

**ROLE OF ALOE VERA KSHARA SUTRA IN THE  
MANAGEMENT OF ARSHA  
A THESIS  
SUBMITTED TO THE  
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DOCTOR OF PHILOSOPHY  
IN  
SHALYA TANTRA  
UNDER THE BOARD OF AYURVED STUDIES**



BY

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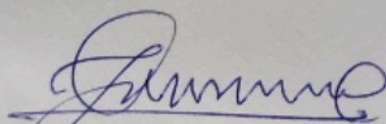
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**Tilak Maharashtra Vidyapeeth, Pune**

**Undertaking**

I **DR. DHARMPAL TRIMBAKRAO PATIL** is the Ph. D. Scholar of the Tilak Maharashtra Vidyapeeth in **SHALYA TANTRA** subject. Thesis entitled "**ROLE OF ALOE VERA KSHRA SUTRA IN THE MANAGEMENT OF ARSHA**" under the supervision of **DR. P. HEMANTHA KUMAR**. Solemnly affirm that the thesis submitted by me is my own work. I have not copied it from any source. I have gone through extensive review of literature of the related published / unpublished research works and the use of such references made has been acknowledged in my thesis. The title and the content of research are original. I understand that, in case of any complaint especially plagiarism, regarding my Ph.D. research from any party, I have to go through the enquiry procedure as decided by the Vidyapeeth at any point of time. I understand that, if my Ph.D. thesis (or part of it) is found duplicate at any point of time, my research degree will be withdrawn and, in such circumstance, I will be solely responsible and liable for any consequences arises thereby. I will not hold the TMV, Pune responsible and liable in any case.

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It is certified that work entitled “**ROLE OF ALOE VERA KSHARA SUTRA IN THE MANAGEMENT OF ARSHA**” is an original research work done by **DR. DHARMPAL TRIMBAKRAO PATIL** Under my supervision for the degree of Doctor of Philosophy (Ph.D.) in **SHALYA TANTRA** subject to be awarded by **Tilak Maharashtra Vidyapeeth, Pune**. To best of my knowledge this thesis embodies the work of candidate himself has duly been completed fulfills the requirement of the ordinance related to Ph. D. degree of the TMV up to the standard in respect of both content and language for being referred to the examiner.

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## ABSTRACT

### 1. INTRODUCTION

Now a day Arsha is one of the most delicate condition to deal with. It is one of the eight major diseases (Ashta Mahagada).Arsha can be correlated with the disease Hemorrhoids mentioned in Modern Surgery. Available conservative therapy for Arsha in modern surgery has too many limitations and available surgical procedures are having complications and without complete cure. Ayurveda has mentioned Para-surgical and Surgical measures for Arsha. Ksharasutra is one of the most successful para-surgical procedure. The standard treatment with SnuhiKshiraKsharasutra is somehow painful and irritative despite being effective. Hence trying a new drug overcome these drawbacks was the prime theme. Title of present study was **“Role of Aloe Vera Ksharasutra in the management of Arsha.”**

#### **Why Aloe Vera Ksharasutra**

Ushna and Teekshnagunas of ApamargaKshara are not reduced by Aloe Vera. Hence there is no pain and irritation when pile mass is removed by Aloe Vera Ksharasutra which is major issue in case of SnuhiKshiraKsharasutra. Due to Shothahara, Bhedana, Vedanasthapaka, Vranaropana, Mrudu, Sheeta Guna-karmas of Aloe Vera cutting of Pile-mass is painless. Aloe Vera acts like good Antibiotic and chances Infection & Sepsis are very rare. Aloe Vera is very cheap, economic, easy to collect and freely available everywhere at any season in India, where as Snuhi is seasonal & scarce.

### 2. REVIEW OF LITERATURE

#### **Previous work done**

Almost 30 previous dissertations were reviewed as a guideline for dissertation.

#### **Ayurvedic Review**

Guda Rachana sharira and Guda Kriya sharira was studied in details for better understanding of Samprati of Arsha. Further Nidanpanchak and Chikitsa of Arsha was studied from all possible Ayurvedic classical texts. The word Arsha is derived from the root word ‘*Ru-gatau*’ after adding the suffix ‘*asuna*’ which means to take life.

There are six types as per Dosha and three types as per sthana. Arsha Chikitsa is classified as – Bhesajachikitsa, Ksharakarma, Agnikarma and Shastra karma.

### **Discription of Kshara&Ksharakarma**

Treatment by **Kshara** is technically termed as Kshara Karma. Due to its corrosive nature (Ksharanata) it is known as Kshara (alkali). **Ksharakarma** performs Chhedana (excision), Bhedana (Incision), Lekhana (Scraping) and Shamana karmas. The **Kshara Sutra** is a para surgical measure capable to perform excision slowly by virtue of its mechanical pressure and chemical action in Arsha. Chakradutta has narrated Snuhi Kshira Sutra preparation in Arsha.

### **Modern Review**

The interior of the anal canal can be divided into three parts - Mucosal part, Mucocutaneous part or Pecten and Cutaneous part. Etiology of Hemorrhoids comprises mainly Hereditary, Anatomical and Physiological causes. Piles are classified as, **1.** Primary & Secondary **2.** Internal, External & Interno-External **3.** 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> degree. Common clinical features include – Bleeding, Prolapse, Discharge, Irritation, Burning, pain. Treatment of Hemorrhoids is mainly of two types **1.** Non-Surgical, **2.** Parasurgical and **3.** Surgical.

## **3. RESEARCH METHODOLOGY**

### **Aims and Objective**

To study and to compare the effect of Aloe Vera Ksharasutra and Snuhi Kshira Ksharasutra in patients of Arsha specifically on Irritation, Cutting and Healing.

### **Methodology**

Total 220 patients fulfilling Inclusion and Exclusion criteria were involved in this study selected by simple randomized sampling method (Computer generated table of Random Numbers), which were further divided into two equal groups 110 each. Sample size calculated according to **Cochran's Formula** was **93**. It was approximated it to **110**. Study was carried out at OPD and IPD, Shalyatantra Department, of Aryurveda Hospital at Manjara Ayurveda College, Latur.



**Study type:** Randomized Controlled Clinical Trials.

### **Research Question**

Does the ligation of Arsha with Aloe Vera Ksharasutra is effective than the ligation of Arsha with SnuhiKshiraKsharasutra or not?

### **Null Hypothesis (H<sub>0</sub>)**

Ligation of Arsha with Aloe Vera Ksharasutra is not significantly effective than Ligation of Arsha with SnuhiKshiraKsharasutra in Arsha vyadhi.

### **Alternative Hypothesis (H<sub>1</sub>)**

Ligation of Arsha with Aloe Vera Ksharasutra is significantly effective than Ligation of Arsha with SnuhiKshiraKsharasutra in Arsha vyadhi.

**Duration of the study:** Total duration of the study was 16 to 18 months after approval of synopsis. Every patient was called and examined at every alternate day up to 9 days.

**Method of Preparation of Ksharasutra:** Aloe Vera Ksharasutra and SnuhiKshiraKsharasutra were prepared according to Ksharasutra method as mentioned in Sushruta Samhita (Su. Chi. 17/29-33). Total 21 layers were applied (11 of Aloe Vera / SnuhiKshira + 7 Apamarga + 3 Haridra). Aloe Vera and SnuhiKshiraKsharasutras were Standardized from authentic analytical lab. Reports are attached in Annexures.

**Method of Ligation of Ksharasutra:** Ksharasutra ligation done in both the groups with respective Ksharasutras. (i.e. Aloe Vera Ksharasutra was used in Trial Group patients, while SnuhiKshiraKsharasutra was use in Control Group patients.) Ksharasutra ligation procedure was carried out O.T. under all aseptic precautions as per standard operative methods in three phases, viz. Pre-operative, Operative and Post-operative.

**Overall Assessment Criteria:** It was defined as Cured, Marked, Moderate, Mild and Poor on the basis of relief in symptom.

## **4. ANALYSIS AND INTERPRETATION**

### **Analysis**

Collected data was classified in the forms of Master Charts groupwise. Further those data (Demographic profile and BT-AT changes in symptoms) were presented in the forms of Tables and Graphs. Parameters were analyzed statistically at 5 % level of significance using

- Wilcoxon Signed Ranks test (within Group A and within Group B)
- Mann-Whitney test (in between Group A and B)

It was observed that, Aloe Vera Ksharasutra ligation (Trial drug) was found more effective than SnuhiKshiraKsharasutra (Trial drug) except in case of Cutting of pile mass. According to statistical analysis,

- Aloe Vera Ksharasutra ligation is effective than SnuhiKshiraKsharasutra ligation in Arsha to reduce Pain, Discharge and Irritation.
- Aloe Vera Ksharasutra ligation is effective than SnuhiKshiraKsharasutra ligation in Arsha to heal the wound on cutting of Arsha.
- SnuhiKshiraKsharasutra ligation is effective than Aloe Vera Ksharasutra ligation in Arsha to cut pile mass.

### **Interpretation**

All data observed, presented and analyzed were undergone critical analysis and logical reasoning to test the hypothesis. All dimensions of study were discussed under discussion section against observations. Discussion was written under following heads – Discussion on selection of topic, Discussion on Arsha, Discussion on Ksharasutra, Discussion on general observations, Discussion on changes in symptoms and Discussion on Statistical analysis. Effect of therapy was calculated as -

- Average % Relief in Patients of **Group A** is **91.10%** and Average % Relief in Patients of **Group B** is **83.67%**.
- Average % Relief in Symptoms of **Group A** is **91.01%** and Average % Relief in Symptoms of **Group B** is **82.61%**.

### **Effect of therapy**

1. Effect of Aloe Vera Ksharasutra,
  - a. 65 patients: Complete cure (100%)
  - b. 31 patients: Marked improvement (75% to 99%)

c. 14 patients: Moderate improvement (50% to 74%)

2. Effect of SnuhiKshiraKsharasutra,

a. 55 patients: Complete cure (100%)

b. 11 patients: Marked improvement (75% to 99%)

c. 44 patients: Moderate improvement (50% to 74%)

### **Mode of Action of Aloe Vera Ksharasutra**

- The cutting piles by Aloe Vera Ksharasutra is by process of Chemical cauterization due to chemical properties of its contents.
- After ligation the pressure is created on muscle mass by the Ksharasutra and due to chemical properties chemical cauterization occurs.
- Healing processes take place at same time.
- Infection / Sepsis does not take place due to antibiotic & antiviral properties.

## **5. CONCLUSION, FINDINGS AND RECOMMENDATIONS**

### **Conclusion**

- Aloe Vera Ksharasutra ligation in Arsha is effective specially in Pain, Irritation and healing without any complications.
- Aloe Vera Ksharasutra ligation is effective than SnuhiKsheeraKsharasutra ligation specially in Pain, Irritation and healing in Arsha patients.
- SnuhiKshiraKsharasutra ligation is effective than Aloe Vera Ksharasutra ligation specially in Cutting of hemorrhoidal mass in Arsha patients.

### **Findings**

Arsha prevalence is more now a days as compared to past. Middle aged persons (33 to 49 yrs.) and males were affected more. Arsha incidences found more in Vata Prakruti, Urban habitat and patients with KruraKoshtha. Long standing, sitting and frequent Non-vegetarian diet may be the causative factors of Arsha as more incidences found in such persons.

## **Recommendations**

1. Larger sample size from larger population may give more correct results.
2. By taking longer duration studies one can conclude about late complications and recurrence of disease.
3. New researchers may study Aloe Vera Ksharasutra in diseases like Sinus and Fistula also.
4. A new method of preparation of Ksharasutra by adding specific content which can increase the cutting effect of Aloe Vera Ksharasutra further more.
5. New drug can be tested in Ksharasutra to compare with Aloe Vera Ksharasutra.

## **ANNEXURES**

Annexures comprised of all other information regarding the dissertation. Viz.

- Master Charts [Demographic Data (Trial Group), Demographic Data (Control Group), Subjective Parameters (Trial Group), Subjective Parameters (Control Group)]
- Case Record Form&Written Consent (English, Marathi)
- Bibliography
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## ABBREVIATIONS

Sr. No.	Abbreviation	Long Form
1	अ. ह. नि.	अष्टांग हृदय निदानस्थान
2	च. वि.	चरक विमानस्थान
3	सु. नि.	सुश्रुत निदानस्थान
4	यो. र.	योगरत्नाकर
5	मा. नि.	माधवनिदान
6	च. चि.	चरक चिकित्सास्थान
7	सु. चि.	सुश्रुत चिकित्सास्थान
8	अ. ह. चि.	अष्टांग हृदय चिकित्सास्थान
9	सु. सू.	सुश्रुत सुत्रस्थान
10	Su. Su.	Sushrut Sutrasthana
11	A. H. Su.	Ashtang Hriday Sutrasthana
12	A. S. Su.	Ashtang Sangraha Sutrasthana
13	GIT	Gastro Intestinal Tract
14	L	Lumber Nerve
15	S	Sacral Nerve
16	MI	mili litre
17	P/R	Per rectum
18	DGHAL	Doppler Guided Hemorrhoidal Artery Ligation
19	KSL	Kshara sutra ligation
20	Su. Chi.	Sushruta Chikitsasthana
21	K.S.	Kshara sutra
22	O.T.	Operation Theatre
23	V	Vata
24	P	Pitta
25	K	Kapha
26	OPD	Outdoor patient department
27	IPD	Indoor patient department
28	H <sub>0</sub>	Null Hypothesis



29	H <sub>1</sub>	Alternate Hypothesis
30	Sr. No.	Serial Number
31	Reg. No.	Registration Number
32	Yrs.	Years
33	%	Percentage
34	No.	Number
35	P	Probability
36	N	Sample size
37	W	Wilcoxon statistic
38	U	Mann-Whitney's statistic
39	SD	Standard Deviation

## 1. INTRODUCTION

### 1.1. Ayurveda and Surgery

Ayurveda, ‘the science of life’ is based on the long–term trials, observations, medical experiences along with the knowledge gained by *Divya chakshu*, *Tapah chakshu* and from *Apta*. Ayurveda has been divided into eight specialized branches and Shalya Tantra is one them. It was a peak time in the field Ayurveda Surgery during period of Sushruta. Many scientific surgical procedures are found in text of Sushruta named Sushruta Samhita. Further glory of Ayurveda Surgery was vanished in the flow of time due to various reasons. Its need of time and duty of Ayurveda students / teachers / researchers to bring back it again. Proctology is one of the fields where Ayurveda is far ahead of recently available streams of medicines. Ayurveda is giving fruitful results in Ano–rectal diseases than other medical streams as well. In the main surgical text of Ayurveda named Sushruta Samhita many concepts and treatment modules regarding ano–rectal diseases are found. Ayurveda can give solution to many such diseases in Proctology on the basis of further evidence–based research.

### 1.2. ‘Arsha’ – one of the eight major disease (Mahagada)

Acharya Sushruta, the father of surgery in his well–known treatise Sushruta Samhita describes different types of anorectal diseases. He has mentioned Arsha as one of them. In fast and stressful 21<sup>st</sup> century with improper lifestyle, stress–strain and heavy competition, incidence of anorectal diseases is more. The junk food, less fibrous diet, irregular times of meal and improper food habits (Mithya ahara) are major factors for constipation and various ano–rectal diseases like Arsha. Among Gudgat vikaras (ano–rectal diseases), Arsha is a one condition to which every surgeon has to face in day today’s practice. Arsha is one of the eight major diseases (Ashta Mahagada) as per Charaka, Sushruta and Vagbhata. Ashta Mahagada are namely Vatavyadhi, Prameha, Kushtha, Mudha Garbha, **Arsha**, Bhagandara, Ashamari and Udara Roga. Nidanpanchak and Chikitsa of Arsha is found in almost each and every Ayurvedic classical text. According to Charakacharya, Arsha, Atisara, and Grahani are the diseases in which Mandagni is the major cause.

### **1.3. Hemorrhoids**

Hemorrhoid is the varicosity of rectal veins which is very much common disease among anorectal diseases. Few of the very common etiological factors of Hemorrhoids are constipation, changed lifestyle, improper food habits, stress–strain and heredity etc. Anorectal disorders mostly give discomfort feel to the patient. Anorectal region is surrounded by various nervous supply and venous drainage and hence is a delicate anatomical structure. Commonly patients shy and feel awkward to consult with physician/surgeon and in turn the condition may get worsen. There are three types of Arsha as per their location **1.** Bahya Arsha (External piles), **2.** Abhyantar Arsha (Internal piles) and **3.** Bahyabhyantar Arsha (Intero–external piles). Piles are further classified into 4 degrees **1.** First degree **2.** Second degree. **3.** Third degree **4.** Fourth degree as per situation of prolapse. Pain, Bleeding and Irritation is the common clinical presentation. Complications may include mild to severe anaemia, thrombosis, suppuration and prolapse.

### **1.4. Current scenario of Arsha (Hemorrhoids)**

Arsha can be correlated with the Hemorrhoids at modern parlance. Its incidence increases with advancing age, at least 50% of people over the age of 50 years have some degree of symptoms of Hemorrhoids as per study [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296345/97%>]. Recent statistics reveal that irrespective of age, sex and socio–economic status, people may suffer from piles. In addition to that some western population statistics reported that the prevalence may be around 37% with an equal frequency in men and women. Hemorrhoid can progressively be enlarged and the prevalence may be increased with advancing age; hence, patients at any age may present with symptoms of Hemorrhoids. According to WHO 40% of people worldwide suffer from it. In India approximately 80% of the sufferers are in age group of 21 to 50 yrs. Also, commonly seen in the people who work many hours in sitting position. **[Ref. [https://docplayer.net/96290738–The–clinical–efficacy–ofshunthyadi–churna–with–gud–in–the–management–of–arshahemorrhoids.html](https://docplayer.net/96290738-The-clinical-efficacy-ofshunthyadi-churna-with-gud-in-the-management-of-arshahemorrhoids.html)]**

### 1.5. Line of treatment

Sushrutacharya and Charakacharya has been stated four types of treatments as follows,

1. Bhaishaja Chikitsa
2. Kshara Karma
3. Agnikarma
4. Shastra Karma

**(Ref. Sushrut Samhita Chikitsasthan chapter 30, Charak Samhita Chikitsasthan chapter 14)**

Acharya Charak clearly stated '*Dhanvantari Adhikar*' (must be treated by Surgeon) regarding Kshara, Agni and Shastra chikitsa. 1<sup>st</sup> and 2<sup>nd</sup> degree Hemorrhoids can be treated by medicine, whereas 3<sup>rd</sup> and 4<sup>th</sup> degree Hemorrhoids need the non-surgical (para-surgical) or surgical procedures like Kshara karma, Kshara Sutra, Agni karma and Shastra karma. Kshara Sutra is one of the routinely applied procedures, especially in third and fourth degree of piles which is very simple, economic and convenient to patient.

Regarding the management of Hemorrhoids, the history can be traced back that the Hemorrhoids have been treated by Surgeons for centuries. Therapies like topical use of medicament for treatment of Hemorrhoids can be dated back to Egyptian Papyri of 1700 BC. The first surgical treatment was described in the Hippocratic Treatises of 460 BC and suggested transfixing them with a needle and tying them with a very thick and large woolen thread. 'Laxatives and Fibrous diet' is considered as the basic of line of conservative treatment of Hemorrhoids. But there are its limitations and no any radical cure. Modern conservative therapies include non-surgical modalities like viz. Injection of Sclerotherapy, Cryo-therapy, Manual dilatation of anus, Electro-coagulation, Rubber-band Ligation etc. Among surgical measures Cryosurgery, Hemorrhoidectomy, Transend Hemorrhoidal Artery Ligation, DGHAL (Doppler Guided Hemorrhoidal Artery Ligation) and Stapled Hemorrhoidectomy etc. are commonly used ones. All the available procedures are having complications and recurrence is again the issue.

