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'Laser Haemorrhoidoplasty versus Ksharsutra Ligation: A Randomized Controlled Trial comparing effect of two surgical procedures in Arsha with special reference to Haemorrhoids.'

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Abstract: **Background***: Arsha* i.e. Haemorrhoids are the dilated veins within the anal canal in sub epithelial region formed by radicals of the superior, middle and inferior rectal veins. *Charaka* has advised *ksharkarma* for the management of *Arsha*. *Chakradatta*, also given indication of *ksharsutra* ligation in *arsha*. Keeping these aspects in mind and to provide satisfactory, efficious solution for the management of *arsha*, present study was conducted. Laser haemorrhoidoplasty (LHP) is a procedure in which haemorroidal arterial flow feeding the hemorroidal plexus is stoped by laser coagulation. LASER, the acronym for Light Amplification by Stimulated Emission of Radiation. **Aim**: To compare the laser haemorroidoplasty procedure with *Ksharsutra* ligation for treatment of symptomatic second and third degree haemorroids. A clinical comparison trial between LHP and *Ksharsutra* ligation on haemorroid was conducted at shri ayurved college and hospital, Nagpur. Patient with grade II and grade III haemorroids were eligible for the study. 31 patients treated with the laser hemorroidoplasty in group A and 31 patients with *Ksharsutra* ligation in group B. Per rectal bleeding, regression of pile mass and postoperative pain were evaluated. **Results**: A total number of 62 patients entered the trial. There was significant difference between the two groups regarding the subjective and objective criteria. **Conclusion**: As per observation, *ksharsutra* ligation procedure was more effective than laser haemorroidoplasty.

Keywords: *Arsha*, haemorrhoids, laser haemorroidoplasty, *ksharsutra* ligation.

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INTRODUCTION:

Ayurveda has immense potential to solve various challenging problems of the developing medical world. *Shalya Chikitsa* being one of the most important and clinical branches of *ayurveda*, having its own originality with authenticity, contributing to the modern surgical technology of today's era. *Sushruta Samhita* is the only available text in surgical practice, and it has been found that there are various diseases that are difficult to manage by conservative treatment alone. Among them, *arsha* is one such grave disease, for which it has been included in *ashta mahagada* by *Sushruta*[1], showing the gravity of this disease[2]. The present westernized lifestyle is adding to the prevalent rate of this disease. The incidence of this disease is showing augmentation as the age advances[3]. At least 50% of the people over the age of 50 years[4,5] have symptoms related to haemorrhoids which are dealt rationally under the concept of *arsha*. As far as the modern modalities are concerned, the conservative treatment of piles consists of use of laxative and high-residual diet. Nowadays, there is an increasing demand of laser surgery for haemorrhoids by patients itself. Because in this hard and fast era everyone wants instant relief and minimum hospital stay. Laser Haemorrhoidoplasty is the most popular and advanced surgical option but it is having its own limitations. In certain studies, it is observed that there is recurrence and postoperative discharge after Laser Haemorrhoidoplasty in many patients. *Ksharsutra* ligation is procedure describe by *Chakradatta* for the treatment of *Arsha* which is timely tested by many *Ayurveda* surgeons and it is one of the effective, safe, and economical treatment for *Arsha* with negligible side effects. Amongst many modern surgical procedures opted for haemorrhoids, Laser Haemorrhoidoplasty is on boom nowadays. So, to compare the results of both therapies this present clinical research work was selected. The aim of this study was to compare pain, per rectal bleeding and regression of pile mass between of the two methods, laser haemorrhoidoplasty (LHP) and *ksharsutra* ligation.

Materials and Methods

In this comparative and prospective study 62 patients were included, of which, 31 patients were treated with laser haemorrhoidoplasty method and 31 patients were treated with *ksharsutra* ligation. Patients were allocated in different groups, according to pain, per rectal bleeding and regression of pile mass. Patients diagnosed with second and third degree haemorrhoids, came to Shalyatantra OPD and IPD of Shri Ayurved college and hospital Nagpur, were taken for the study. Both the procedures were done Under all aseptic precaution and under spinal anaesthesia. The haemorrhoidal masses and their positions identified by a thorough proctoscopic examination. In laser haemorrhoidoplasty, A probe introduced through anal prolapse under surface of anoderm and inserted via submucosal space till about 2cm above haemorrhoid cushion. The laser was set to a power of 8 watts with a single pulse of 3 sec duration. A special probe containing a bare fibre within a special conical glass tip used. It

