Prospective and comparative study.

STUDY CENTRE

- Department of General Surgery, Pacific Medical College and Hospital, Udaipur.

STUDY DURATION

- January 2021 to June 2022

SOURCE OF DATA

- General Surgery Department of Pacific Medical College & Hospital, Udaipur-313001

STUDY POPULATION

- Sample size taken: 50 cases

This prospective study was conducted in the patients of hemorrhoids coming to surgery OPD/IPD at Department of General Surgery of Pacific Medical College and Hospital, Udaipur. Based on the analysis of 50 cases of such patients who were admitted to Pacific Medical College and Hospital, Udaipur.

The patients who came between January 2021 to June 2022 were considered for this study. The study classified the patients randomly into 2 groups, namely, patients who were treated with ligation of internal hemorrhoids with 1-0 vicryl (Group 1) while the patients who received Lord's dilatation (Group 2). The basic characteristics were collected before the surgical intervention and the outcome assessment was done during the follow up at 3 months and 6 months of the intervention.

Inclusion Criteria

The patients attending in outpatient department or casualty department and admitted in General Surgery Department of Pacific Medical College and Hospital, Udaipur, those presented with internal hemorrhoid or later confirmed as internal hemorrhoid who were then planned for surgery, were considered.

Exclusion Criteria

All the patients with symptoms of external hemorrhoids. All the patients managed by other surgical procedures for hemorrhoids and patients who did not follow the treatment protocol were excluded.

The patients who had fissure, fistula in ano and malignancy were excluded from the study.

The patients who did not give consent were also excluded from this current study.

Collection of Data

After registration of the patients, a comprehensive history of patients was obtained including details of the background information, clinical features, type of hemorrhoids were determined and grade was assessed. The grading of hemorrhoids was done as follows. Internal hemorrhoids lies proximal to the pectinate line which can be observed in the anal canal under proctoscopy.

- **First degree**
The number and size veins in anal canal increase and may bleed during the time of defecation.
- **Second degree**
Hemorrhoids is seen to be prolapsed outside the anal canal but reduction occurs spontaneously.
- **Third degree**
Hemorrhoids protrude outside the anal canal and may be managed by manual reduction.
- **Fourth degree**
Constant prolapsing hemorrhoids which are irreducible.

All the patients were operated under spinal anaesthesia. After the surgical intervention, the assessment was done by employing the followings, namely, Visual Analogue Scale (VAS), Wexner Incontinence Grading Scale, post-operative complications, long term complications and patients' satisfaction.

VAS was used for assessing the post-operative pain 5 days after the surgical intervention and it was determined according to its scale ^[7,8]. Again, at 3 months after the surgical intervention, fecal incontinence was assessed using the Wexner Incontinence Grading Scale ^[9, 10]. This scale takes lifestyle, usage of pads and the type of incontinence (may be solid or liquid or gaseous). Post-operative complications was assessed on the day of surgery and the next day of surgery. Long term complications was assessed after 3 months of surgery. After 6 months of surgery, the patients' experience was determined by asking them to rate the whole procedure and the status after the surgical intervention.

Statistical Analysis

The study used SPSS 25 and MS Excel software for effective statistical analysis. The discrete variables were expressed as frequency or both frequency and percentages. The continuous variables were expressed mean ± standard deviation. The outcome assessments were analyzed by employing Mann-Whitney U-test. The level of significance was considered to be =0.05.

Ethical Approval

The study process was explained to each of the patients before collection of data. The study process was approved by the hospital's Ethical Committee. The consent form was obtained from each of the patients.

RESULTS

On the basis of surgical intervention this study is divided into two groups.

Those who had ligation of internal hemorrhoids with 1-0 vicryl are classified as Group 1 while those who had Lord's dilatation, are classified as Group 2.

Table 1: Age incidence

Age (years)	No. of patients	Percentage
0-25	0	0
26-35	0	0
36-45	16	32%

46-55	16	32%
56- 65	18	36%
>65	0	0

Age incidence has been shown in the Table below (Table 1). In this study, the patients in Group 1 and Group 2 were found to be 53.20±6.72 years and 49.48±7.58 years old, respectively. There were 32% patients in age group 36-45 years, 32% patients in age group 46-55 years and 36% patients were in the age group 56-65 years. This concludes that most of the patients in our study were in between the age group of 35 to 65 years.

Figure 7 showing Age incidence

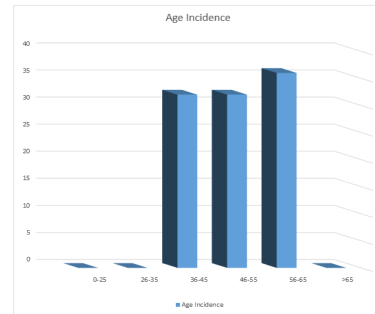


Table 2: Sex incidence

Sex	No. of patients	Percentage
Male	30	60
Female	20	40
Total	50	100

Sex incidence has been shown in Table no 2. In this study there were 60% (30) males and 40% (20) females, which shows that the males were predominantly affected as compared to females.