## **1.6. Ksharasutra: The prime treatment**

A number of new surgical methods have led to a reappraisal of Arsha (Hemorrhoids) over the last few decades. Kshara Sutra is one of the routinely applied procedures which is very simple, economic and convenient to patient. Kshara sutra treatment is easy, fruitful, cost-effective and well-known as compared to other surgical or parasurgical measures in modern surgery. Methods of preparation of Kshara and Ksharasutra have been enlighten by many Ayurvedic classical texts. Currently the most used standard treatment for Ksharasutra chikitsa is Snuhi kshira, which is well-known and widely accepted. But it is having its own limitations like pain, irritation and burning after ligation despite its good results. Hence, its time to test few more drugs to overcome the drawbacks.

## **1.7. Rationale of the study**

As per my opinion though the Ksharasutra procedure well-known and widely accepted there is need of standardization on Kshara Sutra Ligation (K.S.L) procedure. Even though in this era, patients are preferring such a non-surgical process of Kshara Sutra, but irritability is the almost drawback to patients, where they have to tolerate much through Ligation. Hence, here is a need to develop such Kshara Sutra which is less painful and less or no irritative. So, we have decided to work on this disease, by inventing the Kshara Sutra through changing its content. Most researchers attempted clinical trials on Kshara Sutra which is commonly prepared by adding several of Ksharas with Snuhi Kshira, which is more corrosive, irritative, painful to the patients and difficult to prepare in humid climates. But here we have used Aloe Vera pulp instead of the Snuhi Kshira, to release the associated problems created by the Snuhi Kshira Ksharasutra, i.e. post ligation irritation. Aloe Vera being a Sheet Viryatmak it has all the properties of cutting, healing, antiseptic, antibiotic, easily available and prepared in all climates, which are very essential in the removal of the piles.

### **Advantages of Aloe Vera Ksharasutra**

Ushna and Teekshna gunas of Apamarga Kshara are not reduced by Aloe Vera. Hence there is no pain and irritation when pile mass is removed by Aloe Vera Ksharasutra

which is major issue in case of Snuhi Kshira Ksharasutra. Due to Shothahara, Bhedana, Vedanasthapaka, Vranaropana, Mrudu, Sheeta Guna-karmas of Aloe Vera, cutting of Pile-mass is painless. Aloe Vera acts like good Antibiotic and chances Infection & Sepsis are very rare. Aloe Vera is very cheap, economic, easy to collect and freely available everywhere at any season in India, where as Snuhi is seasonal & scarce.

So, considering all these facts we have selected the quality potential drug like drug Aloe Vera to use for preparation of Ksharasutra and to use in trials of present dissertation entitled, **“Role of Aloe Vera Ksharasutra in the management of Arsha.”** We have achieved excellent positive results which are mentioned and discussed further in this dissertation.

## 2. REVIEW OF LITERATURE

### 2.1. PREVIOUS RESEARCH WORK

Several research studies have been conducted at different institutions in all over India on Arsha.

1. **Anathasayanacharya (1987)** – Role of Dhoopana in management of piles. **Hydrabad.**
2. **Baraskar K.G. (1978)** – Arsha mien Ksharapatan – **Jamnagar.**
3. **Arya R.C. (1984)** – Comparative study of role of indigenous drugs in the management of Arsha w.s.r. to Kshara sutra – **GAU, Jamnagar.**
4. **Deekshit ula (1985)** – Effect of Kattapa Taila on prolapsed piles. – **Trivendram**
5. **Upadhyay P.M. (1985)** – Role of Pratisaraniya Kshara in the management of Raktarsh – **Jamnagar.**
6. **Arun Kumar (1986)** – A Role of various forms of Pratisaraniya kshara in Ano-rectal disorders – **B.H.U.**
7. **Dr. Sharma A.L. (1990)** – Arsha Roga Chikitsa men Vibhinna Kshara sutra ka Tulanatmaka Adhyayan – **Jaipur.**
8. **Venkateshwaralu K. (1990)** – Clinical study on the management of Bahya Arshas with Pippalyadi Lepa and Nimbadi Lepa. – **Bangalore.**
9. **Dr. Sharma K.P. (1992)** – Arsha ki Kshara sutra chikitsa men lord vidhi ki upayogita – **Jaipur.**
10. **Shrivastava. S. (1993)** – Arsha chikitsa men kshara sutra evam bandlization ka Karmatmak adhyayan – **Jaipur.**
11. **Reddy Vasudev (1994)** – Clinical study on Karanjadi Choorna in Arshas. – **Hydrabad**
12. **Dr. Subha Reddy (1994)** – Aloe vera Ksharsutra for fistula-in-ano. – **BHU Varanasi.**
13. **Rusia Ranjana (1995)** – Arsha chikitsa men ksharasutra evam samanya sutra ka prayogatmak Adhyayan – **Jaipur.**
14. **Babu P.V. Ramesh, (1996)** – Role of Pratisaraniya Kshara in the Management of Hemorrhoids – **B.H.U.**

15. **Dikshit Mahesh (1997)** – Raktarsha mein Kutajadi rasakriya ki karmukta ka adhyayana. – **NIA Jaipur.**
16. **Umare K.S. (1997)** — Role of Pratisaraniya Kshara in the Management of Arsha – **Akola.**
17. **Pandya P.G. (1998)** – Kshara Patan in the Management of Arsha – **Jamnagar.**
18. **Rao V.S. (1998)** – Effect of Manibhadra Yoga & Kashisadi Taila in the management of Hemorrhoids. **Hydrabad.**
19. **Mutha S.L. (1998)** – To study the effect of Apamarga Kshara Pratisaran on Sushka and Parisravi Arsha – **Nasik.**
20. **Anjaneyalu (1999)** – The management of Arshas with Chitrakadi Taila (ext.) & Chitrakadi Choorna (int.) – **Hydrabad.**
21. **Pareek S.R. (1999)** – A Comparative Study of Pratisaraniya Kshara in the Management of Arsha.
22. **Dhurve N. (2000)** – Study to evaluate the efficacy of Lavantomadya Choorna in the management of Arsha. – **NIA Jaipur.**
23. **Murlidhar N. (2000)** – Effect of Pratisaraniya Kshara on Ardra Arsha– **Hasan.**
24. **Sarkar D. (2002)** – The clinical study of evaluate the efficacy of Arshoghna Mahakashaya in the management of Raktarsha. – **NIA Jaipur.**
25. **Sarkar D. (2002)** – The clinical study of evaluate the efficacy of Arshoghna Mahakashaya in the management of Raktarsha.
26. **Mini P. (2003)** – A Clinical study on the effect of Apamarga Kshara in the Management of Arsha – **Trivendrum.**
27. **Pramila Kumari (2003)** – Arsha Roga ki chikitsa mein Lord's Vidhi evam Arshohara Malhara ka tulanatmak Adhyayan. – **NIA Jaipur.**
28. **Vd. Kedar M. Nita, (2004)** – Clinical evaluation of Haridradi lepa in Arsha – **GAC, Nagpur.**
29. **Sudha Kumari (2004)** – A clinical study on the management of Arshas with Vyoshadi Choorna (internally) and Shirish Beejadi Lepa. – **Hydrabad.**



## 2.2. HISTORICAL REVIEW OF ARSHA

Study highlights understanding and framing an idea about the subject to be projected. It covers everything beginning from the past to the present which is related to the subject and which provide the clear image of the same. The preliminary description of this disease has been seen as **Durnam** in Atharvaveda, means “bad one by name” or “sin from origin”. Arsha could be traced in Vedic literature.

Sushruta has narrated it as one of the Astamahagadas, which shows its grievousness. In the description of Arsha, Sushruta has described its different types and management for curing the disease which includes the surgical and Para surgical methods along with the main concern to the Ksharakarma. Charka has also devoted a chapter for this entity. He has explained vividly the medical management as, there could be damage to the patient if Shastra, Kshara and Agnikarma are not done properly or done by an un-experienced surgeon.

Vagbhata has also mentioned about the disease in best sum from Charka and Sushruta Samhita. Later on, Chakradatta, Rastarangini, Madhava Nidana Sharangadhara Samhita, Bhavaprakasha, as well as Yogratnakara have described Arsha. Vedas are the oldest written testimonials available to mankind on this earth, where plenty of medicinal uses have been enumerated. But no description of Kshara was found in Vedic literature. In Upanishad, the use of word Kshara is found but nothing has been described in detail. In this regard, detailed explanation regarding Kshara has been made by Sushruta. Only Sushruta has dedicated a whole chapter to Kshara. He has narrated Kshara considering its scope in Shalya Tantra due to its Chedana, Bhedana and Lekhana qualities.

Charaka has dealt with definition, varieties, properties & application of Kshara. Charaka has mentioned two types of Kshara Preparation. In 1<sup>st</sup> chapter of Vimana sthana, definition, general properties and adverse effects of Kshara are mentioned. He has also specified that Kshara does not possess a single Rasa, but it possesses multiple Rasas because it is a Dravya prepared from various drugs and consist all Rasas except Amla Rasa. Apart from that, in surgical description also, Kshara has been mentioned as ‘Shastra Pranidhana’ Dalhana, the renowned commentator of Sushruta Samhita explained the word ‘Ksharana’ as one which mobilizes and removes the deformed flesh, skin etc. and also removes the vitiated Doshas from their location.

## 2.3. AYURVEDIC REVIEW

### 2.3.1. GUDA SHARIRA:

The word Guda is used by the Acharyas to denote an organ that performs the actual function of defecation. Acharya Sushruta has given a detailed description of embryological development of Guda in sharira sthana. Sushruta is known for the technique of dissection thus after detailed studies he has also mentioned about the blood supply, nerve supply, and musculature and also functioning of Guda.

गुदः स्थूलान्नसंश्रयः ।

अ. ह. नि. ७/३.

वातव्याध्यश्मरीकुष्ठमेहोदरभगन्दराः ।

अर्शांसि चातिसारश्च ग्रहणीदोष एव च ॥

### Vyutpatti:

It is a word of masculine gender. “Godate” means to play. The word Guda is at times used for both i.e. end part of digestive system and end part of urinogenital system. Thus, the chief site of Apana Vayu is Guda.

### Synonyms:

Amarkosha – Apanam, Payu

Jatadharam – Guhyam, Gudavartma

Vijayarakshita – Apanah, Mahatsrotas

Gangadhara – Bradhanam

Vachaspati – Vitmarga

पुषिवहानां स्रोतसां पक्वाशयो मूलं स्थूलगुदं च .....।

च. वि. ५/४.

Other words that are mentioned in contact to Guda various Acharyas are  
Charaka – Uttaraguda, Adharaguda, Sthulaguda, Gudamukha  
Sushruta – Gudamandhala, Gudavalaya, Payuvalaya, Gudaustha.

**Embryology– genesis:**

In Sushruta sharira sthana, it is clearly noted that Antra, Basti and Guda of the fetus are formed from the cream part of Rakta and Kapha after being digested by Pitta along with the active participation of Vayu.

In the genesis of Guda it is told that it is a Matrija Avayava i.e. it has dominance of the gene from the mother. It is produced in the 3<sup>rd</sup> and 4<sup>th</sup> month of intrauterine life.

**Sharir Rachana:**

While giving details about ‘Koshtha’, Acharya Charaka has mention two parts of Guda. The upper part or the Uttara Guada is the one where feaces is stored as explained by Acharya Chakrapani. The lower part or the Adhara Guda is the part, by which the feaces is defecated.

तत्रस्थुलान्प्रतिबद्धमर्धपन्चाङ्गुलंगुदमाहुः,  
तस्मिन् वलयस्तिस्त्रोऽध्यर्धाङ्गुलान्तरसंभूताः प्रवाहणी विसर्जनी संवरणीचेति ॥  
चतुरङ्गुलायताः सर्वास्तिर्यगेकङ्गुलोच्छ्रिताः ।  
शंखावर्तनिभाश्चपि वर्णतः संप्रकीर्तिताः ।  
रोमन्तेभ्यो यवध्यर्धो गुदौष्ठः परिकीर्तिताः ॥  
प्रथमा तु गुदौष्ठादङ्गुलमात्रे ॥

– सु. नि. २/५-७.

Acharya Sushruta has documented the anatomy of humans has made him site on the heights of honour. Initially he has described in Sutrasthana, the method of dissection by submerging the cadaver in water and then slowly brushing off the tissue, layer by layer. During this cadaveric dissection or during the examination of the patient those features noted by him are documented.

**Size:** Its size is said to be four and a half fingers.

**Colour:** Its colour is like the palate (or buccal cavity) of the elephant which is whitish or blackish pink.

**“Vallies”:** It contains three folds (vallies) namely Pravahani, Visarjani and Samvarni from proximal to distal respectively.

The vallies are situated one above the other like spirals of conch shell. According to Sushruta samhita the meaning of valaya is “ring”. This can be inferred from the fact that while mentioning the types of bones Acharya has said that “Valaya” type of bones makes the “Prishthavansha” i.e. vertebral column. The vertebrae are ring shaped and thus the name.

Gudaushtha is raised one and a half barley from the hair end. The first anal fold measures one finger after the anal lip. Acharya Dalhana has commented about their functional details as –

**Pravahani** – Pravahini is the valli that brings the faeces down.

**Visarjini** – This is the fold which relaxes and evacuates the faeces.

**Samvaranani** – This valli covers the anus and opens during the time of defecation.

Vagbhatta also accepts the concept of these vallies and gives the specific order of their arrangement. He clarifies that, Samvaranani is the distal most Valli, whereas Pravahini is the proximal most from large intestines. Visarjini is situated in between these two vallies.

**Siras:** According to Acharya Sushruta, in Koshta region there are thirty Vayu carrying Siras out of these, eight Siras are situated in the Shroni region, connected with linga and Guda. Similar connection also has been described regarding the Pitta, Kapha and Raktavaha Siras.

**Dhamani:** There are twenty-four Dhamani in the body, out of which ten go onwards and perform the functions of micturation, defecation, ejaculation of semen, menstruation and expulsion of foetus during delivery.

**Asthi:** The visceral organs are well protected by the bony cage of Shroni. This Shroni comprises of five bones out of them four comes are well attached with Guda, Yoni and Nitamba and the remaining one is in the Trika region. The Asthi Sandhi of this region is Samudge type.

**Snayu:** There are sixty snayu in the Pelvic region and eighty are in the Groin. The snayu which are connected with Guda region are of Sushira type.

### **Importance of Guda:**

The importance of Guda can be viewed in the terms of the following facts:

- It is stated by all authors, that Guda is a Marma which means the vital organ of the body, whose damage will cause death. It is categorized under Sadyah Pranahara Marma, due to predominance of Agni Guna. It is included in the Mamsa Marma by Sushruta and Dhamani Marma by Vagbhata.
- Guda is one of “Pranayatan”. It is enlisted under Pranayatan because its proper action is very–very important for normal functioning of the body.
- While enlisting the Indriyas, Guda is categorized under Karmendriya group and the function designated to it, is defecation and releasing of flatus.
- Guda is also act as a Srotas. Pakvashaya and Guda is the root of Purishvaha Srotas, their injury leads to distention of abdomen, foul smelling and matting of intestine.

### **2.3.2. GUDA KRIYA SHARIRA:**

Defecation is the most important function of Guda. The mechanism of defecation too was known in the ancient times. Here “Apana Vayu” is the responsible factors for accomplishment of the process of defecation along with associated efforts of vallies.

Gana Nath Sen has coined the physiology of defecation according to ayurvedic texts.

The role of Vallies is very significant in this context.

#### **Step 1:**

Pravahini as the name goes helps to propel or force the stool down once the stool has occupied its place in rectum.

#### **Step 2:**

There after the 2<sup>nd</sup> Valli i.e. Visarjani relaxes the anal wall and thus promotes further passage of the faeces.

#### **Step 3:**

Samvarani the third valli comes to action. If the conditions are favorable for defecation this valli relaxes and after the faeces has passed it cut the fecal column after Visarjani has completed its work. But if there is no favorable condition then this valli does not allow faeces to pass and provide a voluntary control over the rather involuntary process of defecation. This Samvarani, according to ancient authors, also acts as a valve to guard at the anal orifice.

### 2.3.3. ARSHA VYADHI:

#### A. GENERAL CONSIDERATION:

Arsha occurs at many sites like nasa arsha and shishna arsha but the present context deals with the Arsha occurring at the guda only.

#### Etymology:

The word Arsha is derived from the root word 'Ru-gatau' after adding the suffix 'asuna' which means to take life.

#### Synonyms:

अर्श – अरिवत् प्रणान् श्रृणाति हिनस्तीत्यर्थः ।

दुर्नाम – दुःखप्रदं नाम यस्येति...।

– भैषज्यरत्नावली अर्शरोगचिकित्साप्रकरणम्/१

- Durnama – Bad one by name or sin from origin.
- Gudamaya, Gudaja – Arising from guda
- Gudakila – Peduncle or horn in anus.
- Gudankura – Sprout or swelling in anus
- Anamaka – Unfamous
- Payuroga – Disease of anus

#### Definition of Arsha:

अरिवत्प्राणिनो मांसकीलका विशसन्ति यत् ।

अर्शासि तस्मादुच्यते गुदमार्गविरोधतः ॥

– अ. ह. नि. ७/१., यो. र. अर्शरोगनिदानम्, अर्शानिरुक्ति/१

According to Vagbhata, Arsha is a muscular projection (mans-keel) which troubles the patient like an enemy. According to madhava, Arsha gives pain like an enemy.

पृथकदोषः समस्तैश्च शोणितात्सहजानि च ।

अर्शासि षट्प्रकाराणि विद्याद् गुदवलित्रये ॥

– यो. र. अर्शोरोगनिदानम्/१, – मा. नि. अर्शोनिदानम्/१

## B. CLASSIFICATION OF ARSHA:

There are different opinions of authors regarding the classification of Arsha. They are classified on the basis of origin, bleeding and predominance of Doshas etc. This classification is as follows:

### B.1. According to Dosha Dominance:

षडर्शासि भवन्ति वातपित्तकफशोणितसन्निपातैः सहजानिचेति ।

– सु.नि. २/३

अर्शःसु दृश्यते रूपं यदा दोष द्वयस्य तु ।

संसर्गं तं विजानीयात् संसर्गः स च षड्विधः ॥

– सु. नि. २/२२.

According to Dosha Dominance, there are six types stated by Sushrutachrya

1. Vataj
2. Pittaj
3. Kaphaj
4. Sannipataj
5. Raktaj
6. Sahaj

They have also stated six types of dvandvaja arsha prakar as follows–

1. Vatakaphaja
2. Pittakaphaja
3. Vatapittaj
4. Vataraktaj
5. Pittaraktaj
6. Kapharaktaj



## B.2. On the basis of the origin:

सहजन्मोत्तरोत्थानभेदाद् द्वेधा समासतः ।

शुष्कस्त्राविविभेदाच्च.... ॥ – ह. नि. नि. ७/३.

1. Sahaja
2. Janmottara kalaja

तत्र बीजं गुदवलिबीजोपतप्तमायतनमर्शां सहजानाम् । तत्र द्विविधो बीजोपतप्तौ हेतुः –  
मातापित्रोरपचारः पूर्वकृतं च कर्म तथाऽन्येषामपि सहजानां विकारणाम् ।

– च. चि. १४/

Sahaja Arsha is considered to be a congenital anomaly due to disorders of paternal and maternal chromosomes. It is very difficult to diagnose because of its different size and shape.

Janmottarakalaja Arsha occurs due to the malpractices in daily life like faulty food habits and regimen.

## B.3. On the basis of the per rectal bleeding nature:

Charaka has stated these two types –

1. Aardra
2. Shushka

Aardra also called Sravi, are bleeding piles due to vitiation of Rakta and Pitta mainly and other Shushka Arsha (non-bleeding pile masses) is due to vitiation of Vata and Kapha Doshas.

## B.4. According to site:

1. Bahya
2. Abhyantara

Sushruta has used the word Drishya probably to denote those occurring in Bahya Vali and Adrishya arising from Madhya and Antarvali.

