Original Article

A Randomized Clinical Trial of Photocoagulation Compared with Lifestyle Modification in the Management of First and Second Degree Hemorrhoids

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Abstract

Purpose: Purpose of study is to compare the effectiveness of photocoagulation with the life style modification. There is much controversy regarding the role of photocoagulation(infrared coagulation) in the management of first and second degree haemorrhoids. According to some well known text books, it is considered to be an easy way of treating early haemorrhoids while others are doubtfull about the effectiveness.

Material and Methods: We have included 200 cases of first and second degree haemorrhoids with out any other anorectal disease for this study. They are divided in to two study groups (A and B) of 100 patients each. Group A patients is treated with IRC (infrared coagulation) and Group B patients with life style modification only.

Result: Statistical analysis of the results is very interesting. IRC is not better than simple life style modification! This is enough for the management of first and second degree haemorrhoids.

Conclusion: Strict life style modification is enough for the management of early haemorrhoids.

Key words: Anal cushion, Hemorrhoids, Infrared coagulation, Lifestyle, Photocoagulation

INTRODUCTION

Epidemiological studies conducted by Johanson *et al.* estimates around 10 million people in the USA are having hemorrhoids (prevalence rate 4.4%).^[1] These shows the magnitudes of the problem in western civilization. Whites are more affected than black due to the high socioeconomic status of the former. Increasing age, constipation, pregnancy, and dietary habits influence the etiopathogenesis.

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According to the modern view, hemorrhoid is defined as symptomatic or disrupted anal cushion. [2] Normally anal cushion functions as airtight seal, and it maintains fine continence.[3] It is folded and has uneven mucosa and submucosa above the dentate line. Submucosa consists of vascular (venous plexus and arteriovenous communication), muscular, elastic, and connective tissues (supporting elements).[4] In the prolapsed anal cushion venous stasis occurs due to impaired venous return. Straining at stool produces increases in venous pressure and engorgement of anal cushion while hard stool consistency and aging process are said to be responsible for the fragmentation of supporting structures which lead to the loss of elasticity of it. This leads to the failure of retraction of anal cushion following defecation. Any drugs or a procedure which can revert the changes in the anal cushions is the basis of management.

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Hemorrhoids are classified into four types based on clinical prolapse. [5]

- First degree: Internal hemorrhoids bulge into anus without prolapse.
- Second degree: Internal hemorrhoids prolapsed during defecation and spontaneously reduce.
- Third degree: Internal hemorrhoid prolapse, requiring manual reduction.
- Fourth degree: Internal hemorrhoid prolapsed and irreducible.

Diagnosis is made on physical examination.

For the first and second degree hemorrhoids conservative management, sclerotherapy, [6] cryosurgery, laser, [7] rubber band ligation, [8,9] and photo coagulation [10] are advocated while for 3rd and 4th degree hemorrhoid minimal invasive and invasive procedures are done (stapler hemorrhoidectomy, [11] hemorrhoidal artery ligation using Doppler, [12,13] open [14] and closed hemorrhoidectomy [15]).

In this study, we have used infrared coagulation (IRC) (photocoagulation). [16] IRC is used by general practitioners, specialist, subspecialist and doctors of other systems for the management of piles since the operability of this instrument are simple. Redfield Corporation of USA and Lumatec of Germany are manufacturing and marketing it (infrared coagulator) all over the world. Major drawback of this technique is the cost of the device. It varies from 3,00,00 to 6,00,000 (INR) depending on the brand. It consists of one base unit with programmed timer card, handgun with a trigger and light probe with contact tip. Infrared rays are produced by the tungsten - halogen lamp located in the gun is directed to the required site, at the

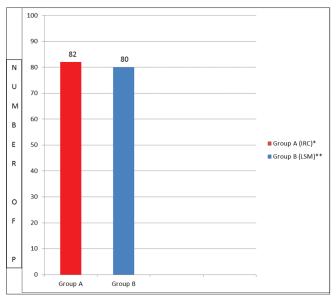


Figure 1: Bar diagram showing percentage of final analysis

apex of each hemorrhoid by contact tip of the light probe. Heat produced by infrared radiation coagulates protein which leads to eschar formation and scarring at the site.^[17] It creates fixing of hemorrhoids. This leads cessation of blood flow to pile mass and size shrinks. The time of exposure can be adjusted (5–3 s) using the timer [Figure 1].