Figure 8 showing sex incidence

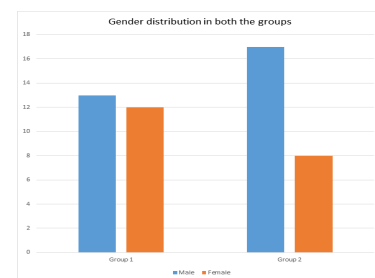


Table 3: Clinical features in Group 1 before surgery

Clinical Features	Group 1			
	Male	Female	Total	%
Pain during	11	12	23	92.00
Bleeding per rectum	12	9	21	84.00
Prolapsed/palpable pile	12	11	23	92.00
Discharge	13	10	23	92.00
Pruritus	11	12	23	92.00
Constipation	12	10	22	88.00
Giddiness/weakness	11	11	22	88.00

Table 3 shows the clinical features in Group 1 before the surgical intervention.

The clinical features that were present are bleeding per rectum, prolapsed/palpable pile, pain during defecation, discharge, pruritus, constipation and giddiness/ weakness.

Patients with fissures, fistula in ano and malignancy were excluded from this study.

Table 4: Clinical features in Group 2 before surgery

Clinical Features	Group 2			
	Male	Female	Total	%
Pain during defecation	14	7	21	84.00
Bleeding per rectum	15	6	21	84.00
Prolapsed/palpable pile	15	8	23	92.00
Discharge	14	7	21	84.00
Pruritus	14	7	21	84.00
Constipation	15	8	23	92.00
Giddiness/ weakness	15	7	22	88.00

Table 4 shows the clinical features in Group 2 before the surgical intervention.

Pain during defecation was the most common clinical feature that was found in 92% patients in Group1 and 84% patients in Group 2.

Constipation was also found to be very common in both the groups, 88% patients in Group 1 and 92% patients in Group 2. Bleeding per rectum was found in 84% patients in both Group 1 and Group 2.

Table 5: Grade of hemorrhoids in Group 1 and Group 2

Grade of hemorrhoids	Group 1		Group 2		Total	%
	Male	Female	Male	Female		
1 st degree	9	5	7	5	26	52%
2 nd degree	4	7	10	3	24	48%

Table 5 shows the Grade of hemorrhoids in each group. Proctoscopy was done to check the grade of hemorrhoids. Among males and females, males in group 1 are the highest number with 1st grade while most of the 2nd grade hemorrhoids were found in group 2 males.

Figure 9 showing Grade of hemorrhoid in each group (male and female)

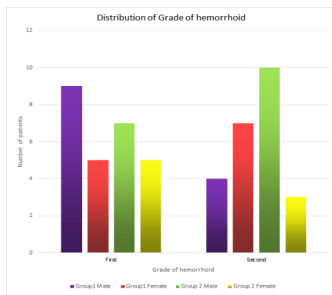


Table 6: Visual Analog Score (VAS) after the surgical intervention in each group

Score	Group 1	Group 2	P-Value
1	0	10	0.0211
2	0	9	0.0315
3	0	6	0.0395
4	0	0	not applicable
5	7	0	0.0396
6	7	0	0.0396
7	5	0	0.411
8	6	0	0.0402
Average	6.40±1.15	1.84±0.80	0.000123

Table 6 shows the VAS results in each group. For determination of efficacy, this study has considered Visual Analog Score (VAS), Patients' Quality of Life (QoL) and

patient's satisfaction upto 6 months after surgery. The study found that Visual Analogue Scale (VAS) for assessment of pain 5 days after the surgical intervention. There was marked difference between the groups. It was found that there were 10 patients, 9 patients and 6 patients with Score 1, 2, 3, respectively, in group 2 while in group 1, there 7 patients with score "5" and "6" while 5 patients with score "7" and 6 patients with score "8". In group 2, there was no patient with score 4 and more. All these scores showed that there was significant difference between the groups with VAS (P<0.05), implying much lesser pain among the patients in group 2.

The average score in group 1 and group 2 were 6.40±1.15 and 1.84±0.80 (P<0.001), which shows that there was highly significant difference between the pain score felt by each group, group 2 being the lesser one.