### **B.5. On the basis of prognosis:**

1. Sadhya (Curable)
2. Yapyia (Palliative)
3. Asadhya (Incurable)

#### **Sadhya variety:**

According to Sushruta, if the Arsha is located in the Samvarani and is of single Dosha involvement and not very chronic then it will be curable (Sadhya).

#### **Yapyia variety:**

The Arsha caused by the simultaneous vitiation of any two Doshas and the location of Arsha in the second Vali, the chronicity of the disease is not more than one year, it can be considered as Yapyia variety.

#### **Asadhya variety:**

Sahaja Arsha, if caused by the vitiation of three Doshas and if the Arsha is placed in the internal Vali, is incurable. In addition to this, if the patient develops edema in hands, legs, face, umbilical region, anal region, testicles and if he suffers from pain in the cardiac region, it is considered as incurable.

Sushruta has mentioned that Arshas associated with Trishna, Arochaka, Shoola, Atisruta Shonitam, Shopha and Atisara kill the patients.

### **B.6. On the basis of management:**

1. Bhaishaja Sadhya Arsha
2. Kshara Sadhya Arsha

### **C. NIDANA OF ARSHA:**

All hetu of Arsha can be classified mainly in two groups, named as sahaj and janmottaraja.

#### **Nidan of Sahaja Arsha:**

The cause of sahaja Arsha is dushti (vitiation) of beej–bhaga, which produces in the guda vali. Beej–bhaga vitiation occurs due to 2 factors.

- 1) Mithya aahar vihar of parents
- 2) Poorvajanma karma

According to Sushruta the vitiated shonita and shukra is the hetu of sahaj – arsha.

#### **The Nidana of Janmottaraj Arsha:**

##### **a) Samanya hetu:**

The samanya hetus which are responsible for all types of Arsha as described by Charaka are as given below.

##### **1. Aaharaj hetu:**

- Guru, madhur, sheeta, abhishyandi, vidahi;
- viruddha–bhojan, pramit– bhojan, asatmya–bhojan;
- matsya, varaha, mahisha, aja–mansa; krusha–prani mansa; shushka mansa;
- nava shuka dhanya, nava shami dhanya, pinak;
- shaluka, shastika, shrungataka, shushka teela, gud–vikruti, vasa;
- viruddha dhanya, aama moolaka, gurushaak;
- kasheruka, kilat, lashuna, mrunala, atikranta madya;
- ati–snehapan, dadhi, guru jala, ikshu ras, ksheer, manda, mansayoosha;
- Sushrut has mentioned only adhyashana, viruddhashana.

## 2. Viharaj hetu:

According to Charaka, Sushruta and Vagbhata the Viharaj hetu are described as shown in the following table.

Table 2.1. Shows Viharaja Hetu of Arsha

Description of Hetu	Sushruta	Vagbhata	Charaka
Agnimandya	+	+	+
Ati Vyayama / Vyavaya	+	+	+
Guda gharshana	+	+	+
Utkatukasana	+	+	+
Vegodeerana	+	+	+
Vego vidharana	+	+	+
Ati Pravahana	-	+	+
Aamagarbha bhransha	-	+	+
Guda kshanan	-	+	+
Kathin aasan	-	+	+
Visham aasan	-	+	+
Aasan such	-	-	+
Asamyak sansodhan	-	-	+
Asamyak bastinetra prapidan	-	-	+
Avyavaya	-	-	+
Basti vibhransha	-	-	+
Divaswapna	-	-	+
Garbhat peedana	-	-	+
Shayya such	-	-	+
Sheetambu sparsh	-	-	+
Ushtra yaan	-	-	+
Amaatissara / Atissara / Grahani	-	+	-
Gulma	-	+	-
Jeerna kaasa	-	+	-
Jwara	-	+	-

Pandu	-	+	-
Kshawathu	-	+	-
Vibandha	-	+	-
Vyadhijanya krishata	-	+	-
Yaan sankshobha	-	+	-

**b) Vishesh Hetu:**

Which are responsible for specific types of Arsha. The types of Arsha are according to the dosha involvement. Hence, the vishesh hetus of Arsha are as shown below:

Table 2.2. Shows Vishesh Hetu of Arsha

Type of Arsha	Aharaja hetu	Viharaja hetu
<b>Vataja</b>	Kashaya, katu, tikta ras sevan, ruksha, sheetal, laghu anna sevan, pramit, teekshna anna sevan.	Ati vyayama, vyavaya, ati vata atapa sevan, shoka, sheetal, desh, kaal sevan.
<b>Pittaja</b>	Katu, Amla, Lavana rasa sevan, ushna ahara/ aushadhi kshara sevan, madyapan, vidahi tikshna anna sevan.	Ati vyayama, agni atapasevan, ushna desh kaal sevan, krodha.
<b>Kaphaja</b>	Madhur, amla, lavana rasa sevan, snigdha, sheetal, guru ahara.	Aasan sukh, diwaswapn, achintana, praak vata sevan, shayya sukha, sheetal desh kaal, sevan.

#### D. POORVAROOP OF ARSHA:

विष्टम्भोऽन्नस्य दौर्बल्यं कुक्षेराटोप एव च ।  
कार्यमुन्नरबाहुल्यं सक्थिसादोऽल्पविकृता ॥  
ग्रहणीदोषपाण्ड्वर्तेराशङ्का चोदरस्य च ।  
पूर्वरूपाणि निर्दिष्टान्यर्शसामभिवृद्धये ॥

– च. चि. १४/२१, २२.

The poorvaroopas of Arsha have been described by all Acharyas. They are as given below.

Table 2.3. Shows Poorvaroop of Arsha

Poorvaroop	Sushruta	Vagbhata	Charaka
Anna Vishtambha / atopa	+	+	+
Grahani / pandu rog ashanka	+	+	+
Udgar bahulya	+	+	+
Shakti saad	+	+	+
Amlika / anna– ashradhdha	+	+	–
Antra koonjana / Guda parikartan	+	+	–
Akshi shoth	+	+	–
Indriya daurbalya	+	+	–
Bhrama / tandra	+	+	–
Kaas / shwas	+	–	–
Kruchchata annapakti	+	–	–
Amashaye paridaha	+	–	–
Bala haani / shosha ashanka	+	–	–
Nidra / pipasa	+	–	–
Alpapurishata	–	+	+
Daurbalya / udarrog ashanka	–	+	+
Aalasya / anga saad	–	+	–

Agnimandya	-	+	-
Atisaar / malavroodhi	-	+	-
Dhoomaka / krodha	-	+	-
Bhinna varnata	-	+	-
Prabhut mutrata	-	+	-
Pindikodweshtana	-	+	-
Sheersha / prushtha shola	-	+	-
Sashabda kartanavat sashool kruchchata vata Nirgaman	-	+	-

## **E. ROOPA:**

Description of type of Arsha according to the Dosha involvement can be found in the text books. The general symptoms are mentioned particular to the Gudavayava like defecation, consistency of stool etc.

Charaka, while describing the treatment for the Arsha, has divided it in two types i.e. Shushka and Sravi. Shushka Arsha is due to the involvement of Vata and Kapha, while in Sravi Arsha there is Pitta and Rakta dominancy. Charaka has described both these types of Arsha in very detail with regards to their form, colour and other properties.

### **Classification of Roopa:**

Roopa of the Arsha are classified in two groups:

- Samanya Roopa
- Vishishta Roopa

Charaka and Sushruta have not mentioned the Samanya Roopa, while Vagbhata and Bhela have explained in detail about their symptoms.

### **Samanya roopas:**

According to Acharya Vagbhata the samanya roopas of Arsha are given below.

### **Subjective General Symptoms:**

Agnimandya	Asya Vairasya	Arochak
Vankshana Shool	Hradaya–Nabhi Shool	Payu Shool
Angamarda	Klama	Swara Krishata
Asthiparva Shool	Vistambha	Deenata
Asarata	Jwara	Swasa– Kaasa
Sarakta Stheevana	Shoth	Baadhirya
Peenasa	Pipasa	Timir
Vaman	Vaivarnya	Pandu

Kvachit Amla/ Harit/ Rakta/ Pita/Vibandha Malpravrutti.



## Vishesha Roopas:

### 1. Sahaja Arsha

Sahaja Arsha shows Roop either like roopa of any dosha.

### 2. Vataja Arsha

Table 2.4. Shows Roopa of Vataja Arsha

Sr. No.	Roopa	Sushruta	Vagbhata	Charaka
<b>Related to pain</b>				
1.	Kati–parsvha shool	+	+	+
2.	Prushtha shool	+	+	+
3.	Nasa / nabhi / medhra / gud–shool	+	–	–
4.	Parvabheda	+	–	–
5.	Karna / prushtha / shool	–	+	+
6.	Mansa / vankshana shool	–	+	–
7.	Trik /basti/kukshee / shankha shool	–	–	–
8.	Angmarda / shirobhitaap	–	–	+
<b>Related to mal–mutra vega</b>				
1.	Mutra purish krushnata	+	+	–
2.	Sappravahikopaveshi	–	+	+
3.	Safen–sashabda–sthoolopaveshi	–	+	–
4.	Granthil –pichchil –vibandhopaveshi	–	+	–
5.	Arun / Parush / Shyav–Mutra purish	–	+	–
6.	Vibandha –vata –mutra	–	–	+
7.	Prabhoot mutrata	–	–	+
<b>According to color change of different parts of body</b>				
1.	Vadan–nakh–nayan–twaka krushnata	+	+	+
2.	Arunata / parushata / shyavata	–	–	+
<b>According to upashayanupshay</b>				
1.	Snigdha ushnopashayani	–	–	+
<b>Others</b>				

1.	Asthhila / gulma / pleehodar	+	+	-
2.	Chimchimayana at Arsha	+	-	+
<b>According to consistency</b>				
1.	Shuska	+	+	+
2.	Kathina / parusha / rooksha	-	+	+
3.	Khara	-	+	-
<b>According to size and shape</b>				
1.	Kadamba – pushpakruti	+	+	-
2.	Tundikeri – sadrusha	+	+	-
3.	Mukula / Naadi – sadrusha	+	-	-
4.	Suchimukhakaruti	+	-	-
5.	Bimbeefala / Karpasfala – sannibha	-	+	-
6.	Kharjura / Sidhdharthak – sannibha	-	+	-
<b>According to Color</b>				
1.	Arun varna	+	+	-
2.	Shyav varna	-	+	+
<b>According to surface</b>				
1.	Mlan / sphutit – mukhani	-	+	+
2.	Teekshnagrani / vakrani	-	+	+
3.	Visham visrutani	-	-	+

### 3. Pittaja Arsha:

Table 2.5. Shows Roopa of Pittaja Arsha

Sr. No.	Roopa	Sushruta	Vagbhata	Charaka
<b>Related to mal-mutra vega</b>				
1.	Pita – mutrata	+	-	+
2.	Sadah – sarudhir – atisarvet	+	-	-
3.	Bhinna varchansi	-	+	+
4.	Prachur / visragandhi vidmutrata	-	-	+
5.	Aama / drava / ushna varchansi	-	-	+

6.	Neel / rakta varchansi	-	+	-
<b>According to color change of different parts of body</b>				
1.	Nakha, nayana, twak peetata	+	+	+
2.	Nakha, nayana, twak harita	-	+	-
<b>According to upashayanupshay</b>				
1.	Sheetopashayani	-	-	+
<b>Local deformity and others</b>				
1.	Daha	+	+	+
2.	Guda – paak / rudhira – vahana	-	+	+
3.	Kandu / nistoda / shool	-	+	+
4.	Daaha, jwara, pipasa	+	+	+
5.	Moorchha	+	+	-
<b>According to consistency</b>				
1.	Mruduni	-	+	+
2.	Sparsha asahani	-	-	+
<b>According to size and shape</b>				
1.	Yava / jalauka – mukha sadrushya	+	+	-
2.	Shuk – jimvha sannibha	+	+	-
3.	Yakruta khanda sannibha	-	+	-
<b>According to color</b>				
1.	Neelagrani / peetani	+	+	+
2.	Yakrut – prakashani	+	+	+
3.	Aaseet – prabha	-	+	-
<b>According to surface and discharge</b>				
4.	Rudhir–vahani / visragandhi–sravani	+	+	+
5.	Swedopkleda bahulani	+	+	+
6.	Tanuni / visarpini	+	+	-

#### 4. Kaphaja Arsha

Table 2.6. Shows Roopa of Kaphaja Arsha

Sr. No.	Roopa	Sushruta	Vagbhata	Charaka
<b>Related to mal–mutra vega</b>				
1.	Mutra – purisha swetata	+	+	+
2.	Analpa – sashleshma atisarayet	+	+	–
3.	Mansa–dhavan–prakasham atisarayet	+	–	–
4.	Pravahika / mutra– kruchhata	–	+	+
5.	Mutra – Purish Guruta / Pichhilata	–	–	+
<b>According to color change of different parts of body</b>				
1.	Nakha–nayan–twak–vadana shuklata	+	+	+
2.	Dashana shuklata	+	–	–
3.	Twaka–adi / vadana panduta	–	+	+
<b>According to upashayanupshay</b>				
1.	Rooksha – ushna upashayani	–	–	+
<b>Local deformity and others</b>				
1.	Kandu	+	+	+
2.	Guruta / stambhata / stimitata	–	+	+
3.	Manda – ruja	–	+	–
4.	Arochak / shoth / sheeta – jwara	+	+	+
5.	Avipaka	+	–	–
<b>According to consistency</b>				
1.	Snigdhani	+	+	+
2.	Sthirani	+	–	+
3.	Picchilani/ slakshani	–	+	+
4.	Sparsh sahani	–	+	+
<b>According to size and shape</b>				
1.	Gostana / kareera – sannibha	+	+	–
2.	Panasasthi – sannibha	+	+	–
<b>According to color</b>				

1.	Shwetani	+	+	+
2.	Panduni	+	-	+
<b>According to surface and discharge</b>				
1.	Maha – moolani / vruttani	+	+	-
2.	Upchitani / pramaanvanti	-	+	+
3.	Ghana / utchhritani	-	+	-
4.	Pichhastravini	-	-	+

## 5. Raktaja Arsha

Table 2.7. Shows Roopa of Raktaja Arsha

Sr. No.	Roopa	Sushruta	Vagbhata	Charaka
1.	Dushta rakta pravrutti	+	+	-
2.	Pittaj arshavat lakshanani	+	+	-
3.	Avagadha purishata	+	+	-
4.	Analpa rakta – sahasaa visrujanti	+	+	-
5.	Bala – varna heenata / ojakshaya	-	+	-
6.	Kalushendriya	-	+	-
7.	Ushna rakta– pravrutti	-	+	-
<b>Local deformity</b>				
1.	Kakantika phala sadrusha	+	+	-
2.	Vidruma sadrusha	+	+	-
3.	Nyagrodha praroha sadrusha	+	+	-
<b>Symptoms of vatanubandhi raktaj arsha</b>				
1.	Adho – vata apravrutti	-	+	+
2.	Guda – kati shool	-	+	+
3.	Vit – kharta / rookshata / shyavata	-	+	+
4.	Daurbalya / uroo shool	-	-	+
5.	Vit kathina	-	-	+
6.	Fenil – tanu– aruna varna rakta srav	-	-	+
<b>Symptoms of kaphanubandhi raktaj arsha</b>				

1.	Guda picchilata / stimitata	-	+	+
2.	Vit – shwetata, snigdhata	-	+	+
3.	Ghana rakta – strav	-	+	+
4.	Guda – guruta, snigdhata	-	-	+
5.	Pichhil, tanumaya, rakta– strav	-	-	+
6.	Pandu rakta – strav	-	-	+
7.	Vit – guruta, peetata, sheetata	-	-	+
8.	Vit – shithilata	-	-	+

### **6. Sannipataja Arsha:**

The symptoms of sannipataja Arsha have not described separately by any Acharya. All Acharya said that the symptoms of sannipataja Arsha are depending upon the involvement of dosha. The symptoms of concern doshaja Arsha occurs unitedly are the symptoms of sannipataj Arsha.

## F. SAMPRAPTI OF ARSHA:

दोषास्त्वडमांसमेदांसि सन्दूष्य विविधकृतीन् ।

मांसाङ्कुरानपानादौ कुर्वन्त्यर्शांसि ताञ् जगुः ॥

– अ. ह. नि. ७/२.

पञ्चात्मा मारूतः पित्तं कफो गुदवलित्रयम् ।

सर्व एव प्रकुप्यन्ति गुदजानां समुद्भवे ॥

तस्मादर्शांसि दुःखानि बहुव्याधिकराणि च ।

सर्वदेहोपतापीनि प्रायः कृच्छ्रतमानि च ॥

– च. चि. १४/२४, २५.

Samprapti is a complex of etiological factors to produce disease. Samprapti is nothing but etiopathology of disease.

**According to Acharya Sushruta**, due to nidan sevan dosha prakop occurs. The main hetu for Arsha is mandagni, which is mentioned as “visheshto mandagne.” These prakupit doshas alone or all together with or without rakta, enters in the pradhan dhamani (main channel), go downward and reach at guda. By vitiating the guda valies, produces the mansa–prarohas are known as arsha. Acharya Charak and Vagbhat also support this description of samprapti.

### **Shat–Kriya kaal**

These are the complex stages of etio–pathological process of disease. It is mentioned only by Sushruta. The management of disease in each stage of shat kriya kaal is different. The symptoms of disease occur after sthan sanshraya avastha. Hence if the treatment up to this stage is given, disease can not occur.

The Samprapti of Janmottara Kalaja Arsha can be delineated on the basis of the Kriyakala as follows:

**Sanchayavastha:**

The intake of the junk food stuffs and other Nidan sevana causes the accumulation of Dosha in normal site. It causes the general symptoms like fullness of abdomen, yellowishness of skin, low temperature and heaviness of limb.

**Prakopavstha:**

When the provocative factors are still allowed to act, then the previously accumulated Doshas get more vitiated. According to Sushruta here Dosha get agitated separately or jointly or with partaking of Shonita. Simultaneously due to Malabaddhata vitiation of Apana vayu takes place.

**Prasaravastha:**

Next to this step, vitiated Doshas migrate from their own place and these Doshas further circulate all over the body and tend to go downward. During this stage appearance of incomplete generalized symptom are noticed

**Sthanasanshrayavastha:**

Vitiated Dosha localized in Guda vali, pradhan dhamani and mansdhara kala. Localized Dosha cause Twak, Mansa, Meda, and Rakataj Dushti. In this stage, normal functioning of tissue is affected, but the actual clinical symptomatology of the particular disease has yet to be manifested.

**Vyakatavastha:**

In this stage of Kriyakala it can be explained as differentiation of pile mass with respective characters of Doshas. In the disease Arsha, subjective and objective signs of pile mass are recognized.