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was having sharp distal end for easy tissue penetration. It provides wide illumination of laser light ensuring gentle application of energy. The energy up to 100 to 200 joules delivered in single shots of 3 seconds up to the shrinkage of pile mass. During each shot, the probe was held in position while being gently rotated around its axis to ensure uniform application of light and prevention of adherence to tissue. While, in the procedure for *ksharsutra* ligation, the main pile mass held with pile holding forceps at respective positions and retracted outwards. The pile masses were crushed until it becomes like a thinned-out shape. Then the pile mass transfixed and ligated by round body curved needle loaded with the *Apamarga Ksharsutra*. The base of pile mass crushed by artery forceps. In case of externo-internal third-degree haemorrhoid incision taken at mucocutaneous junction and then transfixed. Haemostasis ensured. Gauze soaked in lignocaine jelly and betadine placed inside the anal canal and dressing was done. In the Postoperative procedure, patient is kept NBM for 6 hrs, Light diet allowed by the evening, Syrup Lactulose 30ml given orally at bed time, Sitz bath with warm water advised for 15-20mins from next day. Three doses of third generation antibiotics i.e. Cephalosporins by intravenous route 12 hourly administered.

The patients were assessed on the subjective and objective parameters and the relevant data collected for analysis. Subjective criteria are *Raktasrava* (Per Rectal Bleeding) and *Shula* (Pain) while Objective criteria is Degree of reduction of pile mass.

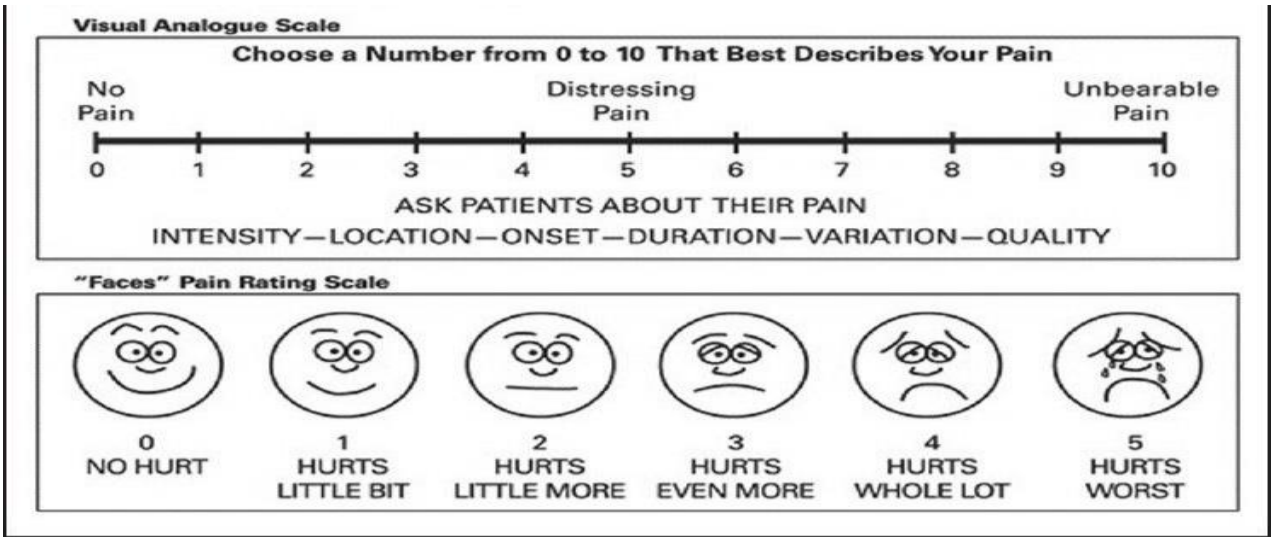
1. *Raktastrava* (Per Rectal Bleeding) The grading was made based on
patient's version. Attempts were made to have a gross quantitative analysis of bleeding in terms of drops.

Symptom are as follows:

- No bleeding
- Bleeding during defecation up to 10 drops
- Bleeding during defecation 10 to 20 drops
- Splash in a pan

2. *Shula* (pain)

Table-2: Assessment criteria for *Shula* (pain) by visual analogue scale (VAS):



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To assess the Pain level, symptoms are as follows:

- No pain
- Mild Pain: last for 1 hour after defaecation.
- Moderate pain: last for 1 to 3 hours.
- Severe pain: lasts for more than 3 hrs after defaecation.