Table 7: Assessment of Patient's Quality of Life (QoL) post-operatively in each group

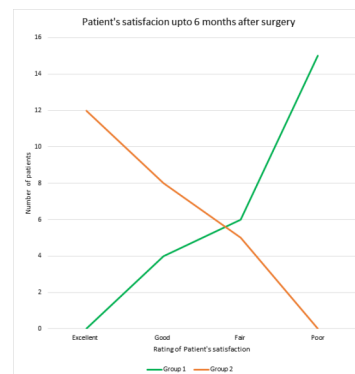
	Parameters	Group 1	Group 2	P-Value
Postoperative complications	Pain and edema	14	0	0.0124
	Bleeding	2	0	
	Infection	1	0	
	Discharge	1	0	
	Tenesmus and diarrhea	22	11	
	Total number of complications			0.0124
Long term complications	Pain	10	0	0.0015
	Re-bleeding	3	0	
	Prolapse	2	0	
	Stenosis	4	0	
	Fistula in ano	3	0	
	Total number of complications	22	0	0.0015

Table 7 shows the detailed findings of the complications.

In addition, Wexner Incontinence Grading Scale shows that group 1 had 0.96±1.31 score while group 2 had score of 3.60±2.53 (P> 0.05). Hence, there is no significant difference between the two groups in the continence grading.

Again, the study assessment was also done by post-operative complications at day 0 to 3 of the surgical intervention and also by long term complications in each group at 3 months of the surgery.

Figure 10 showing the satisfaction rating of the patients in each group upto 6 months after surgery.



This Figure no. 10 shows the number of patients in each group with their satisfaction level. After 3 months of the surgery, it was found that 12 (48%) patients had rated "excellent", 8 (32%) had rated "good" and 5 (20%) patients rated "fair in

Group 2 (lord's dilatation). While in Group 1 (ligation with 1-0 vicryl), 4 (16%) patients rated "good", 6 (24%) patients rated "fair" and 15 (60%) patients rated "poor".

DISCUSSION

On the basis of surgical intervention this study is divided into two groups. Those who had ligation of internal hemorrhoids with 1-0 vicryl are classified as Group 1 while those who had Lord's dilatation, are classified as Group 2.

Hemorrhoids rarely develop before the age of 20, and their highest prevalence in both sexes occurs between the ages of 45 and 65. Whites and people with higher socioeconomic status were more frequently impacted than black people and people with lower socioeconomic status.

Age:

In our study the patients in Group 1 (ligation with 1-0 vicryl) and Group 2 (lord's dilatation) were found to be 53.20 ± 6.72 years and 49.48 ± 7.58 years old, respectively. There were 32% patients in age group 36-45 years, 32% patients in age group 46-55 years and 36% patients were in the age group 56-65 years (shown in Table 1). All patients in our study were in between the age group of 35 to 65 years.

Similarly, In a study by saxena et al, (2017), most of the patients (74.28%) were between 30-60 years of age. The common complains for which the patient presented to hospital was bleeding per rectum (100%), prolapse of piles (65.62), painful defecation (32.81), discharge, pruritus etc^[9].

In a study by Arshad ahmad et al, The mean age of the patients in group A was 45 versus 42.2 years in group B. In both the groups, most patients had grade 2 hemorrhoids^[11].

In the above mentioned studies, findings are found to be similar to that in our study.

Sex:

In our study, out of 25 patients in group 1 (ligation with 1-0 vicryl) affected males are 13 (52%) and females are 12 (48%), and out of 25 patients in group 2 (lord's dilatation) affected males are 17 (68%) and females are 8 (32%) as shown in Table 2. In this study males seem to be affected predominantly more frequently as compared to females.

Similarly, In a study by Arshad ahmad et al. Total 245 patients were included in the study analysis. There were 69 males and 47 females in group A, whereas in group B, there were 76 males and 53 females. There was a predominance of males in both the groups, but without any significant difference^[11].

Similarly, In a study by Pradeep saxena et al. among 64 patients majority were males 41 (64.06 %) and 23 were females^[9].

When compared to all the above mentioned studies, our study findings are found to be nearly similar.

Clinical features:

In our study as shown in Table 3, (92%) 23 patients in Group 1 and (84%) 21 patients in Group 2 complained of pain during defecation. 84% in Group 1 (ligation with 1-0 vicryl) and Group 2 (lord's dilatation) came with the complaint of bleeding per rectum. 92% patients from Group 1 and Group 2 complained of palpable pile. 92% patients from Group 1 and 84% patients from Group 2 had complain of discharge per rectum. 23 patients (92%) from Group 1 and 21 patients (84%) from Group 2 had complain of pruritus.

All patients who were included in the present study complained mainly of pain during defecation and bleeding

per rectum. Similarly high incidence of complaint of bleeding had also been observed by other workers [Dovidar et al. (2004) 78%; Ezzeldeen (2005) 50%; Choudhary (2006) 90% and Pradeep saxena et al. (2017) 100%].