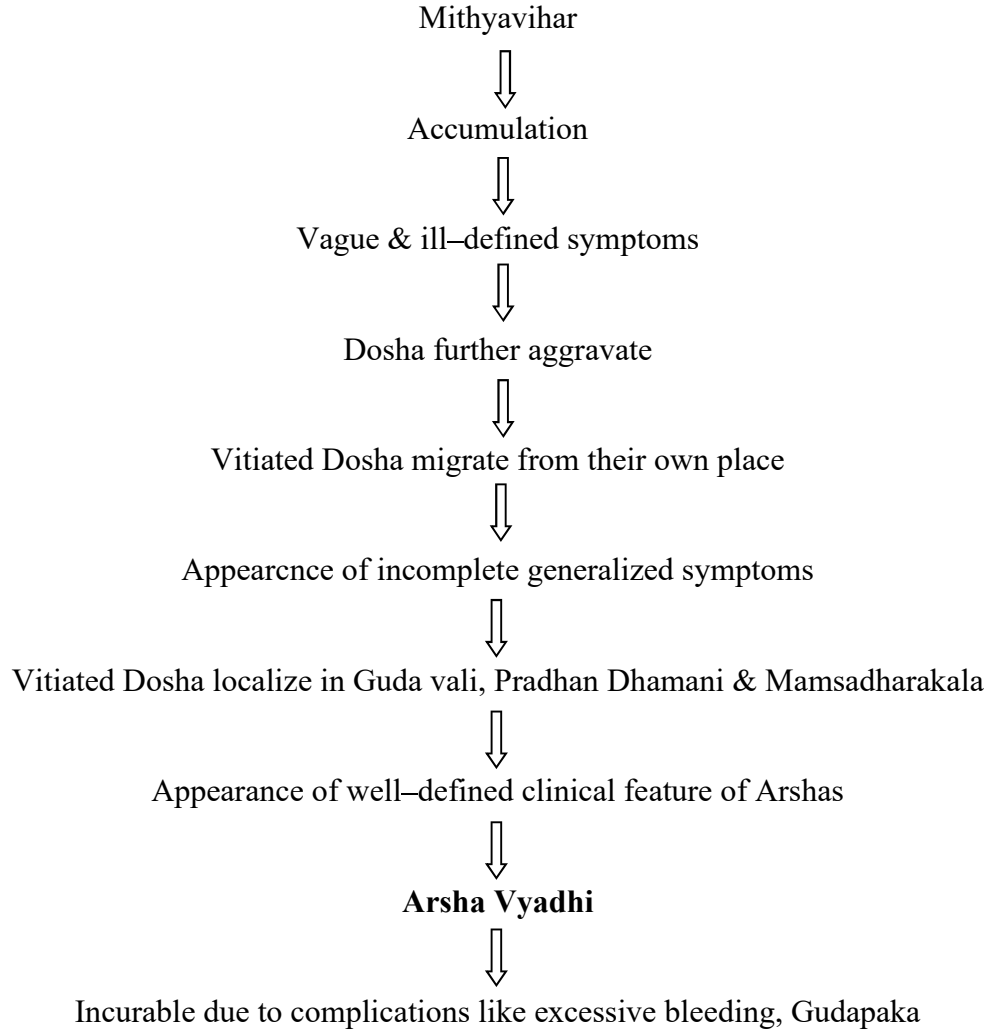
**Bhedavastha:**

If proper treatment is not taken in the above-mentioned stage of Kriyakala the last stage takes place which is known as Bhedavastha. In this stage a number of



complications occur like Pandu, Grahani, Pravahika, Shotha, Guda Bhramsha and even Mrityu. Samprapati can be summarized in following chart–

**Samprapti Flow Chart:**



- Sankhya** : Six  
**Vikalpa** : Pradhana Dosa Vata, Anubandha Pitta and Kapha  
**Pradhanya** : Swatantra Vyadhi  
**Bala** : Differs from individual to individual  
**Kala** : No specific season  
**Dosa** : Vata specially deranged: Apana Vayu

		Pitta deranged: Pachaka Pitta
		Kapha deranged: Kledaka Kapha
<b>Dushya</b>	:	Twak, Rasa, Rakta, Mansa and Meda
<b>Srotas</b>	:	Annavaha, Purishvaha and Raktavaha
<b>Adhithana</b>	:	Gudavalies
<b>Udbhavasthana:</b>		Aam–pakwashaya
<b>Srotodushti</b>	:	Atiprivrutti (Rakta)
		Sanga (Purisha)
		Siragranthi (Gudankura)
		Vimargagaman (Apana)
<b>Agnimandya</b>	:	Jathargnimandya,
		Mansagnimandya
		Medagnimandya
<b>Ashaya</b>	:	Malashaya
<b>Svabhava</b>	:	Chirkari

### 2.3.4. ARSHA CHIKITSA:

Sushruta has mentioned four broad principles of treatment as.

चतुर्विधोऽर्शासां साधनोपायः ।

तद्यथा – भेषजं क्षारोऽग्निः शस्त्रमिति ।

– सु. चि. ६/३.

दुर्नाम्नां साधनोपायश्चतुर्धा परिकीर्तितः ।

भेषजक्षारशस्त्राग्नि- साध्यत्वादाद्य उच्यते ॥

– भैषज्यरत्नावली अर्शोरोगचिकित्साप्रकरणम्/१

1. Bheshaj Chikitsa
2. Ksharakarma
3. Agnikarma
4. Shastrakarma

The indications of these treatment principles are:

#### 1. **Bheshaj Chikitsa:**

Arsha ankura which are achirkalajata, alpadoshayukta, alpa- lakshana yukta and alpa upadravayukta.

#### 2. **Ksharakarma:**

Arsha ankura which are- mrudu, prasruta, avagadha and uchrita.

#### 3. **Agnikarma:**

Arsha ankura which are- karkasha, sthira, pruthu and kathina.

#### 4. **Shastra karma:**

Arsha ankura which are- tanu mool, uchrita and kledayukta.

## A. BHESHAJ CHIKITSA:

In Arsha, Agni deepana chikitsa is vital as majority of the patients of Arsha will be having mandagni<sup>53</sup>.

दोषाणां पाचनार्थं च वह्निसन्धुक्षणाय च ।

संग्रहाय च रक्तस्य परं तिकैरुपाचरेत् ॥

– अ. ह. चि. ८/९९.

तत्र वातश्लेष्मनिमित्तान्यग्निक्षारभ्यां साधयेत्, क्षारेणैव मृदुना पित्तरक्तनिमित्तानि ॥

– सु. चि. ६/५.

### A.1. Arsha chikitsa sutra according to dosha predominance:

Doshas	Chikitsa sutra
• If Vata is predominant	Snehana, Swedana, Vaman, Virechan, Asthapana and Anuvasana Basti
• If Pitta is predominant	Virechana
• If Kapha is predominant	Vamana and use of Adaraka and Kulatha
• If Tridoshaja	Tridoshaghna chikitsa and Takraprayoga

### A.2. Chikitsa of Raktaja arsha:

Condition	Chikitsa sutra
• Vata anubandhi Raktaja arsha:	Snigdha, Sheeta– Ahara Vihar
• Kapha anubandhi Raktaja arsha:	Rooksha, Sheeta– Ahara Vihar and Bsheshaj
• Pitta Kaphaja anubandhi:	Vamana and Virechana
• Pitta pradhana Raktaja arsha in Greeshma rutu and Durbal rogi:	Rakta–sthamabhana
• In Balavana rogi if Raktasrava	Allow to bleed and do Langhana
• After dushta Raktasrava	Rakta–sthambana, Jatharagni pradeepana
• Kutaja is the drug of choice in Raktaja Arsha	

### **A.3. Chikitsa of Shushka Arsha:**

<b>Condition</b>	<b>Chikitsa sutra</b>
• Baddha malapravratti	Udavarta vatchikitsa
• Bhinna malapravratti	Atisara vatchikitsa
• Takra, Bhallataka are the drugs of choice in Shushka Arsha	

### **A.4. Other formulations:**

Kasis, Hartaala, Saindhav, Karvir, Vidang, Karanj, Krutvedhan, Jambuk, Arka, Bhumiamalaki, Danti, Chitrak, Alark, Snuhi siddh Tail are used in the form of local application. Hartaaladi lepa is also useful in Arsha as local application.

### **B. KSHARAKARMA:**

Almost all classics mention that Ksharas are to be used externally or internally according to the ailments of the body. Kshara has been told to be having the topmost place among all surgical and para-surgical measures in Ayurveda, due to its efficacy even in surgical measures though being considered as parasurgical one (Chhedya, Bhedya, Lekhya Karnat). While commenting on the verse Dalhana clarifies that Chhedana, Bhedana etc. do not come under the preview of Agnikarma or Jalaukavacharna, while Kshara does these actions. In the same way, commentator of Ashtanga Hridaya, Arundutta, clarifies that Kshara is easily applicable and gives result even when Agnikarma and Shashtrakarmas are either contraindicated or difficult to perform in certain diseases. Ksharakarma procedure is of two types namely, Pratisarana kshara and Kshara sutra. Both these procedures were described here in next session.

#### **Method of Kshara sutra ligation:**

Patients made to be lie down in lithotomy position. Anal canal and perianal area to be cleaned with antiseptic lotion. Infiltration of local anesthesia at the base of the Hemorrhoidal mass to be done. Masses are made to protrude from anal orifice. Hemorrhoidal mass is clamped by pile holding forceps. Transfixation of the mass is done by kshara sutra. Procedure is repeated on other mass also, if present.

**Advantages:**

- Simple, safe & OPD procedure.
- No chance of recurrence.
- No surgical complications like stenosis, stricture or incontinence.

**C. SHASTRAKARMA:**

Hold Arsha ankura by arsho grahi yantra and perform Chedana with the help of sharp instrument like mandalagra shastra, sarpavakra shastra and excised part should be treated with agnikarma. kavalika has to be applied and gophana bandhana has to be done. This procedure is very much similar to that of ligation and excision procedure (hemorrhoidectomy) in present day.

**D. AGNIKARMA:**

Agnikarma is an important para surgical measure and is still used extensively in the surgical practice in modified form by way of electric heat cautery and freezing. It is regarded as superior to other surgical and para surgical procedures because of non-recurrence of the disease.

**E. RAKTAMOKSHANA:**

Sushruta enumerated Arsha as one of the diseases contraindicated for bloodletting. But in the management of Arshas, he advised Raktamokshana (blood letting) under certain conditions like protruding out with full clinical picture of Arsha. This controversy was probably intentional because of its limited applicability in the management and unsuitability as a general measure in all types of Arshas.

### 2.3.5. SADHYA SADYATA (PROGNOSIS)

Sushruta has enumerated Arsha as one amongst eight mahagadas, hence by nature the disease is very much difficult to treat. Assessment of sadhyasadhyata is based on the factors like doshik involvement, vyadhi sthana, vyadhi kala and association of upadravas.

Opinions of different Acharyas regarding prognosis can be summarized as follows,

1. Those arise in the bahyavali, caused by single dosha and manifested recently are sukha sadhya.
2. Those which are caused by combination of two doshas, located in the madhyam vali and of more than one year, are kashtasadhya.
3. Those which are caused by combination of three doshas, located in the madhyam vali and of more than one year, are kashtasadhya.
4. Tridosha Arshas are yapya.
5. Arsha, which are sahaja, involving all the three doshas and located in the abhyantara vali should be discarded due to kashta sadhya nature. If rogi (patient) has developed shotha in hasta, pada, mukha, nabhi, guda, andakosha, severely debilitated and also if hrudaya and parshva shoola is present should be discarded due to asadhya. However, if life span is remnant, the chikitsa chatushpada is provided and agnibala can be stimulated, then they can be treated otherwise should be rejected.

### 2.3.6. PATHYAPATHYA IN ARSHA:

#### A. PATHYA:

**Anna Varga** – Godhuma, Yava, Raktashali, Sastika, Kulattha, Priyangu, Neem Juice, Yusha.

**Shaka Varga** – Surana, Nimba, Patola, Punarnava, Shringu, Balamula, Kusumbha, Jeera, Sohanjana, Shali, Rasana, Chitraka, Bathua.

**Ksheera Varga** – Aja Ksheera, Takra.

**Phala Varga** – Amalaki, Kapittha.

**Ahara Upavarga** – Palandu, Maricha.

**Mamsa Varga** – Goha, Mushaka, Go, Vanara, Ashva, Hirana, Kukuta, Aja, Chataka.

**Mutra Varga**– Gomutra.

#### B. APATHYA:

**Ahara**– Viruddha, Vishtambhi, Abhishyandi, Guru Ahara, Anupa Mamsa, Dushta Udaka, Dosha Prakopaka Anna, Anupa Desha Pashu And Pakshi Mamsa, Matshya, Tila Khalli, Dadhi, Rooksha Ahara, Kareer, Bilva Patra, Tumbi, Jaliya Kanda.

**Vihara**– Vegadharana, Atistreesanga, Uttkatukasana, Prushtayana, Atapasevana, Atijalapana, Vamana, Basti, Poorva Desha Vayu Sevana, Viruddha Dravya In Rasa, Veerya, Vipaka.



## **2.4. MODERN REVIEW:**

Proctology is the branch of medicine which deals with the description and management of various diseases occurring in Anorectal region. The majority of the Anorectal diseases by nature are very troublesome. The reasons being the part is always subjected to natural stress and strain, exposed to fecal contamination and difficulty in maintaining local hygiene.

The modern surgery has made rapid progress as in the present era no organ or the tissue is spared from surgical approach. In spite of such progress the surgical procedures in Anorectal diseases are not so encouraging. The surgery in these diseases invariably leads to immediate or delayed complications, as well as, chances of high incidence of relapse of the diseases.

The management of Hemorrhoids in modern surgical practice is changing from conventional surgical procedure i.e. Hemorrhoidectomy to other minimal invasive procedures like Sclerotherapy, Band ligation, Cryosurgery, Laser therapy etc. As the result of all these procedures have their limitations and complications as well as relapse of the diseases.

### **2.4.1. ANATOMY**

#### **ANATOMY OF ANAL CANAL:**

A detailed descriptive study of anatomy and physiology of the body as a whole and individual parts or organs is the chief tool for a surgeon to reach a proper diagnosis as well as carry out the surgery. The anal rectal area besides being complex structurally and functionally is the commonest site for diseases of lower G.I.T. these diseases are frequently encountered by the surgeon in day to day practice. Thus, great stalwarts of anorectal surgery Milligan and Morgan and Mc Gregor have provided detail description of the part, the aspects of general as well as applied anatomy.

## **GENERAL ANATOMY:**

The anal canal is the terminal part of the large intestine. It is situated below the level of the pelvic diaphragm. It lies in the perineum. The anal canal is 3.8 cm. long it extends from the anorectal junction to the anus. It is directed downwards and backwards. Sphincters that keep the lumen closed in the form of an anterior– posterior slit surround the anal canal. The anorectal junction is marked by the forward convexity of the perineal flexure of the rectum and lies 2–3 cm in front of and slightly below the tip of coccyx. The anus is the surface opening of the anal canal, situated about 4cm below and in front of the tip of coccyx in the cleft between the two buttocks. The surround skin is pigmented and thrown into radiating folds and containing a ring of large apocrine glands.

## **RELATION OF THE ANAL–CANAL:**

### **A. Anteriorly: –**

- In both sexes: perineal body
- In males: Membranous urethra, urogenital diaphragm and bulb of penis.
- In females: lower end of posterior vaginal wall

**B. Posteriorly:** Ano–coccygeal ligament– an intervening of fibrous fatty and muscular tissue.

### **C. Laterally:** Ischiorectal fossa, containing

- Fat
- Inferior Hemorrhoidal vessels
- Inferior Hemorrhoidal nerves

## **INTERIOR OF ANAL CANAL:**

The interior of the anal canal shows many important features and can be divided into three parts.

- 1) The upper part about 15 mms. – Mucosal part

- 2) The middle part about 15 mms. – Mucocutaneous part or Pecten.
- 3) The lower part about 8 mms. – Cutaneous part

Each part is lined by a characteristic epithelium and reacts differently to various diseases of this region.

#### **A. The mucosal part:**

This mucosal part can be markedly seen in cadaveric dissection as well as in living subjects on Proctoscopy, as a purplish red part above the pectinate line (MILLIGE Netal–1937). Here the mucosa is thrown into 8 to 14 longitudinal folds, known as the rectal columns or columns of Morgagni. Each adjacent column is connected below at the pectinate line by an anal valve which is a short transverse fold of mucous membrane. Above each valve there is a depression called the anal sinus. The anal valves together form a transverse line that runs all around the anal canal. This is the pectinate line. Occasionally the anal valves show epithelial projection called anal papillae. These are remnants of the embryonic cloacal membrane.

Histologically it is lined by columnar epithelium like that of the rectum and the large intestine till immediately to the pectinate line. Here it is lined by cuboidal cells. When traced upwards from the line these give way, at a variable distance, usually about 0.5 to 1 cm. from the valve, to a single layer of columnar cells.

#### **B. The Mucocutaneous part**

This middle part is also known as a transitional zone or Pecten. This consists of about 15 mms. or so of anal–canal. It is also lined by mucous membrane but anal columns are not present here. It appears as a thin, smooth, pale and stretched part. The mucosa is less mobile than the upper part of the anal–canal.

The lower limit of the Pecten often has a whitish appearance because of which it is referred to as the “White line of Hilton”.

The pectinate line marks the junction of Potallantoic gut and the Proctodeum. It lies opposite the junction of the middle and lower thirds of the internal sphincter.

Histologically the mucosa here is stratified squamous skin, devoid of hair and transitional zones of cuboidal and columnar epithelium in the upper part of about 0.5 to 1

mm. The skin in this region is devoid of sweat glands, sebaceous glands and is closely adherent to the underlying tissue.

### **C. The cutaneous part**

It is the lowermost, 8 mms. long part lined by true skin. There appears an intersphincteric groove as seen in proctoscopy of live subjects, in this part. Below it lies in the longitudinal muscle coat demarking the separation of internal and external sphincteric muscles.

Histologically this part is lined by the skin in which there sebaceous and sweat glands present. Just outside the orifice it is pigmented and thrown into radial folds.

### **D. Musculature of the anal canal:**

#### **D.1. Anal sphincters:**

##### **Internal sphincter:**

It is formed by the thickened circular muscle coat of the hind-gut. It surrounds the upper 3/4<sup>th</sup> (30mm) of the anal canal extending from the upper end of the canal to the white line of Hilton.

##### **Histology:**

In longitudinal sections of the anal canal in both coronal and sagittal plans show that the internal sphincter consists of plane muscle fibers. Superiorly, it is continuous with the circular muscle coat of the rectum, and inferiorly it ends with a well defined rounded edge 6 – 8 mm above the level of the anal orifice and 12 – 8 mm below the level of anal valves. Its constituent muscle fibers are disposed in to discrete elliptical bands which in the upper part of the sphincter lie obliquely with their transverse axis running internally and downward, giving this an imbricate arrangement. The obliquity becomes progressively less when traced downwards and some of the lower ones even incline slightly upward.

**External sphincter:**

The external sphincter, in contrast to the internal sphincter is extrinsic in origin and is under voluntary control. Contrary to Milligan and Morgan (1934) the muscle is one continuous sheath and is not divided into three parts viz. subcutaneous, superficial and deep.

Attachments of external anal sphincter

- (A) Puborectalis
- (B) Pubococcygeus
- (C) Perianal skin

In gross dissection of the perineal and anal region, the external sphincter is an elliptical cylinder muscle which surrounds the anal orifice and traced upwards on the lateral sides becomes continues with the Puborectalis and Pubococcygeus Muscles.

- (A) Anteriorly many fibers are inserted into the perianal skin is and near the midline, they merge into the transverse perineal muscles by a process of decussation at the central point of the perineum or perineal
- (B) Posteriorly above the perineal insertion of the external sphincter fibers, the cylinder is attached at the lowest level, to the skin of the perianal region, in and close to the mid time. At slightly higher level these fibers form an Anococcygeal raphe which run backward and to attached to the coccyx. Anteriorly, still higher to the fibers attached to the coccyx, lie most of the peripheral fibers of the external anal musculature run to proceed forward as puborectalis. They get insertion on the posterior aspect of the symphysis pubis.

**Histology:**

On the coronal and post saggital section, the external anal muscle sphincter is seen to be made of striated muscle–fibers. It extends further downward than the internal sphincter. The lowermost portion comes medially to occupy a portion below and slightly lateral to the lower rounded edge of the internal sphincter. It lies close to the skin of the anal orifice and this was named by Milligan and Morgan as the subcutaneous part.

This part, as such, does differ from the rest in a feature that it is traversed by a fan shaped of the longitudinal muscle fibers of the anal canal which split it up in to 8 –12 discrete muscle bundles.

At the upper end or the deep part of the external sphincter it fuses with Puborectalis part of the Levator ani muscle, and practically merges with in so that it is indistinguishable with the later. It arises from the Anococcygeal ligament, and is inserted into the perineal body where the fibers decussate and become continuous with those of superficial transverse perineal muscles.