Role of lifestyle modification in reverting the pathological changes in the early hemorrhoids is not fully understood. However, fiber-rich diet, fluids, cessation of smoking, alcohol abstinence, and avoiding straining contributes much to the healing of disrupted anal cushion. [18] Fiber with plenty of water makes the stool very soft, this shortens gut transit time and minimizes the straining leads to a reduction in venous stasis and trauma to the anal cushion. Blood supply to the mucosa and submucosa is enhanced by stopping smoking. All these factors retard fragmentation of connective tissue which supports the anal cushion.

MATERIALS AND METHODS

This study was done for a period of 5 years from 2010 to 2015. 200 cases of male adult patients in the age group of 25–45 years are selected for this study [Table 1].

Inclusion Criteria

Male adult patients in the age group of 25–45 years with complaints of itching, bleeding, discharge, or mass per annum which reduces spontaneously is considered for this study. This age group and male sex ensure homogeneity patient population by comparatively having normal anorectal anatomy in all cases. Moreover, functional status of internal sphincter and external sphincter is assessed by evaluating the resting anal pressure (normal value: 40–80 mm hg) and squeeze pressure (normal value: Above 40–80 mm hg), respectively. Patients with abnormal resting and squeeze pressure are excluded from this study.

Exclusion Criteria

Patients with painful hemorrhoids, acutely thrombosed hemorrhoids, anal fissure, fistula-in-ano, anal stenosis, colitis, rectal prolapse, fecal incontinence, and inability to understand the instructions are excluded from this study

They are randomly divided into two groups of 100 each (Group A and Group B). Group A patients are given photocoagulation and Group B patients are treated with lifestyle modification.

IRC is performed in the left lateral position (Sims). They were given bisacodyl 10 mg at bedtime on the previous day. A lubricated slotted proctoscope is introduced gently in the anal canal and lower rectum. The entire quadrant is properly inspected by rotating it. Each internal hemorrhoid

is identified, and IRC is applied at the apex of it at four points above dentate line. The timer is adjusted to 2 s in all cases. A white spot is visible at the site of contact due to coagulation necrosis. Maximum time taken for this procedure is 10 min. It is done as an office procedure. There is no need for rest, and they can have routine activities. Patients acceptance is very high with this procedure. Exposure is repeated after 6 weeks. These patients are evaluated after 3 months for the result. 82 patients had a complete cure and 18 failures.

Group B patients are given counseling regarding the importance of lifestyle modification. No drugs are given. They are strictly advised to adhere to the following instruction for 3 months.

- 1. Take three glass of water (one glass = 200 ml) 3 h prior or after meals.
- 2. Avoid straining and prolonged sitting on the toilet.
- 3. Use abundant vegetables (high fiber diet).
- 4. Avoid smoking and alcohol.
- 5. 30 min brisk walking daily.

Selection of patient to this group was taken after considering their social and educational background. Each patient is given counseling for 30 min before enrolling for the study.

A self-reported symptom questionnaire was answered and clinical examination performed after 3 months. 80 patients were fully relieved of the symptoms.

Statistical Analysis

Results were recorded. Observations obtained were analyzed using appropriate statistical methods. P < 0.05 was accepted as significant. Groups were compared by X^2 homogeneity test at 5% probability. Results showing

Table 1: Distribution of cases according to age

Age group (years)	n=200
25–30	30
30-35	50
35-40	62
40–45	58

normal distribution were given as mean with standard deviation.