Hemorrhoidal development has allegedly been caused by a number of conditions, including constipation and extended straining^[2] 22 patients (88%) in Group 1 and 23 patients (92%) in Group 2 had history of constipation. 14 (56%) patients in Group 1 and 12 (48%) in Group 2 had first degree hemorrhoid. 11 (44%) patients in Group 1 and 13 (52%) patients in Group 2 had second degree hemorrhoids as shown in Table 5.

Post-operative complication-

The study assessment was done by post-operative complications at day 0 to 3 of the surgical intervention. Major complications such as pain and edema, bleeding, infections, etc. were noticed.

Pain and edema:

In this study, pain and edema was found to be present in 14 (56%) patients out of 25 in Group 1 (ligation with 1-0 vicryl), whereas no (0%) patient had post-operative pain and edema in Group 2 (lord's dilatation).

Bleeding:

(8%) 2 patients complained of bleeding post-operatively in Group 1 and no (0%) patient had post-operative bleeding in Group 2.

Infection:

4% patient had infection post-operatively in Group 1 and no patient had post-operative infection in group 2.

Long term complications-

Assessment of the study was also done by long term complications in each group at 3 months of the surgery. Long term complications such as pain, re-bleeding, prolapse, stenosis, etc. were noticed 10 patients (40%) developed pain as a long term complication in Group 1 and no patient developed pain as a long term complication in Group 2. (12%) 3 patients complained of re-bleeding from group 1 and no patient had such complication in group 2. (16%) 4 patients complained of anal stenosis from group 1 and no patient had such complication in group 2.

It was found that there is significantly less post-operative complications and long term complications in group 2 (Lord's dilatation) as compared to group 1 (ligation with 1-0 vicryl).

The satisfaction rate of the patients in both groups upto 6 months after surgery was recorded and it was found that 12 (48%) patients had rated "excellent", 8 (32%) had rated "good" and 5 (20%) patients rated "fair in Group 2 (lord's dilatation). While in Group 1 (ligation with 1-0 vicryl), 4 (16%) patients rated "good", 6 (24%) patients rated "fair" and 15 (60%) patients rated "poor".

Probably, Role of anal cushion in normal rectal examination is preserved in Lord's anal dilatation, hence it will provide normal sphincter contraction thereby assisting its closure, loose textures above and tougher below leading to a water tight seal^[12], this may be the criteria of satisfaction in Group 2. Whereas ligation may affect the above mechanism and patient may develop perianal soiling and pruritus due to it, thereby reporting level of satisfaction accordingly.

Anal dilatation is simplest form of surgical treatment, usually preferred under outpatient surgical conditions. Basic principle of anal dilatation is tearing or disrupting the fibres of internal sphincter muscle, possibly damaging the external sphincter muscle. It should not be done more than once as it can cause

tears in two different places leading to urinary incontinence and unfortunately incontinence rates are 3-5%. It is usually temporary, lasting only a few months, but can be permanent [13].

CONCLUSION

The efficacy of ligation of internal hemorrhoids with 1-0 vicryl and Lord's dilatation has been carried out statistically. It has been concluded that ligation of internal hemorrhoids with 1-0 vicryl and Lord's dilatation is significantly less painful. Again, incontinence was significantly less in patients who underwent ligation with 1-0 vicryl and Lord's dilatation and they had shown significantly lower complications.

The study found marked improvement in pain score and specially the complications. Long terms complication was not found in the patients who underwent Lord's dilatation which shows that this intervention should be preferred at first place. Although, it needs more studies of similar design to find out strong evidence and also need to have conducted clinical trials before it can be considered as a guideline. The study used two types of grading scales (VAS and Wexner Incontinence Grading Scale) for efficient assessment and statistical analysis have been conducted with both of them. The higher patient's compliance shows that ligation with 1-0 vicryl and Lord's dilatation can be used in clinical setting over other modalities.

This study neither found any appreciable long term complication nor any patient reported with recurrence with Lord's dilatation.

There were some limitations in this study. The study included smaller number of patients and it was a single-center study whose analysis may be not be suitable for other kinds of population. We suggest to carry out similar studies with more varied population and with larger sample. However, this study has revealed important points about hemorrhoids management and to improve its compliance. The intervention has shown higher acceptance among the patients and significantly much lesser number of complications 6 months after the intervention.

The study highlights that the usage of Lord's dilatation should be encouraged after conducting some more clinical trials with larger sample size. This may be expected to improve the surgical management of hemorrhoids significantly more than ever. Since the sphincter fibers are broken in Lord's dilatation they heal by fibrosis, hence recurrent Lord's dilatation is not recommended as it can lead to anal stenosis due to recurrent fibrosis of sphincter. However, follow up was up to 6 months only, whereas fibrosis matures after 6 months.

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