## **BLOOD SUPPLY:**

### **A. Arterial supply:**

- i) The part of the anal canal above the pectinate line is supplied by Superior Rectal artery which is the chief artery of the anus, it is also called superior hemorrhoidal artery. It is the continuation of the inferior mesenteric artery beyond the root of the sigmoid mesocolon. Its two branches pierce the muscular coat of the rectum and divide into several branches, which anastomose with one another at the level of anal sphincter, to form loops around the lower level of rectum. These branches communicate with middle and inferior rectal arteries in the submucosa of the anal canal.
- ii) Middle Hemorrhoidal arteries: They spring from anterior division of internal iliac and proceed medially and forward below the pelvic peritoneum in the lateral ligament to reach the rectal wall. It may be absent.
- iii) Inferior rectal artery: the part below the pectinate line is supplied by the inferior rectal artery. It arises at the post end of the pudendal canal from the internal pudendal artery and accompanies the nerve of the same name. The artery supplies the skin and muscles of the anal region and anastomoses with the superior & middle rectal arteries.

### **B. Venous Drainage:**

- i) The internal rectal venous plexus (hemorrhoidal plexus): Lies in the sub-mucosa of the anal canal. It drains in superior rectal vein and communicates freely with the external plexus and thus with the middle and inferior rectal veins. It is site of communication between portal & systemic veins.

ii) External hemorrhoidal plexus: Lies outside the muscular coat of anal canal. It communicates freely with internal plexus.

- Lower part of external plexus to internal pudendal vein
- Middle part to middle rectal plexus to internal iliac vein.
- Upper part to superior rectal plexus to inferior mesenteric vein

iii) Anal veins:

Arranged radially around the anal margin subcutaneously, they communicate with internal rectal plexus and with the inf. rectal vein.

### **C. Lymphatic Drainage:**

Lymph vessels from the part above the pectinate line drain with those of the rectum into the internal iliac nodes. Vessels from the part below the pectinate line drain into the medial group of superior inguinal nodes.

### **NERVE SUPPLY:**

#### **A. Motor Innervations:**

i) Internal sphincter: It is supplied by both sympathetic and parasympathetic nerves of the autonomic nervous system. Stimulation of sympathetic plexus (L1, L2) causes contraction of the muscle and that of parasympathetic (pelvic splanchnic S2, 3, 4) causes relaxation.

iii) External sphincter: It has somatic innervations and thus has quality of voluntary contraction. It is supplied by inferior rectal nerve (S2, 3, 4,) a branch of internal pudendal nerve, and perianal branch of 4<sup>th</sup> sacral nerve.

## **B. Sensory Innervations:**

- i) Above the pectinate line by parasympathetic innervations same as internal sphincter (S2, 3, 4). The pain sensation is very dull and indefinite.
- ii) Below the pectinate line it is supplied by somatic nerves i.e. inferior rectal (S2, S3, S4) which give out the afferent cutaneous sensations.

## **C. The Pudendal nerve:**

The pudendal nerve leaves the pelvis, medial to the sciatic nerve through the greater sciatic foramen. It then crosses the external surface of the ischial spine and re-enters the pelvis through the lesser sciatic notch and passes along the lateral wall of the ischiorectal fossa.

### **Branches of the pudendal nerve:**

1. The inferior rectal nerve supplies the external sphincter, Levator ani and skin of the anal canal and anus. The latter is also supplied by the perineal branch of the 4<sup>th</sup> sacral nerve, perforating cutaneous branches of the 2<sup>nd</sup> and 3<sup>rd</sup> sacral nerves and gluteal branches of the posterior cutaneous nerve of the thigh.
2. Perineal nerve which gives off labial or scrotal branches and continues to supply the muscles of the urogenital diaphragm.
3. Dorsal nerve of clitoris or penis which is a sensory nerve.

## **ANAL GLANDS:**

### **1. The Crypts of Morgogni:**

The crypts are 5–10 in number (Gray's) and / are present in the anal canal. Between the inferior extremities of the column of Morgogni, small pocket like structures are present which are called the crypts. Most of them are situated posteriorly and each open into anal glands by a narrow duct called anal ducts. These ducts bifurcate and pass to enter the internal sphincter muscle, where there is an ampulla. The ducts from the



crypts extends through the mucosa and forms anal glands, which are first described independently by Chiari (1878) and Herman & Desfosses (1880) Parks (1961) did an excellent anatomical study with special reference to their role in the pathogenesis of infections in the anal region. There are 4–8 glands in the normal anal canal. Their extensions are found in submucosa, internal sphincter, intersphinctric longitudinal layer (Park) and even up to ischiorectal fossa.

**2. Column of Morgogni:** These are longitudinal folds, 5 to 10 or 8 to 12 in numbers known as the columns of Morgogni (Walls).

## **2.4.2. PHYSIOLOGY**

Two branches of science— anatomy and physiology – provide the foundation for understanding body's parts and functions without which none of the abnormalities can be diagnosed. Thus, one has to gain a basic understanding of how the body is organized, how its different parts normally work, and how various conditions affect its operation to maintain life and health.

The physiological function associated to the anus is the act of Defecation

### **A. DEFINITION – DEFECTION:**

It is an act of emptying of entire distal colon from the sigmoid flexure through the anal orifice in to the exterior, which is a reflex process.

### **B. MECHANISM:**

Most of the time rectum is empty of faeces. When a mass of faeces makes movement into rectum desire for defecation is normally initiated including reflex contraction of rectum and relaxation of anal sphincters. Experimentally it has been concluded that when the intraluminal pressure of rectum reaches about 20–25 cm of H<sub>2</sub>O the pressure receptors which not only detect the increase of pressure but also differentiates whether the increase in pressure is due to gas, liquid or solid, getstimulated.

### **C. NORMAL ANORECTAL FUNCTION:**

- The rectum function as a capacitance organ, holding 650 – 1200 ml, where as daily stool output is 250–750ml.
- The anal sphincter mechanism allows defecation and continence. The internal sphincter accounts for 80% of resting pressure, whereas the external sphincter account for 20% of resting pressure and 100% of squeeze pressure. The internal and external sphincters are contracted at rest.
- Continence requires normal capacitance, normal sensation at the transition zone above

the dentate line, puborectalis function for solid stool, external sphincter function for fine control, and internal sphincter function for resting pressure. The puborectalis maintains the anorectal angle, and contraction prevents solid stool passage.

### **2.4.3. HEMORRHOIDS:**

Hemorrhoids are certainly one of the commonest ailments that affect mankind. It is difficult to obtain any accurate idea of their incidence, but clinical experience suggests that many people of either gender suffers from Hemorrhoids. The incidence of piles apparently increases with age, and it seems likely that at least 50% of people over the age of 50 have some degree of Hemorrhoid. However, the disease is by no means confined to older individuals, and piles are encountered in people of all ages including young children occasionally.

By common consent the terms “Hemorrhoids” and “piles” are used quite interchangeably, but etymologically the words have entirely different meanings. The term “Hemorrhoid” is derived from the Greek adjective Hemorrhoid, meaning bleeding (Hema = blood, rhoos= flowing) and emphasizes the most prominent symptom in the majority of cases. But it cannot be accurately applied to all the conditions diagnosed as Hemorrhoids; for a number of them do not have bleeding. The term “pile” on the other hand, derived from the Latin word pila, a ball, can be aptly used for all forms of Hemorrhoid or piles.

#### **A. ETIOLOGY OF HEMORRHOIDS:**

Etiology of Hemorrhoid is discussed under two headings i.e pre–disposing causes and exciting causes.

##### **A.1. Pre–disposing causes:**

The most important pre–disposing causes of Hemorrhoids are as follows:

##### **Hereditary factor:**

- a) Abnormally large arterial supply to the internal Hemorrhoidal plexus.
- b) Structural weakness of vein wall.
- c) Congenital dilatation of the capillary plexus.
- d) Absence of valves in the superior Hemorrhoidal veins.
- e) The radicles of superior rectal vein lie unsupported in loose submucous connective tissue of the rectum.

**Anatomical factors:**

- f) Erect posture of human being.
- g) The venous return may be obstructed by impaction of the hard–fecal mass in the rectal lumen.
- h) The compression of the veins as they pass through the muscular wall of rectum.

**Physiological factors:**

- i) Corpus cavernosum with direct arterio – venous communication.
- j) Hyperplasia of the corpus cavernosum rectum.

**Diet:** Low fiber diet and rich protein diet is predisposing factors for Hemorrhoids formation.

**A.2. Exciting causes:**

1. Straining during defecation: This is associated cause with persist rectal constipation to empty rectum or with bad habit of routine prolong sitting.
2. Straining at work or play: Who do heavy manual work such as porters, laborers, are very liable to develop Hemorrhoids.
3. Prolonged standing: Drivers, conductor, post office sorters, shop worker are prone to develop Hemorrhoids.
4. Sphincter relaxation: Ageing factor or after any severe illness, there may be some loss of sphincter tone.
5. Abdominal and pelvic causes: Physiological cause such as pregnancy or pathological cause such as abdominal tumor, uterine fibroid may lead to Hemorrhoids. In men prostatic enlargement or urethral stricture may result in habitual straining.

**A.3. Hemorrhoids may be symptom of some other conditions like**

1. Carcinoma of rectum
2. Pregnancy
3. From straining at micturition
4. From chronic constipation

## **B. PATHOLOGY:**

Internal piles have traditionally been regarded as essentially varicosities of the venous plexuses in the wall of the anal canal. These form swellings covered with mucosa, which bulge into the lumen of the anal canal, especially when the portal venous pressure is raised and the sphincter are relaxed during defecation and straining. The veins concerned are chiefly those of the submucous or internal Hemorrhoidal plexus, which are mainly radicals of the superior rectal (Hemorrhoidal) vein. But, except in the very earliest stages of internal Hemorrhoidal, the subcutaneous or external Hemorrhoidal venous plexus also participates in the varicose.

In intero-external pile, an upper two-thirds, above the level of the anal valves, covered with mucosa and a lower one-third below the valves, covered with the skin of anus. In addition to veins, the contents of the pile include a small arterial twig, which is one of the ultimate branches of the superior rectal (Hemorrhoidal) artery. The artery can sometime be quite palpated from internal sphincter muscle by the examining finger in the anal canal and also a certain amount of loose submucosa and subcutaneous areolar tissue surrounding the vessels. In long-standing piles this connective tissue is converted into denser fibrous tissue so that the piles instead of being collapsible venous swelling become palpable on rectal examination.

## **C. CLASSIFICATION:**

### **C.1. According to cause: Primary and Secondary**

#### **Primary Hemorrhoids:**

These are three in number seen at 3, 7 & 11 o'clock positions. This arrangement attributes to the termination of superior rectal artery which divides into right and left main branches. The left branch continues as a single vessel and terminates at 3 o'clock, whereas the right branch divides into two branches— one terminates at 11 o'clock [Anterior branch] and the other terminates at 7 o'clock [Posterior branch]. In this way, the varicosity of the associated radicals of the superior rectal vein results into two sets of Hemorrhoids one set on the right side and one set on the left.

#### **Secondary Hemorrhoids:**

Presences of Hemorrhoids in between the primary Hemorrhoids are known as the secondary Hemorrhoids.

### **C.2. According to site: Internal; External; Interno–external**

1. Internal piles: These piles arising in the upper two-thirds of the anal canal which is lined by columnar– epitheliumcell.
2. External piles: These piles lie in lower one-third of the canal or at the anal orifice itself and are covered by skin.
3. Interno–external piles: It has mixed features of above mentioned both types i.e. internal and external piles.

### **C.3. According to clinical degree**

#### **1<sup>st</sup> degree:**

Hemorrhoids does not come out from anus, occasionally feels only swelling.

**2<sup>nd</sup> degree:**

At first the prolapse only occurs during defecation noticed by patient and slips back spontaneously when the expulsive effort ceases.

**3<sup>rd</sup> degree:**

In later stage Hemorrhoids come down on walking, prolonged standing or any extra exertion and remain outside until it has been replaced by finger pressure.

**4<sup>th</sup> degree:**

Hemorrhoids become permanently prolapsed, external swelling is present from venous obstruction, the sphincter may become stretched, feeling of heaviness and discomfort in rectum.



## **D. CLINICAL FEATURES:**

### **D.1. Bleeding:**

It is first symptom of internal Hemorrhoids. At first it occurs during or after defecation, when the Hemorrhoids are come down just far enough to be grasped by the external sphincter, it becomes congested, and bleeds either from a pin–point rupture or ulcer. The blood is bright red and may spurt out with considerable force “A Splash in the Pan”.

### **D.2. Prolapse:**

Prolapse of internal Hemorrhoids are classified into four stages according to clinical presentation. (as mentioned above in clinical classification)

### **D. 3. Discharge:**

A mucoid discharge from the rectum is a common accompaniment of a prolapsed Hemorrhoid (3<sup>rd</sup> degree) and is most marked with the permanently prolapsed Hemorrhoids (4<sup>th</sup> degree).

### **D.4. Irritation:**

This is a common type of 3<sup>rd</sup> degree Hemorrhoids; it is caused by a constant leakage of mucous on to the anal skin, which is become moist.

### **D.5. Pain:**

It is not a common symptom of Hemorrhoids. It is caused by acute attack of prolapse with thrombosis and much related to external edema, congestion and over stretching of skin. The complaint of severe pain would associate with other conditions like fissure/abscess.

## **E. DIFFERENTIAL DIAGNOSIS:**

### **E.1. Bleeding per-rectum:**

#### **1) General Disorders:**

- Blood disorders i.e. gastric ulcer, GI cancer etc.
- Medications i.e. aspirin, diuretics, antibiotics etc.
- Hepatic / Renal insufficiency.i.e. Hepatitis

#### **2) Local Perianal:**

- Cutaneous lesions i.e. trauma
- Fissure in ano

A crack or laceration in the lining of the anal wall can cause acute constipation. Patient may notice a few drops of blood streaking stool.

- Prolapsed thrombosed piles
- Condyloma acuminatum

It is a type of viral infection in external genitalia

- Tumour
- Traumatic lesions

#### **3) Anal canal:**

- Ulcerations e.g. Syphilitic
- Tumor
- Traumatic lesions

#### **4) Colorectal:**

- Polyps

Colorectal polyps are the most common cause of intermittent bleeding in adults younger than age 60.

- Diverticulitis

Most common in the sigmoid colon, diverticulitis may produce a left-lower- quadrant mass that's usually tender, firm, and fixed. Other findings may

include alternating constipation and diarrhoea, bleeding, nausea, low-grade fever, and a distended and tympanic abdomen.

- Colitis (e.g. Ischaemic Colitis, Infectious and Parasitic Colitis)

Ischemic colitis commonly causes bloody diarrhoea, especially in elderly patients. Rectal bleeding may be slight or massive and is usually accompanied by severe, cramping lower abdominal pain and hypotension.

Ulcerative colitis typically causes bloody diarrhoea that may also contain mucus. Blood loss may be slight or massive and is preceded by mild to severe abdominal cramps.

- Tumor

#### 5) Small bowel:

- Crohn's disease

In Crohn's disease, tender, sausage-shaped masses are usually palpable in the right lower quadrant and, at times, in the left lower quadrant. Attacks of colicky right-lower-quadrant pain and diarrhoea are common.

- Meckel's diverticulum
- Ischaemic lesion
- Tumor

#### 6) Gastroduodenal:

- Mucosal erosions
- Ulcerations
- Tumor
- Traumatic lesions

#### **E.2. Prolapse per Rectum: (Only in 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> degree Piles)**

- prolapse through rectum
- Rectal polyp especially at younger age.
- Tumour e.g. Malignancy especially at older age.

### **E.3. Pruritus ani:**

#### **Primary dermatosis:**

- Eczema, Psoriasis
- Allergic eruptions
- Perianal lesions contact dermatitis
- Local anaesthetic, antibiotic ointments Local
- Fissure– in–ano
- Crohn'sdisease
- Infections
- Fungul infection
- Worm infestation
- Sexually transmitted diseases

#### **Secondary Irritative Cutaneous Lesions:**

- Transpiration i.e. excessive sweating
- Inadequate anal hygiene
- Mucous
  - Excessive production in prolapse of rectum
- Pus
  - Fistula in ano
- Stool
  - Diarrhoea
  - Incontinence
- Systemic disorders
  - Diabetes
  - Obstructive Jaundice
  - Idiopathic and Psychogenic

#### **E.4. Peri-anal Pain:**

➤ Peri-anal region

- Thrombosed varix
- Haematoma
- Fissure in ano
- Herpes

This common viral infection produces groups of vesicles on an inflamed base, most commonly on the lips and lower face. In about 25% of cases, the genital region is involved. Vesicles are preceded by itching, tingling, burning, or pain; develop singly or in groups.

➤ Anus

- Cryptitis –Papillitis
- Acute submucous abscess
- Thrombosed and prolapsed hemorrhoid

➤ Rectum

- Solitary ulcer Invagination

➤ Pelvic floor

- Proctalgia fugax

With this disorder, muscle spasms of the rectum and pelvic floor produce sudden, severe episodes of rectal pain that last up to several minutes and then disappear.

- Idiopathic pain

➤ Non proctological origin

- Gynecological
- Urological
- Neurogenic
- Musculoskeletal

#### **E.5. Per Rectum Discharge:**

- Eczema
- Fissure– in–ano

- Fistula in ano
- Abscesses

#### **E.6. Differential diagnosis of external Hemorrhoids:**

The differential diagnosis of the external Hemorrhoids should include anal epithelioma, chondiloma, rectal polyp etc.

Obvious red blood passed per anum may be due to a fissure, fistula, polyps, syphilitic ulceration, and amoebic proctitis. In the elderly fresh bleeding per rectum may be due to carcinoma.

Internal Hemorrhoids complicated by thrombosis, oedema or the factors are unlike to cause difficulty in diagnosis. Partial rectal prolapsed must be differentiated from the Hemorrhoidal prolapse.

## **F. EXAMINATION**

### **F.1. Inspection:**

There may be no evidence of internal Hemorrhoids. In more advance cases, redundant folds or tags of skin can be seen in the position of one or more of the 3 primary Hemorrhoids, when the patient strains internal Hemorrhoids may come into view transiently or if they are of the 3<sup>rd</sup> degree are remained prolapsed.

### **F.2. Palpation:**

Internal Hemorrhoids can be felt by P/R index figure– digital examination.

### **F.3. Proctoscopy:**

Proctoscopy is the essential step in the examination for internal Hemorrhoids. If Hemorrhoids are present, they tend to bulge into the end of the proctoscope like grapes, when the patient bears down slightly and the instrument is gradually withdrawn. Sometimes when this is done one of the piles starts to bleed and the actual spot from which the hemorrhage is occurring can be clearly seen.

To assess the size and degree of the Hemorrhoids the withdrawal of the proctoscope as continued till it just emerges from the anal orifice. If now no red anal mucosa is evident at the anal orifice the piles are only first degree; alternatively, if mucosa does project the piles are second or third degree. The patient is next requested to cease straining. If the piles are of second–degree variety, they immediately slip back into the anal canal out of view, and the anal orifice closes over them. But if they are third degree piles the mucosal prolapse persists after the cessation of straining till it is reduced digitally.

### **Complications**

- Profuse Haemorrhage and Anaemia
- Strangulation with Thromobosis
- Suppuration
- Fibrosis
- Sloughing

- Ulceration
- Gangrene
- Pylephlebitis (Portal pyaemia)

#### **F.5. Investigations**

- **Haematological:** Total blood count, differential count, haemoglobin, E.S.R, bleeding time, clotting time, blood group.
- **Bio-chemical:** Fasting Blood Sugar, Post Prandial Sugar, Liver Function Test, lipid profile, Renal Function Test, H.I.V, V.D.R.L, HbsAg.
- **Urine:** Routine and Microscopic.
- **Stool:** Routine and Microscopic.
- **Imaging studies:**
  - Radiography–Chest X–Ray for rule out of any pathology.
  - Ultrasonography– Abdomen and pelvic scan to rule out any other pathology.