RESULT

A total of 242 patients were eligible for enrolling this study, out of which 210 were considered and randomized for the evaluation. Of this 32 were excluded and 20 does not meet the inclusion criteria because of other anorectal diseases and 12 were not willing to participate in the study [Figure 1]. In Group A the cure rate is 82% and in Group B is 80% [Figure 2].

Data analysis gives us some interesting results [Table 2]. In Group B, it is found that in the age group 25–30 years failure rate is high (13 failure out of 15 patients). On further review, it is found that patients of 25–30 years from Group B had not followed the counseling properly. On extrapolating the data, it can be concluded that lifestyle modification is better than IRC. In young adults who are

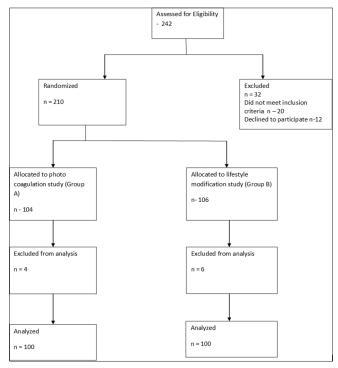


Figure 2: Consort flow diagram for study

Table 2: Comparative analysis of study groups

Age group	Group A			Group B		
	n	Symptom-free (n)	Failure (n)		Symptom-free (n)	Failure (n)
25–30 years	15	12 (80)	3 (20)	15	2 (13.33)	13 (86.66)
31–35 years	25	21 (84)	4 (16)	25	23 (92)	2 (8)
36-40 years	31	25 (80.64)	6 (19.35)	31	28 (90.32)	3 (9.67)
41–45 years	29	24 (82.76)	5 (17.24)	29	27 (93.10)	2 (6.89)
•	100	82 (82)	18 (18)	100	80 (80)	20 (20)

Values in parenthesis are percentages, Chi-square 0.1583 P=999922, Chi-square 49.0933 P<0.00001

reluctant to follow lifestyle modification, IRC is considered as a better alternate option.

DISCUSSION

Various modalities and innovations are employed in the management of hemorrhoids. Starting from fiber diet, drugs, [19] heat and cold energy, [20] laser, electric current, radiofrequency ablation, ligating the arteries, mucosal excision, excision, and ligation, etc., are employed according to clinical assessment and expertise of surgeon. Pathophysiologically hemorrhoid plexus is not a disease; it is an essential part of anorectal anatomy. Its role in fine continence (act like airtight seal after defecation) is well established. Around 15% of anal resting pressure is contributed by anal cushion. Only when the individual develops symptoms such as bleeding, discharge, itching, and prolapsed is it considered as a disease. Here the aim of the treatment is to restore the integrity of anal cushion by lowering pressure in the venous plexus which prevents further fragmentation and moreover it enhances the regeneration of connective tissues also.^[21] By this size of the pile mass shrinks and symptoms disappears. A segment of patients who had undergone open hemorrhoidectomy complained of mild form of fecal incontinence due to the damage of anal cushion. In this scenario role of lifestyle modification is important. This study confirms that lifestyle modification gives almost the same results as photocoagulation. Hence, this procedure should not be emphasized in the management of the first and second degree hemorrhoids. Manufacturers of IRC instruments, some hospitals and doctors show over enthusiasm to this procedure. The unholy nexus must be controlled by policy makers by implementing effective legislation. The financial loss to the society is very huge due to unwanted healthcare spending. Now healthcare cost has become very expensive worldwide. In US 17% of the annual gross domestic product is spent every year for health.^[22] Variation in healthcare provision is not explained by disease, patient's preferences or the dictates of evidence-based practices are frequently cited as evidence of unnecessary or wasteful resource utilization. [23,24] Our study results are an eye-opener to the health policy makers to highlight the importance of lifestyle modification by patients education through multiple awareness programs in the management of hemorrhoids.

CONCLUSION

Since there is no financial burden to the patient, lifestyle modification has important role in the management of the first and second degree hemorrhoid compared to the office procedures like IRC. Patient education and doctors role are very important here. High claims by the manufacturers are doubtful since patient education gives almost the same result.

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