3. Signs of degree of regression of pile mass are as follows:

- Complete disappearance of pile mass
- 1st degree piles
- 2nd degree piles
- 3rd degree piles

After assessment of subjects through individual criteria overall assessment was done by using improvement in subjective and objective parameters after the treatment and the results were categorized as:

- Complete relief: 75 to 100% improvement
- Moderate relief: 50 to 74% improvement
- Mild relief: 25 to 49% improvement
- No relief: Below 24% improvement

OBSERVATIONS AND RESULTS

After the surgical procedure, patients in each group were assessed using criteria of assessment and the collected data was summarized and presented statistically in terms of quantitative data:

The distribution of age between the groups is stated as, 19.35% patients were found in 51-70 years age group, 6.45% in 41-50 years age group, 48.39%% in 31-40 age group, 16.13% in 18-30 years age group. Youngest patient was 18 years and oldest was 68 years in group A.

In Group B, 12.90% patients were observed in 51-70 years age group. 9.68% in 51-60 years age group, 19.35% in 41- 50 age group, 42.26% in 31-40 years age group and 16.13% in 21-30 years of age groups.

This study concluded that 31-40 years of age group more affected by second and third degree haemorrhoids.

In the present study total 62 patient were included out of which 24.19% are female and 75.81% are male. 31 patients were from group A, sex wise distribution of all thirty-one Patients has been shown that there were 23 male patients. i.e., 74.19% and 8 female Patients i.e., 25.81% who underwent LASER haemorrhoidoplasty. And another 31 patients were from group B, sex wise distribution of all thirty-one patients has been shown that there were 24 male patients which is 77.42% and 7 patients are female which is 22.58%. Among the above observation it can be stated that male: female ratio was approximately 3:1.

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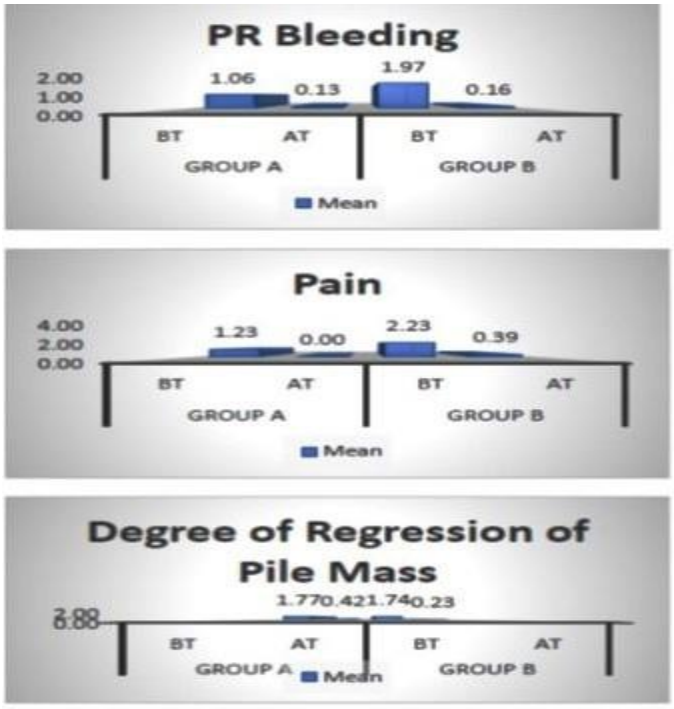
OBSERVATIONS ON EFFECT OF THERAPY

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
PER RECTAL BLEEDING	Group A	31	23.32	723.00	227.000	0.00018
	Group B	31	39.68	1230.00		
	Total	62				
PAIN	Group A	31	24.77	768.00	272.000	0.00117
	Group B	31	38.23	1185.00		
	Total	62				
DEGREE OF REGRESSION OF PILE MASS	Group A	31	30.24	937.50	441.500	0.54038
	Group B	31	32.76	1015.50		
	Total	62				
	Group B	31	36.74	1139.00		
	Total	62				

Table no. 01: Table showing comparison of effect of both surgical procedures on different parameters between experimental and control group.

Mann Whitney U Test was carried out for comparison between LHP and *ksharsutra* ligation (KSL) procedure. From above table, we can observe that, P-Value for almost parameters is less than 0.05. Hence, we can conclude that, there is significant difference between LHP and KSL.

Further, we can observe that, mean rank for KSL is greater than LHP. Hence, we can conclude that, effect observed in KSL is better than LHP.