#### **2.4.4. TREATMENT OF HEMORRHOIDS**

Treatment of Internal Hemorrhoids:

Number of treatment modalities is available for the management of ‘Internal Hemorrhoid’ as

##### **A. Non-Surgical:**

- Medical Treatment.

##### **B. Parasurgical:**

- Sclerotherapy
- Rubber band ligation
- Manual Dilatation
- Cryo-surgery
- Infra- red- coagulation
- Bipolar diathermy
- Galvanic generator
- DGHAL

##### **C. Surgical:**

- Stapler Hemorrhoidectomy
- Formal Hemorrhoidectomy

##### **A. NON-SURGICAL:**

When the symptomatic Hemorrhoid is treated by oral and local medicines like suppository, ointments etc. without any surgical intervention named as “Non-Surgical” or “Medicinal” treatment.

This therapy is recommended when the Hemorrhoid is having less symptoms & is a symptom of some other condition or disease. It consists of correcting probable pre-

disposing factors responsible for Hemorrhoid like constipation, dietary and bowel habit, life style etc.

Constipation is corrected by using unprocessed grain, mild laxatives. Patient is advised to take high fiber–diet which should be free from spices. Hot fomentation like sitz bath with local hygiene to be used to relieve pain and local inflammation.

## **B. PARA SURGICAL TREATMENT:**

Those Hemorrhoids not responding to medical treatment and lifestyle modifications are treated by parasurgical methods. It is directed to the non–sensitive Hemorrhoid lying above “Dentate line”.

### **B.1. Injection treatment:**

Indicated in 1st degree Hemorrhoids, 5% phenol in almond oil is injected into submucosa above the dentate line, hence it is painless. Injection of chemicals into Hemorrhoids for their cure was practiced by Morgan, in 1869.

Two possible modes of action may be postulated.

- Possibly the fibrous tissue that forms, surrounds and constricts the veins (and arteries) in the submucosa. If the injection has been given low into the pile itself this fibrous tissue may provide a supporting and encasing layer protecting the veins from the trauma associated with the passage of feces. It also contracts on the vessels and may even obliterate their lumen or lead to thrombosis, as has been shown. If the injection has been given high, above the pile, the fibrosis will constrict and possibly complete obliterate the radicles of the superior Hemorrhoidal vein and accompanying branches of the superior Hemorrhoidal artery in the pile itself from becoming distended by increased back– pressure in the portal system during the exertions of defaecation and straining. 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.
- The fibrosis may also increase the fixation of the pile or its pedicle to the underlying muscular coat and in the way, it may reduce the amount of prolapsed, but though sometime very striking this is a much less certain effect.

**Advantages:**

- This method is quick
- Relatively painless
- Free from complication

**Disadvantages:**

- Contraindicated in prolapsed piles
- Faulty technique may lead to sloughing

**B.2. Rubber band ligation:**

This operation was developed by Barron (1963) as a modification of an outpatient ligation method originally proposed and practiced by Blais–Dell (1958). 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 seven to ten days this elastic band gradually cuts through the tissue and the pile sloughs out spontaneously.

No anesthetic is required for rubber band ligation. Barron (1963) claimed that it was a virtually painless maneuver as a rule or at least caused no more discomfort than does an injection for Hemorrhoids. It seems that rubber band ligation is best suited to 2<sup>nd</sup> degree Hemorrhoids, while in 1<sup>st</sup> degree piles, there is insufficient tissue available to pull into the ligation drum to make the method worthwhile, and in any event such small piles can be very successfully managed by injections. For 3<sup>rd</sup> degree Hemorrhoids with large skin covered components particularly if multiple, the rubber band ligations are of very limited and temporary value and are no substitute for a formal Hemorrhoidectomy.

**Advantages:**

- Operation can be done without assistance
- The band can be placed over larger piles

**Disadvantages:**

- Pain is more
- Secondary haemorrhage

### **B.3 Manual dilation of the anus and lower rectum:**

Lord (1968) believed that there exist fibrous band in anal canal and rectum which interfere with venous drainage; hence they are responsible for development of Hemorrhoids. If these bonds are broken by stretching the anus and the rectum, the causative factors are removed and condition improves.

This procedure is done under general anesthesia. The anus and rectum are gradually dilated using both hands by initially introducing two fingers then four fingers and finally eight fingers. At the end a sponge is introduced in anus and left there for hours or so from the next day onwards regular dilation with a rectal dilator is done.

#### **Disadvantages:**

Three complications have been encountered, though only in a small proportion of the cases.

- Splitting of the anal and perianal skin
- Mucosal prolapsed in some patients who had third-degree piles
- Anal incontinence

### **B.4. Cryosurgery (Cryo-Hemorrhoidectomy):**

Lewis et al (1969) applied cryogenic technique in management of Hemorrhoids. The essential item is a cryoprobe, capable of being cooled by nitrous oxide or liquid nitrogen. Liquid nitrogen produces a reduction of temperature to  $-180^{\circ}\text{C}$  compared with nitrous oxide to  $+70^{\circ}\text{C}$ . The probe is applied along the axis of Hemorrhoids. The tissue easily seems to freeze and returns to normal after rewarming swelling occurs 6 hours later.

Thrombosis with infarction occurs at 24 hours. Necrosis occurs over 10–14 days.

#### **Advantages:**

Completely painless technique.

#### **Disadvantages:**

Profuse watery discharge.

### **B.5. Infra–Red Coagulation (Photo coagulation) I.R.C.:**

Neiger et al (1979) used infra–red coagulator for the 1st time for the treatment of Hemorrhoids. It causes localized tissue destruction, by rapidly increasing the temperature. Neiger mentions oedema of the underlying tissue with development of granulation tissue in submucosa and thrombosed vessels.

#### **Advantages:**

- Cost effective
- Less pain & fewer complication

### **B.6. Bipolar diathermy:**

This is a very recent method in treatment of Hemorrhoids. It produces tissue destruction, ulceration and fibrosis by local application of the heater probe, developed by Dr. David Auth.

### **B.7. Galvanic generator:**

This therapy was developed by Dr. Daniel Norman and has been utilized in all four degrees of Hemorrhoids. This method is different from infra red coagulation and bipolar diathermy. A low voltage current is passed between a probe which is unipolar and earth plate of patient. The mode of action is, formation of NaOH with subsequent local effects, causing tissue destruction.

### **B.8. DGHAL:**

Doppler Guided Hemorrhoidal Artery Ligation (D.G.H.A.L.) is the least invasive technique, because there is no tissue removal but only the application of stitches on the rectal mucosa, an area lacking in pain receptors.

It utilizes a specially designed instrument with a Doppler transducer to locate the terminal branch of the superior rectal artery, which was then ligated, through an instrument 3 cm above the dentate line.

**Advantage:**

Being the only resolute surgical treatment which can be conducted with local anaesthesia as a day case, Negligible post-operative pain and highly effective. Sufferer can resume his normal activity within 24 hrs.

**Disadvantage:**

Costly treatment modality.

**C. OPERATIVE TREATMENT:****C.1. Formal Hemorrhoidectomy:****I. Excision and ligation:**

Fredrick Salmon the founder of St. Marks hospital modified the ancient method of ligation and excision of Hemorrhoids, which consisted of making a cut with scissors at mucocutaneous junction of pile and stripping the mucosa covered portion upto the top of anal canal, where it was ligated and excess tied.

Miles (1919) introduced the low ligation technique. He suggested making the scissors cut not at the mucocutaneous junction but at perianal and anal skin upto, but not beyond mucocutaneous junction. This separated a 'V' shaped piece of skin together with the mucosal part of pile which when tied dragged the mucosa to the level of mucocutaneous junction.

**II. Submucosal Hemorrhoidectomy:**

Parks (1956) proposed a modification of ligation operation. Originally proposed by Petit (1774) and termed it as submucosal Hemorrhoidectomy with high ligation.

**Advantages:**

Ligature does not include anal mucosa, hence is less painful as claimed by Parks. There is no extensive raw area hence less fibrosis and scarring.

**Disadvantages:**

It is more time consuming as compared to previous technique, dissection is very difficult because of continuous oozing. Recurrence is more common.

### **III. Excision with suture:**

Introduced by Mitchell (1903) the Hemorrhoid was drawn down as far as possible and a clamp was applied radially across its base, distal portion of the Hemorrhoid was cut. Next a ligature suture on curved needle was passed as a continuous stitch. This was then tightened controlling bleeding, more recently Ferguson (1959) has advocated a method of Hemorrhoidectomy without use of clamp.

### **IV. Excision of entire pile bearing area with suture:**

This is the operation described by White-head (1882) of Manchester which provides for excision of Hemorrhoid bearing area of anal canal as a tubular segment, the lower edge of anal mucosa then sutured circumferentially to anal skin.

The result of this operation was most unsatisfactory, it caused considerable blood loss, sensory incontinence and formation of stricture.

### **V. Excision with clamp and cautery:**

Cusack (1846)<sup>1</sup>, in Dublin first used this method. The procedure was similar to Mitchell's method except thermal cautery was used instead of suture.

#### **Advantages:**

It caused less pain and less chance of stricture formation.

#### **Disadvantages:**

Increased chances of reactionary haemorrhage.

### **C.2. Stapler Hemorrhoidectomy:**

In 1993 Antonio Longo used the method, it was later named after him. A basic feature of stapler Hemorrhoidectomy is minimally invasive intervention, with transanal simultaneous ligation of all terminal branches of a Hemorrhoid involved in internal Hemorrhoid vascularization and with the reduction of rectal mucosal prolapse.

Method:

Patient was placed into the lithotomic position under general anaesthesia. Detailed exploration of the anorectal region is performed with anal retractor. After dentate line identification, mild eversion of the anal canal is performed with atraumatic clamps. At 4–5 cm from the dentate line cranially, beginning from the anterior rectal wall clockwise tobacco pouch suture was made, pertaining to involve the mucosal and submucosal layer. For the pouch suture, monofilament suture 2.0 is used.

After that a maximally open Ethicon Endo Surgery 33 mm Hemorrhoidal stapler is inserted in the anal canal direction to the point where its 'Head' reaches the position above tobacco pouch suture. The suture is then tightened around the axis of the automatic suture device. In that position it is necessary to check the position of the tightened pouch suture i.e. whether is positioned symmetrically at least 2 cm from the dentate line.

After the stapler is triggered, it is gently pulled out of the anal canal in a maximally open position. The dissected tissue around the stapler axis is checked (whether there is the total circumference) and the samples to be send for histopathology. After removal of stapler, haemostasis is monitored.

**Advantage:**

Less painful than traditional surgical methods but certainly not pain free.

**Disadvantage:**

Serious complications reported after procedure as requires hospitalisation and several days of recovery.



## 2.5. DURG REVIEW

Ayurveda, the science of life, speaks about many types of treatments to get rid of human ailments. Ayurvedic medicines are mainly based on the plants and herbs. Even in the present era, when the science has reached to its maximum, the herbo–mineral drugs are still considered as an effective source of therapy.

The prime etiopathological factor behind Arsha is Mandagani i.e. weak digestive enzymes, which in turn leads to Vibandha that causes development of Arsha. In regards to its management, Sushruta states four modalities i.e. (i) Bhaishaja Chikitsa (Palliative treatment) (ii) Kshara Karma (Potential cauterization agent therapy) (iii) Agnikarma (Direct cauterization agent therapy) and (iv) Shastra Karma (Operation by sharp instrument).

The above said measures have been indicated in order of treatment for Arsha. Kshara Karma therapy has been identified along with Agnikarma therapy as the parasurgical measures having minimal invasive procedures. These procedures have many advantages like–simple, safe, effective, ambulatory and known for minimal or no complications, less time to stay in the hospital and minimal disturbance in patient’s routine work. That’s why it is readily acceptable to patient.

Sushruta has mentioned Kshara is the most superior procedure among Shastra and Anushastra (sharp instruments and substitute for sharp instruments respectively) because it is having superior qualities than latter one like Chedana (Excision), Bhedana (incision and drainage), Lekhana (scraping) etc. Kshara sutra treatment is very much suitable and acceptable as compared to prevalent methods in modern medical science. Even then, after having maximum acceptability in society and having good efficacy there is still need of standardization on Kshara sutra ligation (K.S.L) procedure.

Taking in to consideration of above all factors, the present research work has been planned to evaluate the effect of Kshara Sutra Ligation. As per classical opinions, Kshara sutra ligation procedure has a radical curing effect in Arsha. Regarding Kshara sutra and Kshara applications few works have been conducted and the effect of these procedures has been found encouraging.

There are number of drugs mentioned to be used for Kshara preparation in Ayurvedic classics. Thus, this research work was designed to evaluate the effect of Aloe Vera (Kumari) Kshara sutra ligation in management of Arsha. For that control group is taken as standard Snuhi Kshira Ksharsutra.

**In Trial group:** Patients will be treated with application of Aloe vera Ksharsutra.

**In control group:** Patients will be treated with application of standard Snuhi–kshira Ksharsutra

**Ingradients:**

Aloe Vera Ksharsutra prepared by following ingradients to be coated on Linen thread No. 20 –

1. **Kumari**
2. **Apamarga Kshara**
3. **Haridra Choorna**

Snuhi Kshira Ksharsutra prepared by following ingradients to be coated on Linen thread No. 20 –

1. **Snuhi Kshira**
2. **Apamarga Kshara**
3. **Haridra Choorna**

**2.5.1. ALOE VERA KSHARSUTRA**

**(Trial Drug: Description of The Ingradients)**

**A. KUMARI:**

**Latin Name:** – Aloe vera

**Family:** – Liliaceae

**Synonyms:** – Kanya, Gruhkanya, Gruhkumari, Ghrutkumari, Deerghapatrika, Sthleruha, Bahupatra, Sukantaka, Mrudu, Kapila etc.

**Vernacular Names: –**

English: – Common Indian Aloe, Musabbar.

Hindi: – Ghikuaar, Gwar patha, Ghigwar.

Marathi: – Korphad.

Gujarati: – Kunwar.

**Parts Used: – Patra**

**Properties: –**

**Rasa** – Tikta, Madhur

**Vipak** – Madhur

**Veerya** – Sheeta

**Guna** – Guru, Snigdha, Picchila.

**Doshghnata** – Tridoshashamak.

**Karma: –**

Vedanasthapana, Shothahar, Vranashodhan, Ropana, Deepana, Pachana, Bhedana, Balya, Bruhan etc.

**Chemical Constituents: –**

All Aloe species contain anthraquinone glycosides. Barbaloin (aloe-emodin anthrone C-10 glucoside) is the major active constituent. Aloes also contain isobarbalin, aloe-emodin, resins, aloetic acid, homonataloin aloe-sone, chrysophanic acid, chrysamminic acid, galactouronic acid, choline choline salicylate, saponins, mucopolysacchrides, glucosamines, hexuronic acid, coniferyl alcohol.

**Pharmacological Activities: –**

It is bitter, cooling, purgative, alteratve, fattening, tonic, aphrodisiac, anthelmindic and alexiteric. It is useful in eye-disease, tumours, spleen enlargement, liver complaints, vomiting, bronchitis, skin diseases, biliousness, asthma, jaundice and ulcers. The fresh gel or its solid extract is used for medicinal purpose. The plant is equally salutary both internally as well as externally. Aloe gel is formed in inner parenchymal cells of the

leaves. This gel is used in cosmetic industry and is in heavy demand. The gel possesses good moisturizing properties and also has formulation role for oil in water (approved by FDA) preparation. Aloe gel also contains anti-wrinkle properties. Aloe is the dried juice of leaves of *A. barbadensis*, known as curacao aloes, or of *A. perryi*, known as socotrine Aloes; or of *A. africana* and *A. spicata*, known as cape aloes.

#### Reference:

कुमारी भेदनी शीता तिक्ता नेत्र्या रसायनी ॥

मधुरा बृंहणी बल्या वृष्या वातविषप्रणुत् ।

गुल्मप्लीहयकृद्वृद्धिकफज्वरहरी हरेत् ॥

ग्रन्थ्यग्निदग्धविस्फोटपित्तरक्तत्वगामयान् ॥ – भावप्रकाशनिघण्टु गुडुच्यादिवर्गः/ २२९, २३०.

#### B. APAMARGA:

**Botanical name:** *Achyranthus aspera* Linn.

**Family:** Amaranthaceae.

**Gana – Charak –** Shirovirechana, Krumighna, Vamanopaga.

**Sushrut –** Arkadi.

**Sansrit Name –** Adha Shalya, Kharamanjari, Mayuraka, Markati, Durgraha, Pratyakpushpee, Shikhari, Kiniha, Kandakanta, Markatpippali.

**English –** Prickly-chaff flower, rough chaff tree.

**Hindi –** Chirchira, Chirchitta, Latjira, Chirachiri

**Habitat:** Throughout India, up to an altitude of 2100 meters and in the south Andaman Island, commonly found as a weed on waysides and waste places.

**Parts used –** Whole plant

#### Properties:

**Rasa –** Katu, Tikta

**Veerya –** Ushna

**Vipaka –** Katu

**Guna** – Laghu, Ruksha

**Doshghnata** – Kaphavataghna

**Karma** – Deepana, Pachana, Vatanulomana, Kaphavilayan, Srotorodhnashak, Mootral, Lekhan, Vishaghna etc.

**Uses:**

In Sushruta Samhita, Apamarga Kshara along with Kshara of some other plants taken with sheep's urine is said to be best to destroy urinary gravel. In Ashtanga Hridaya, same recipe is mentioned in the treatment of gravel and stone. Chakradatta has mentioned that paste of Apamarga root Kshara and Haridra should be applied on Ling Arsha. Likewise, in successive texts; Apamarga Kshara is incorporated in many formulations for the treatment of various diseases.

**Chemical Constituents:**

The ethanolic extract of the plant contains alkaloids and saponins. The shoot yielded a new aliphatic dihydroxyketone, characterized as 36, 47–dihydroxyhenpentacontan–4–one together with tritriacontanol. The root was found to be contained oleanolic acid as the aglycone from the saponin fraction.

**Kshara Karma:**

The procedures that utilize the Kshara, are mainly two, like Pratisarana as well as Kshara Sutra, in case of the Arsha. The simple application of Kshara, over the Mamsankura for a stipulated period, will leave the Dagdha (burn) area of the Ankura, which will fall off in succeeding days. Whereas, the transfixed Kshara Sutra around the Arshankura, induces the falling off of the Ankura by both the Chedana and Lekhana Karma.

**Reference:**

अपामार्गः सरस्तीक्ष्णो दीपनस्तिककः कटुः ।

पाचनो रोचनश्छर्दिकफमेदोऽनिलापहः ।

निहन्ति हृद्गुजाध्मार्शः कण्डूशूलोदरापचीः ॥ भावप्रकाशनिघण्टु गुडुच्यादिवर्गः/ २१९, २२०.

## **C. HARIDRA:**

**Latin name:** Curcuma longalinn.

**Family:** Sciataminaceae

**Gana:** Charak – Kushthaghna, Kandughna, Vishghna, Tiktaskandha, Shirovirechana,

**Sushrut** – Haridradi, Mustadi, Shleshmasanshamana etc.

**Synonyms:** Rajani, Gauri, Varnavat, Haridra, Nisha, Kanchani, Varvarnini, Krumighna, Yoshitapriya, Hattavilasinee etc.

**English:** – Indian Saffron, Turmeric

**Hindi:** – Haldi

### **Plant description and habitat:**

It is a tall herb and leaves are very large, flowers are half inch in length. Its seeds are round and knotted and root stalks are large, cylindrical tubers and orange coloured inside. It is extensively cultivated all over India and south Asian countries.

**Part used:** Tubers

### **Properties:**

**Rasa:** Tikta, Katu

**Veerya:** Ushna

**Vipaka:** Katu

**Guna:** Ruksha, Laghu

**Doshagnata:** Kaphapitta shamak

### **Karma:**

Shothahar, Vedanasthapana, Vranapachana, Shodhana, Ropana, Sadnyasthapana, Rochana, Deepana, Garbhashayshodhan, Vishaghna etc.

### **Chemical Constituents:**

Essential oils, alkaloids and a colouring matter (curcumin). Oil does not contain any phenol, aldehyde or ketones. Caproic acid and valeric acid are found.

### **Use:**

The volatile oils and curcumin of Curcuma longa exhibit potent anti-inflammatory effects. Oral administration of curcumin in instances of acute inflammation was found to

be as effective as cortisone or phenylbutazone, and one– half as effective as in cases of chronic inflammation. In monkeys, curcumin was shown to inhibit neutrophil aggregation associated with inflammation. Curcumin anti– inflammatory properties may be attributed to its ability to inhibit pro–inflammatory arachidonic acid, as well as neutrophil function during inflammatory states. Curcumin may also be applied topically to animal skin to counteract inflammation and irritation associated with inflammatory skin conditions and allergies. Turmeric has been found to have a hepatoprotective characteristic similar to that of silymarin.

The rhizome is laxative antihelminthic, antibiotics and bacteriostatic. It is used internally as anthelmintic. Externally it is used in painfull swellings. It is used externally and internally for skin diseases, especially in case of Arsha it used as Lepa. The smoke obtained after putting Haridra Churna over fire is very beneficial in case of Asthama and Hikka. A paste of turmeric with the pulp of Nimba leaves is used in ringworm, obstinate itching eczema and other parasitic skin diseases. It is used in intermittent fever and dropsy.

#### **References:**

हरिद्रा कटुका तिक्ता रूक्षोष्णा कफपित्तनुत् ।

वर्ष्या त्वग्दोषमेहास्त्रशोथपाण्डुव्रणापहा ॥ – भावप्रकाशनिघण्टु हरितक्यादिवर्गः/ १९६, १९७.

#### **2.5.2. SNUHI KSHIRA KSHARSUTRA**

##### **(Control Drug: Description of The Ingredients)**

#### **A. SNUHI:**

**Latin Name:** Euphorbia nerifoliaLinn.

**Family:** Euphorbiaceae.

**Gana:** Charak – Virechana, Shatshodhan Vruksha

**Sushruta** – Adhobhaghar, Shyamadi etc.

**Synonym:** Snuhi, Vajra, Vijari, Snuk, Sudha.

**English:** – Common milkhedge.

**Hindi:** – Thuhar, Sehund, sij.

**Plant Description and Habitat:**

It is large succulent shrub or small tree up to 20 ft. The stem and branches are of the shape of round and covered with thorns. Its leaves are fleshy, deciduous, ovate–oblong 6–12 inches long. The flowers are yellow in colour. Its seeds are flat and consisting of hairs.

Plant is common in rocky ground. It is often cultivated for hedge in villages throughout India.

**Part used:** Latex and root

**Properties:**

**Ras:** Katu, Tikta

**Virya:** Ushna

**Vipaka:** Katu

**Guna:** Laghu, Ruksha

**Doshagnata:** Kaphavataghna

**Karm:** Lekhan, Vedanasthapana, Shothahar, Raktashodhana, Vishaghna etc.

**Chemical Constituents:**

Euphorban, resin, gum, malate of calcium etc.

**Chemical Constituents of Latex:**

1. Total solid	:	29.57%w/w
2. Water soluble substance	:	8.14%w/w
3. Dry rubber content	:	21.43%w/w
4. Resin content	:	13.81%w/w
5. Ash value	:	1.17%w/w
6. Acid insoluble ash	:	trace
7. Rubber hydrocarbon	:	0.42%w/w



**Use:**

It can be used internally as purgative and digestive stimulant. The leaves are applied over the Vranashotha. Juice mixed with ghritha is given in syphilis and in spleen and liver enlargements due to continued intermittent fever. Turmeric powder mixed with latex is used for external piles. The thread kept in above mixture is used for ligation of hemorrhoids and for the fistula.

**Reference:**

सेहुण्डो रेचनस्तीक्ष्णो दीपनः कटुको गुरुः।

शूलामाष्ठीलिकाऽऽध्मानकफगुल्मोदरानिलान् ॥

उन्मादमोहकुष्ठार्शः शोथमेदोऽश्मपाण्डुताः ।

व्रणशोथज्वरप्लीहविषदूषीविषं हरेत् ॥

– भावप्रकाशनिघण्टु गुडुच्यादिवर्गः/ ७३, ७४.

**B. APAMARGA:** Described earlier in trial drug ingredients.

**C. HARIDRA:** Described earlier in trial drug ingredients.

**Ingredients of Aloe Vera Ksharasutra**



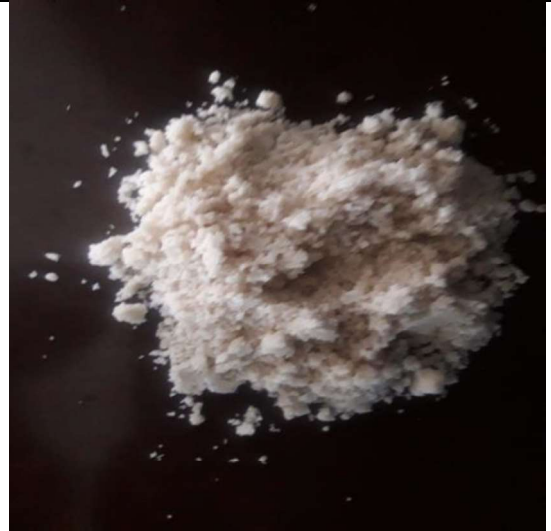
**Aloe Vera (Kumari)**



**Aloe Vera Pulp**



**Apamarga**



**Apamarga Khara**



**Haridra Khanda**



**Haridra Powder**

**Ingredients of Snuhikshira Ksharasutra**



**Snuhi**



**Snuhi Kshira**



**Apamarga**



**Apamarga Khara**



**Haridra**



**Haridra Churna**

**Ksharasutra Cabinet**



**Aloe Vera Ksharasutra**



**Snuhi Kshira Ksharasutra**

### 3. RESEARCH METHODOLOGY

#### 3.1. AIMS AND OBJECTIVES

##### 3.1.1. AIM

- To study the effect of Aloe Vera Ksharasutra in the management of Arsha.

##### 3.1.2. OBJECTIVES

- To study properties and mode of action of Aloe Vera Ksharasutra.
- To study the efficacy of Aloe Vera Ksharasutra Ligation in patients of Arsha.
- To compare the effect of Aloe Vera Ksharasutra and Snuhi Kshira Ksharasutra in patients of Arsha specifically on **Irritation, Cutting and Healing**.

## **3.2. MATERIALS**

### **3.2.1. Patients**

Total 220 patients were involved in this study selected by simple randomized sampling method. Further two equal groups 110 each were made.

### **3.2.2. Place of study**

OPD and IPD, Shalyatantra Department, of Aryurveda Hospital at Ad. B. V. Kale Ayurveda College, Latur.

### **3.2.3. Literary Materials**

Ayurved text books, samhitas, tika, Modern text books, online literature and works carried out earlier were literary materials.

### **3.2.4. Drugs**

#### **A. Aloe Vera Ksharasutra (for Trial Group)**

- Aloe Vera Ksharasutra was prepared in Shalyatantra department, under the supervision of Rasashastra Expert.
- Details of Aloe Vera are mentioned earlier under Drug Review.
- Method of preparation of Aloe Vera Ksharasutra is mentioned in present topic under Methods.

#### **B. Snuhi Kshira Ksharasutra (for Control Group)**

- Snuhi Kshira Ksharasutra was prepared in Shalyatantra department, under the supervision of Rasashastra Expert.
- Details of Snuhi are mentioned earlier under Drug Review.
- Method of preparation of Snuhi Kshira Ksharasutra is mentioned in present topic under Methods.

### **3.2.5. Other Materials**

#### **A. Materials for Ksharasutra preparation**

##### **A.1. Aloe Vera Ksharasutra**

- Aloe Vera pulp
- Apamarga Kshara
- Haridra Churna
- Surgical linen thread of size 20
- Sterile cotton gauze piece
- Ksharasutra cabinet

##### **A.2. Snuhi Kshira Ksharasutra**

- Snuhi kshira
- Apamarga Kshara
- Haridra Churna
- Surgical linen thread of size 20
- Sterile cotton gauze piece
- Ksharasutra cabinet

#### **B. Materials for Ksharasutra ligation**

- Proctoscope
- Piles Holding Forcep
- Cheatle Forcep
- Gauze Holding Forcep
- Artery Forcep
- Allies Forcep
- Babcock's Forcep
- Retractors
- Suture cutting scissor

- Surgical Gloves
- Betadine
- H<sub>2</sub>O<sub>2</sub>
- Spirit
- Gauze
- Cotton
- Inj. Xylocaine 2%
- Syringes
- Cautery machine
- Ksharasutra



### 3.3. METHODS

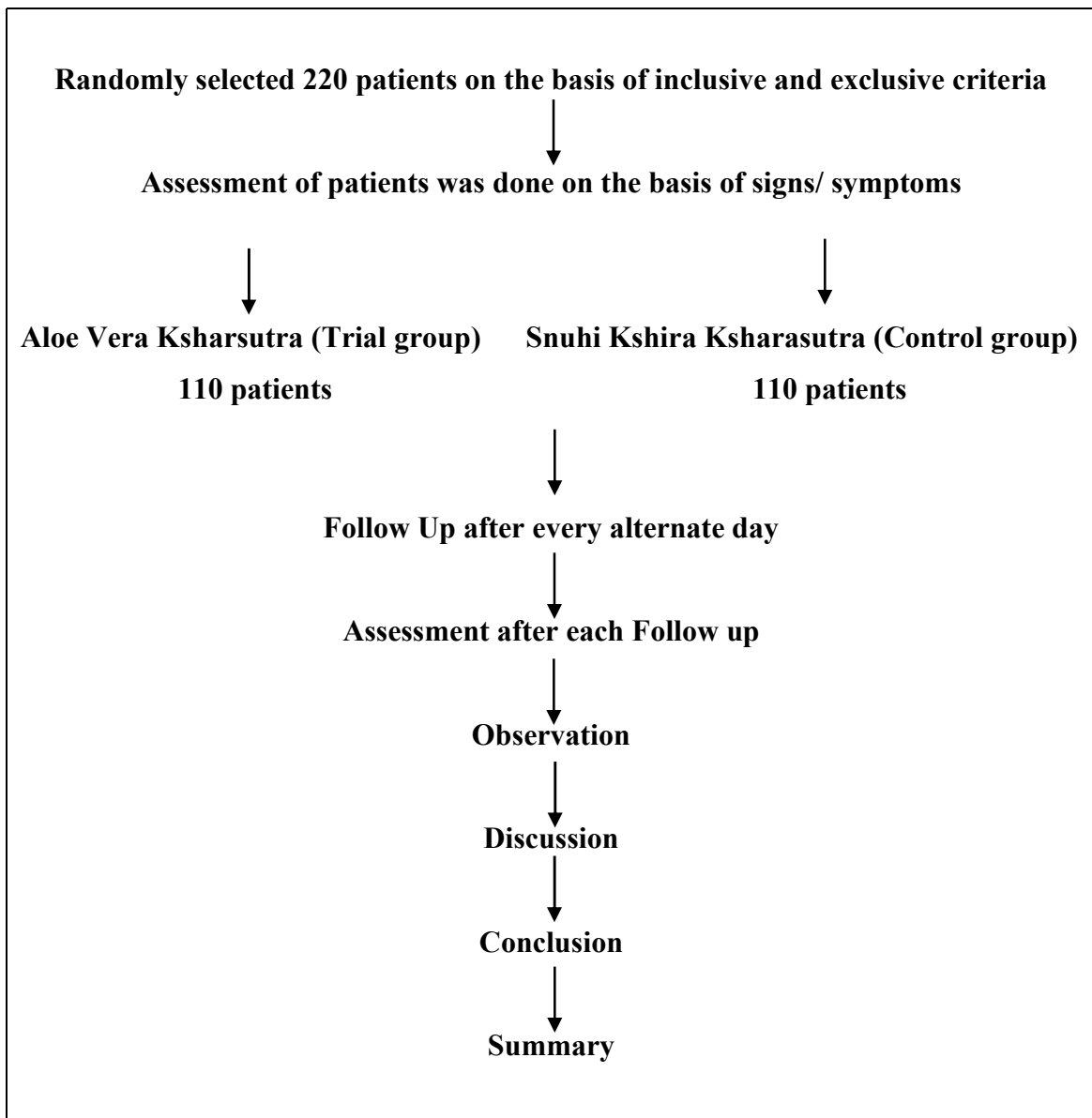
#### 3.3.1. Study Design

##### A. Study type

Randomized Controlled Clinical Trials.

##### B. Study Design

Figure 3.1. Shows flow chart of Study design



## **C. Methodology**

Present study of worked out in three phases.

1. Diagnostic Phase

2. Interventional Phase

3. Assessment Phase

### **C.1. Diagnostic Phase**

- The patients approached to OPD were examined thoroughly on the basis of physical examination, anorectal examination and lab investigation and were diagnosed as Arsha patients.
- Further among all those patients, 220 patients were randomly selected for further study.

### **C.2. Interventional Phase**

- The selected Arsha of patients were ligated group wise with Aloe Vera Ksharasutra and Snuhi Kshira Ksharasutra.
- All required subjective parameters were observed and noted in case record form before treatment, at every follow up and after treatment.

### **C.3. Assessment Phase**

- All collected data was classified and presented in the forms of Master charts. Further data was presented in the form of tables and graphs.
- Finally, statistical analysis was done to draw the conclusion.

## **D. Research Question**

**D.1.** Does the ligation of Arsha with Aloe Vera Ksharasutra is effective or not?

**D.2.** Does the ligation of Arsha with Aloe Vera Ksharasutra is effective than the ligation of Arsha with Snuhi Kshira Ksharasutra or not?

## **E. Hypothesis**

### **E.1. Null Hypothesis (H<sub>0</sub>)**

Ligation of Arsha with Aloe Vera Ksharasutra is not significantly effective than Ligation of Arsha with Snuhi Kshira Ksharasutra in Arsha vyadhi.

### **E.2. Alternative Hypothesis (H<sub>1</sub>)**

Ligation of Arsha with Aloe Vera Ksharasutra is significantly effective than Ligation of Arsha with Snuhi Kshira Ksharasutra in Arsha vyadhi.

## **F. Variables**

### **F.1. Independent Variables**

1. Aloe Vera Ksharasutra
2. Snuhi Kshira Ksharasutra

### **F.2. Dependent Variables**

1. Pain
2. Discharge
3. Irritation
4. Cutting
5. Healing

## **G. Duration of the study**

### **G.1. Total duration**

Total duration of the study was 24 to 30 months after approval of synopsis.

## **G.2. Duration of treatment and Follow ups**

Every patient was called and examined at every alternate day up to 9 days. Required parameters were noted in case record forms time to time.

### **3.3.2. Sample Size**

The prevalence rate of Arsha is approximately **40 %** in India, hence the sample size calculated according to **Cochran's Formula** was **93**. It was approximated it up to **110** and hence we have taken **110** patients in each group. Total sample size was **220**.

### **3.3.3. Methods of Selection of patients**

#### **A. Sampling Technique**

220 patients of Arsha were selected by Simple Randomized Sampling Technique irrespective of age, sex, religion, socioeconomic status, education etc.

#### **B. Grouping and Randomization**

Those 220 patients were further divided randomly in two equal groups named Group A and Group B respectively each group containing 110 patients.

**Group A (Trial group):** Aloe Vera Ksharasutra ligation

**Group B (Control group):** Snuhi Kshir Ksharsutra ligation

### **3.3.4. Pharmaceutical Study**

#### **A. Collection and Authentication of raw materials**

Aloe Vera was collected from botanical garden and other raw materials (Ghatak dravya) were purchased from market. They were authenticated in Dept. of Rasashastra of our college.

## **B. Method of Preparation of Ksharasutra**

Aloe Vera Ksharasutra and Snuhi Kshir Ksharsutra were prepared according to Ksharsutra method as mentioned in Sushruta Samhita (Su. Chi. 17/29–33). Ksharsutra preparation method was as follows–

- Two surgical linen threads of size 20 were spread throughout the length and breadth of two hangers of the specially designed cabinet known as Ksharsutra (K.S.) cabinet.
- The ultra violet lamp was kept in of the K.S. cabinet daily for 20–30 min. to maintain sterile atmosphere right from 1st day of coating.
- One thread was smeared with Snuhi Kshira uniformly and carefully with the help of clean gauze piece soaked on the Snuhi Kshira.
- Other thread was smeared with Aloe Vera pulp uniformly and carefully with the help of clean gauze piece soaked on the Aloe Vera pulp.
- After smearing both the threads on the hanger, the hangers were kept in two separate Ksharasutra cabinets for drying.
- All the outlets of the Ksharsutra cabinets were properly closed in order to prevent the entry of moisture in to the cabinet. The cabinets were closed and temperature was maintained 40<sup>0</sup>C leaving them overnight.
- **11** such coatings with Snuhi Kshira were done on one thread and **11** such coatings with Aloe Vera pulp were done on other thread.
- Next day after 12<sup>th</sup> coat of Snuhi Kshira / Aloe Vera pulp, the wet threads were passed through a heap of finely powdered Apapmarga Kshar immediately.
- After smearing all the threads with Apapmarga Kshar, the hangers were shaken gently allowing the excess particles of Kshara to fall down. The hangers were placed again in two seperate K.S. Cabinets to let Ksharasutra dry.
- This process was repeated till **7** coatings of Snuhi Kshira / Aloe Vera pulp, and Apamarga Kshara were achieved.
- Further, **3** coatings each were done with Snuhi Kshira / Aloe Vera pulp and the fine powder of Haridra on respective threads per the above said procedure.

- In this way total **21** coatings were applied on the threads to prepare Snuhi Kshira Ksharasutra and Aloe Vera Ksharasutra.
- The threads were cut of uniform length of 30–32 cm. for packing. Two sealed glass tubes of two types of Ksharasutra were put in separate cabinets and exposed to ultraviolet radiation.
- Finally, dark yellow and dark brown colored threads were formed respectively by snuhi and aloevera.

Table No. 3.1. Method of preparation of Aloe Vera Ksharasutra

<b>Sr. No.</b>	<b>Aloe vera Ksharasutra</b>	<b>No. of Coatings</b>
<b>1</b>	Aloe vera	11
<b>2</b>	Aloe vera + Apamarga Kshara	7
<b>3</b>	Aloe vera + Haridra Churna	3
<b>4</b>	<b>Total</b>	21

Table No. 3.2. Method of preparation of Snuhi Kshira Ksharasutra

<b>Sr. No.</b>	<b>Snuhi Kshira Ksharasutra</b>	<b>No. of Coatings</b>
<b>1</b>	Snuhi Kshira	11
<b>2</b>	Snuhi Kshira + Apamarga Kshara	7
<b>3</b>	Snuhi Kshira + Haridra Churna	3
<b>4</b>	<b>Total</b>	21

### **C. Standardization of Ksharasutra**

Both Aloe Vera and Snuhi Kshira Ksharasutras were Standardized from authentic analytical laboratory. Reports are attached in Annexures.

### 3.3.5. Method of Ligation of Ksharasutra

Classical reference of Method of ligation of Ksharasutra is found in Sushruta Samhita. (सू. चि. १७/२९-३२)

Table 3.3 Shows Ksharasutra Ligation details

Sr. No.	Head	Group A	Group B
1.	Group Type	Trial Group	Control Group
2.	Ksharasutra	Aloe Vera	Snuhi Kshira
3.	Follow up	Alternate Day	Alternate Day

Ksharasutra ligation done in both the groups with respective Ksharasutras. (i.e. Aloe Vera Ksharasutra was used in Trial Group patients, while Snuhi Kshira Ksharasutra was use in Control Group patients.) Kaharasutra ligation procedure was carried out in O.T. under all aseptic precautions as per standard operative methods in three phases, as follows.