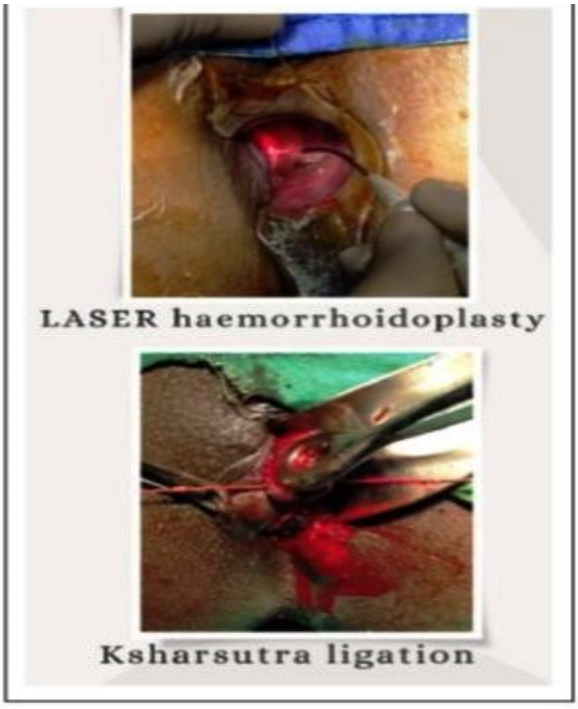


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Table no. 02: Table showing overall effect of therapy.

Overall Effect	LHP		KSL	
	N	%	N	%
Marked Improvement	24	77.42%	26	83.87%
Moderate Improvement	5	16.13%	5	16.13%
Mild Improvement	1	3.23%	0	0.00%
No Change	1	3.23%	0	0.00%
TOTAL	31	100.00%	31	100.00%

DISCUSSION:

Recent years have witnessed the introduction of many new surgical techniques for haemorrhoids in response to the need for a painless treatment modality with outpatient utility. The present RCT demonstrated the results of both the surgical procedures as follows; Comparative effect of therapy in between two groups viz; LASER haemorrhoidoplasty verses *ksharsutra* ligation:

Per rectal bleeding: On comparison between two groups before treatment and post-operative follow-up PR bleeding was 87.88% relieved in LHP while in *ksharsutra* ligation there was 91.80% relief in the PR bleeding was noted. it can be stated that effect observed in ksharsutra ligation is significant than laser haemorrhoidoplasty.

Pain: The application of diode lasers, in a manner, and is associated with reduced post-operative pain. On comparison between two groups before treatment and post-operative day 3, there was change in mean score of pain. As in both the groups almost every patient had pain prior to treatment. On operative day, pain was increased due to procedure. Laser Hemorrhoidoplasty (LHP) is a non-excisional procedure. Clinically pain was greater in patients with *ksharsutra* ligation than LHP. After POD1 pain decreases in both the groups but decrease in pain is more in LHP than *ksharsutra* ligation which finally result into 100% decrease in pain in LHP at the end of study which is more significant than group B which is 82.61%. thus, LHP is less painful and minimally invasive technique.

Size of pile mass: In the present study observations on comparison of LHP and KSL in two groups shows that there is 87% reduction in size of pile mass in patients of *ksharsutra* ligation and 76% reduction in size was noted in patients with LHP. Almost 10 patients had complaints like bleeding and feeling of mass during defaecation which mainly occurs in symptomatic haemorrhoids within 1 year of span. From these, 3 patients have recurrence within 3 to 4 months which revealed on proctoscopic examination. This value of recurrence rate is approximated as 6.45%. Statistical data shows that there is more significant reduction in size of pile mass in patients of *ksharsutra* ligation than LHP. So can be stated that KSL is an effective method for the treatment of 1st and 2nd degree piles

in regression of size up to 87%. On contrary to this, the *LHP* shows 76% regression in size of pile mass with recurrence of the disease within 1 year of span in almost 10 patients showed that LHP was associated with a high recurrence rate.

CONCLUSION:

From above observations it can be stated that LHP was associated with a high recurrence rate, including a serious adverse event i.e., bleeding and high procedural costs, mainly related to the cost of the laser-diode probe. It reduces pain as a minimally invasive procedure hence regarding pain it can be considered that laser technique in the treatment of haemorrhoids was safe, effective, and painless. In spite of being associated with less pain scores and shorter operative times, in Laser haemorrhoidoplasty, patients have to be counselled on possibility of higher complication rates than with conventional KSL procedure. On the basis of observations of the study, *Ksharsutra* ligation can be stated as a better surgical procedure in *Arsha*. This treatment is devoid of any side effects.

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