#### B.1. Pre-operative

- Written consent for operation was taken.
- Perianal hair shaving and cleaning of the part was done with antiseptic solution 1 day earlier.
- Patient was advised to take light food just first night before operation.
- Dulcolax 10 mg was administered orally on the same night.
- Bowel evacuation was done 2 hours prior to surgery with Sodium Phosphate Enema.
- Patient was kept 6 to 8 hours NBM for spinal anesthesia, whereas 2 to 4 hours for local anesthesia before procedure.
- Sensitivity of Inj. Xylocaine 2% was tested in each patient before procedure.
- Inj. TT 0.5 cc was given IM before surgery.

(Ref. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296345/>)

## B.2. Operative procedure

- The patient was made to sleep in lithotomy position on OT table.
- Operative area was painted with antiseptic solution Betadine liquid and was draped.
- According to the fitness of patient the local or spinal anesthesia was planned and given.
- Positions of piles masses were assessed.
- **Catch hold:** The pile mass was held with the help of pile–holding forceps.
- **Trans–fixation:** Each pile mass was transfixed by passing the curved round body needle mounted with Ksharasutra at its base.
- **Ligation:** After trans–fixation of Ksharasutra, the pile mass was ligated anteriorly and posteriorly with adequate knots.
- After ligation again, the operative site was cleaned by the Mixture of Betadine and H<sub>2</sub>O<sub>2</sub> and then by plane Betadine liquid gauze and was closed by dressing.

(Ref. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296345/>)

## B.3. Post–operative

- Patient was allowed to sip liquids after 4 to 6 hours till 48 hours later.
- There after semisolid food was advised for further 48 hours. Then after patient was shifted to normal diet with less Spicy and Chilli long ever.
- Patient was advised to apply Xylocaine jelly and Antiseptic cream after Sitz bath of Triphala Kwatha.

(Ref. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3296345/>)

### 3.3.6. Selection Criteria

#### A. Inclusion Criteria

- Patients of age group 18 to 65 years and both sexes irrespective of religion, socioeconomic status, education etc.
- Patients of External, Extero–Internal and Internal piles of last 2<sup>nd</sup> degree onwards was selected.
- Patients who were fit for surgery.
- Patients who were ready to give written informed consent.



## **B. Exclusion Criteria**

- Age less than 18 years and more than 65 years.
- Patients of 1<sup>st</sup> degree and initial 2<sup>nd</sup> degree of piles (Arsha).
- Pregnancy
- Malignancy
- Rectal prolapse
- Hemorrhoids associated with Fissure and Fistula-in-Ano.
- Hepatitis B, Tuberculoses, HIV & VDRL positive cases.
- Uncontrolled HTN, DM, Heart disease.

(Ref. <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=CTRI/2015/08/006069>)

## **C. Withdrawal Criteria**

- Intolerance of therapy.
- Unwillingness to continue with the treatment.
- Patients with irregular follow-up.
- Development of any condition requiring any other specific management.

## **D. Diagnostic Criteria**

The patient will be diagnosed on the basis of Ayurvedic as well as modern symptomatology / examinations as per follows–

- History
- Inspection
- Palpation / Digital per rectal examination
- Proctoscopy / Sigmoidoscopy

## **E. Investigations (Only before treatment)**

- 1. Haemogram:** TLC, DLC, Hb%, ESR, BT, CT
- 2. Blood Sugar:** FBS & PPBS
- 3. Blood group**
- 4. KFT:** Blood Urea, Serum Creatinine

5. LFT: Serum Bilirubin, SGPT, SGOT
6. VDRL, HIV, HBsAg
7. X– Ray chest PA view
8. ECG (if required)

### 3.3.6. Observation table / Follow Up table

Observations found at every follow up were noted down in observation tables.

Table 3.4 Shows Observation Table for Subjective parameters

Sr. No.	Subjective Parameter	Follow Up (Day)				
		D1	D3	D5	D7	D9
1	Pain					
2	Discharge					
3	Irritation					
4	Cutting					
5	Healing*					

(\*Healing was assessed after cutting of pile mass.)

### 3.3.7. Assessment Criteria (Gradation of Subjective parameters)

Table 3.5 Shows Gradation of Subjective parameters

Sr. No.	Symptom	Description	Grade
1	Pain	No pain	0
		Dull pain and no requirement of medicine	1
		Pain requires oral medication	2
		Unbearable pain requires injectable drug	3
2	Discharge	No discharge/bleeding	0
		Discharge/Bleeding along with defecation only	1
		Discharge/Bleeding in the forms of drops after defecation also	2
		Continuous discharge/bleeding	3
3	Irritation	No irritation	0
		Irritation only during defecation	1
		Irritation on movements	2
		Continuous, unbearable irritation	3
4	Cutting	Complete removal of pile mass	0
		Pile mass partially cut	1

		Pile mass not cut	2
<b>5</b>	<b>Healing</b>	Completely healed wound	0
		Partially healed wound	1
		Unhealed wound	2

### 3.3.8. Overall Assessment Criteria

#### A. Effect of therapy

It was decided in the form of percentage as per the table given below.

Table 3.6 Shows Effect of Therapy

<b>Sr. No.</b>	<b>Improvement</b>	<b>Criteria</b>
<b>1</b>	Cured	100%
<b>2</b>	Marked	75 % to 99 %
<b>3</b>	Moderate	50 % to 74 %
<b>4</b>	Mild	25 % to 49 %
<b>5</b>	Poor	00 % to 24 %

#### B. Statistical analysis

All parameters were analyzed statistically at 5 % level of significance using –

- Wilcoxon Signed Ranks test (within Group A and within Group B)
- Mann–Whitney test (in between Group A and B)

## 4. ANALYSIS AND INTERPRETATION

### 4.1. ANALYSIS (OBSERVATIONS AND RESULTS)

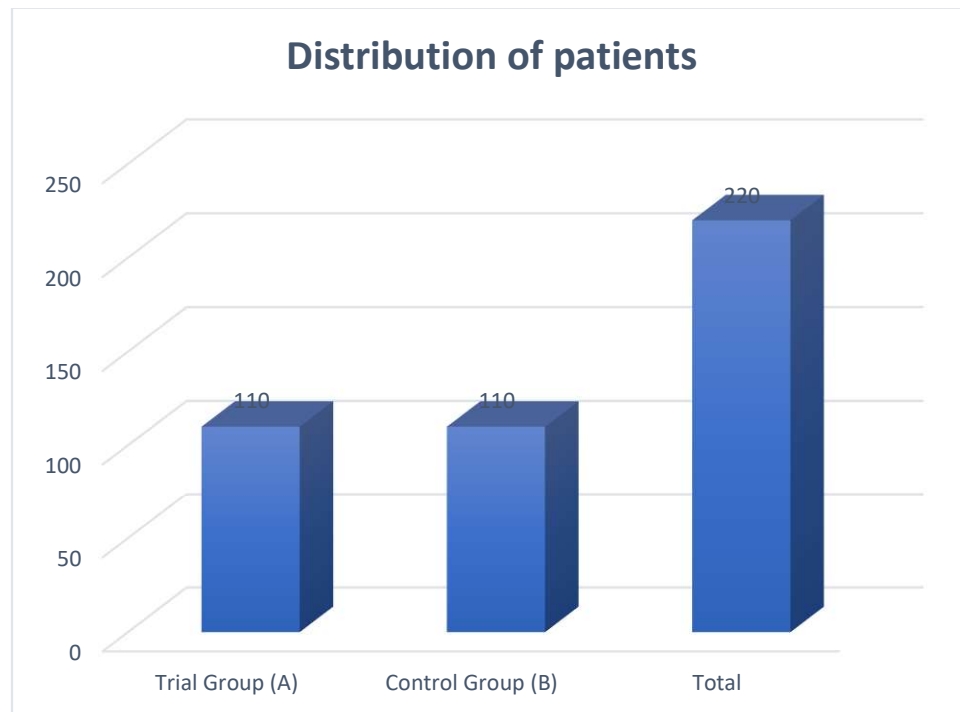
#### 4.1. General Observations

##### A) Distribution of patients

Table 4.1 Shows distribution of patients in groups

Group	No of Patients
<b>Trial Group (A)</b>	110
<b>Control Group (B)</b>	110
<b>Total</b>	<b>220</b>

Figure 4.1 Shows distribution of patients in groups

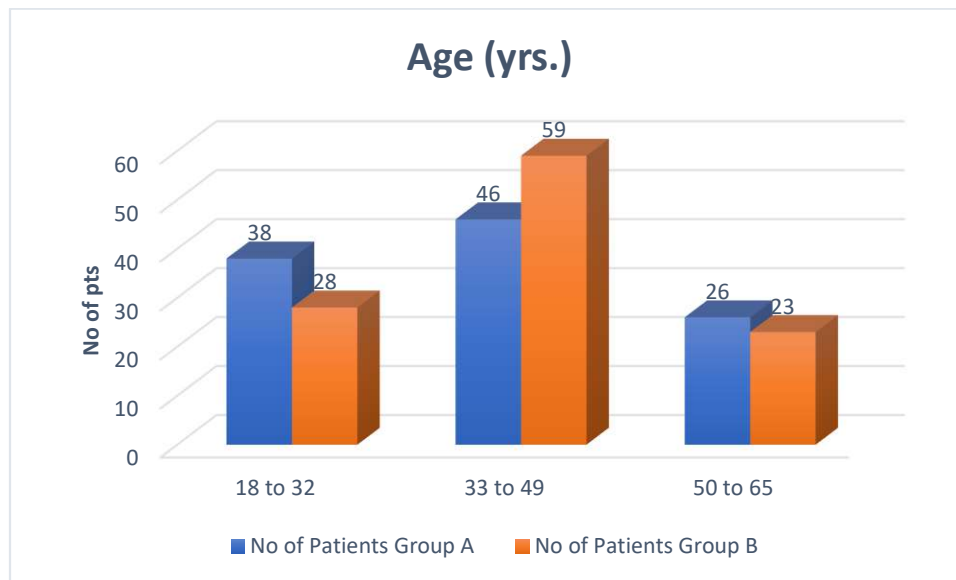


## B) Age

Table 4.2 Shows Age wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Age (yrs.)	Group A	Group B		Group A	Group B	Total
1	18 to 32	38	28	66	34.55	25.45	30
2	33 to 49	46	59	105	41.82	53.64	47.73
3	50 to 65	26	23	49	23.64	20.91	22.27
4	<b>Total</b>	<b>110</b>	<b>110</b>	<b>220</b>	<b>100</b>	<b>100</b>	<b>100</b>

Figure 4.2 Shows Age wise distributions in both groups

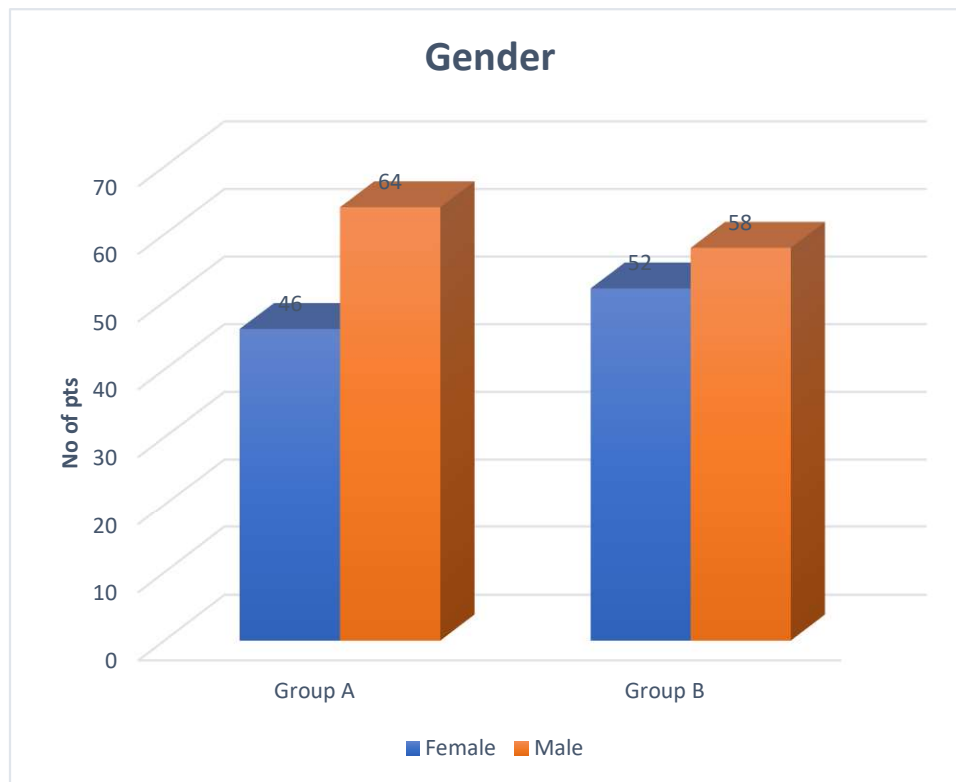


### C) Gender

Table 4.3 Shows Gender wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Gender	Group A	Group B		Group A	Group B	Total
1	Female	46	52	98	41.82	47.27	44.55
2	Male	64	58	122	58.18	52.73	55.45
3	Total	110	110	220	100	100	100

Figure 4.3 Shows Gender wise distributions in both groups

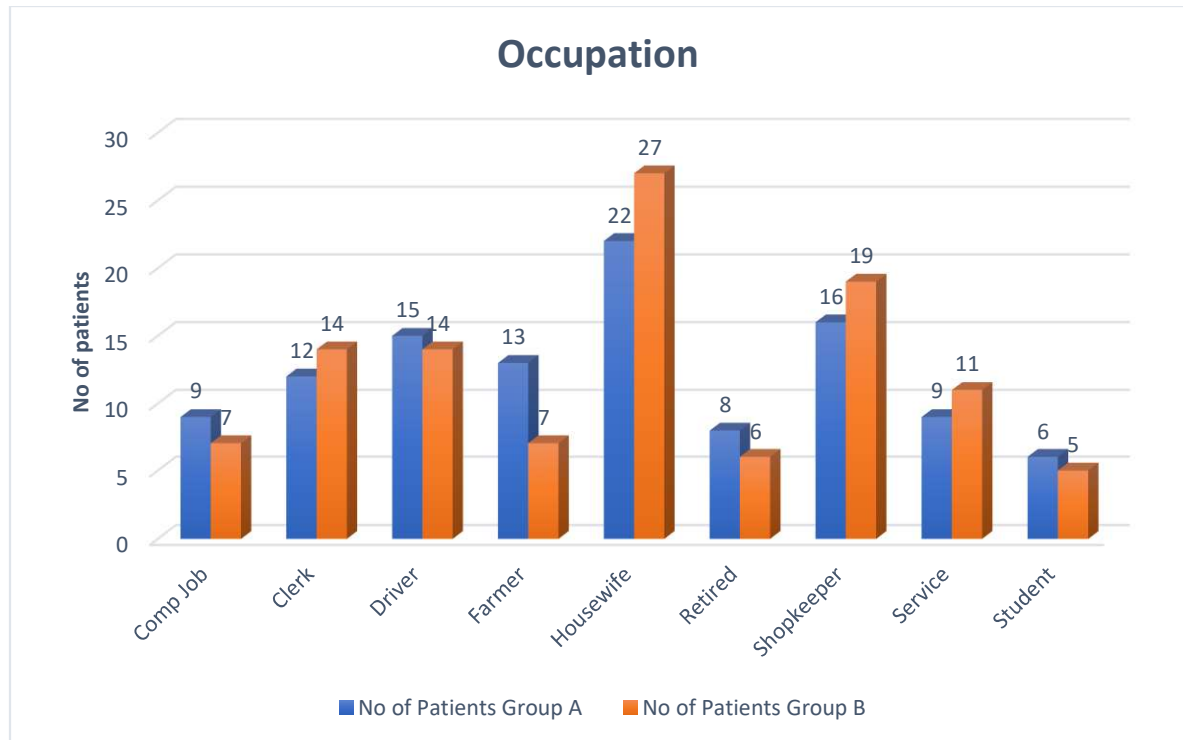


## D) Occupation

Table 4.4 Shows Occupation wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Occupation	Group A	Group B		Group A	Group B	Total
1	Computer Job	9	7	16	8.182	6.364	7.273
2	Clerk	12	14	26	10.91	12.73	11.82
3	Driver	15	14	29	13.64	12.73	13.18
4	Farmer	13	7	20	11.82	6.364	9.091
5	Housewife	22	27	49	20	24.55	22.27
6	Retired	8	6	14	7.273	5.455	6.364
7	Shopkeeper	16	19	35	14.55	17.27	15.91
8	Service	9	11	20	8.182	10	9.091
9	Student	6	5	11	5.455	4.545	5
10	Total	110	110	220	100	100	100

Figure 4.4 Shows Occupation wise distributions in both groups

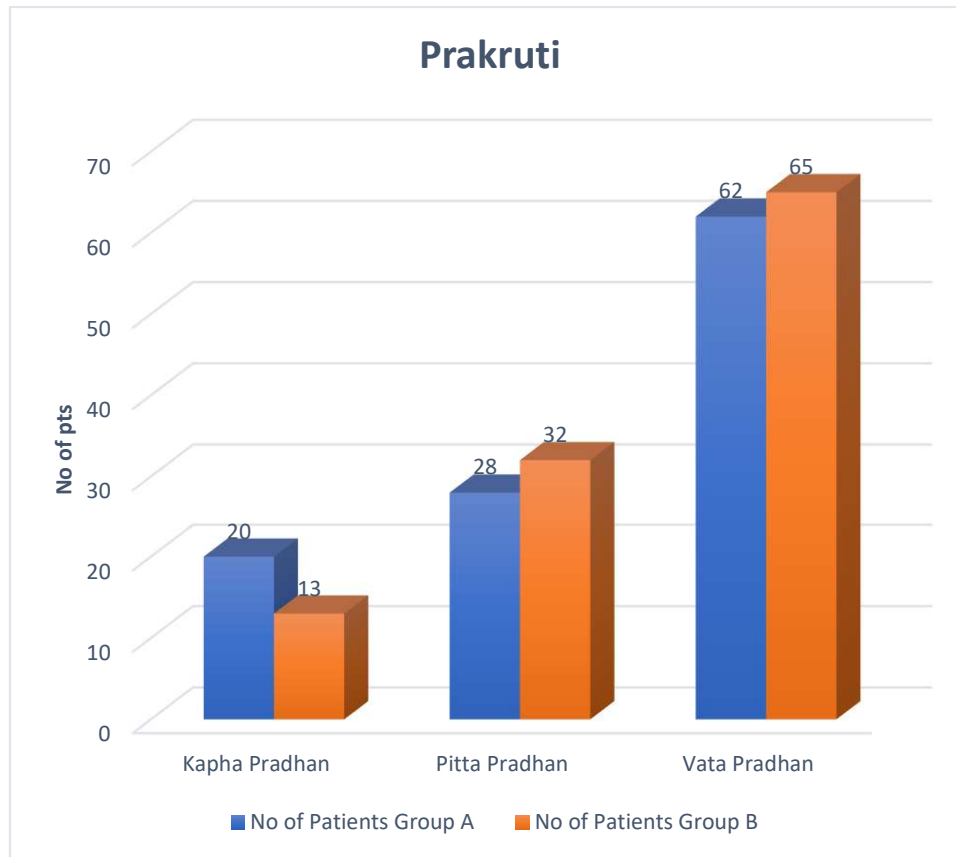


## E) Pradhan Prakruti

Table 4.5 Shows Pradhan Prakruti wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Pradhan Prakruti	Group A	Group B		Group A	Group B	Total
1	<b>Kapha Pradhan</b>	20	13	33	18.18	11.82	15
2	<b>Pitta Pradhan</b>	28	32	60	25.45	29.09	27.27
3	<b>Vata Pradhan</b>	62	65	127	56.36	59.09	57.73
4	<b>Total</b>	<b>110</b>	<b>110</b>	<b>220</b>	<b>100</b>	<b>100</b>	<b>100</b>

Figure 4.5 Shows Pradhan Prakruti wise distributions in both groups



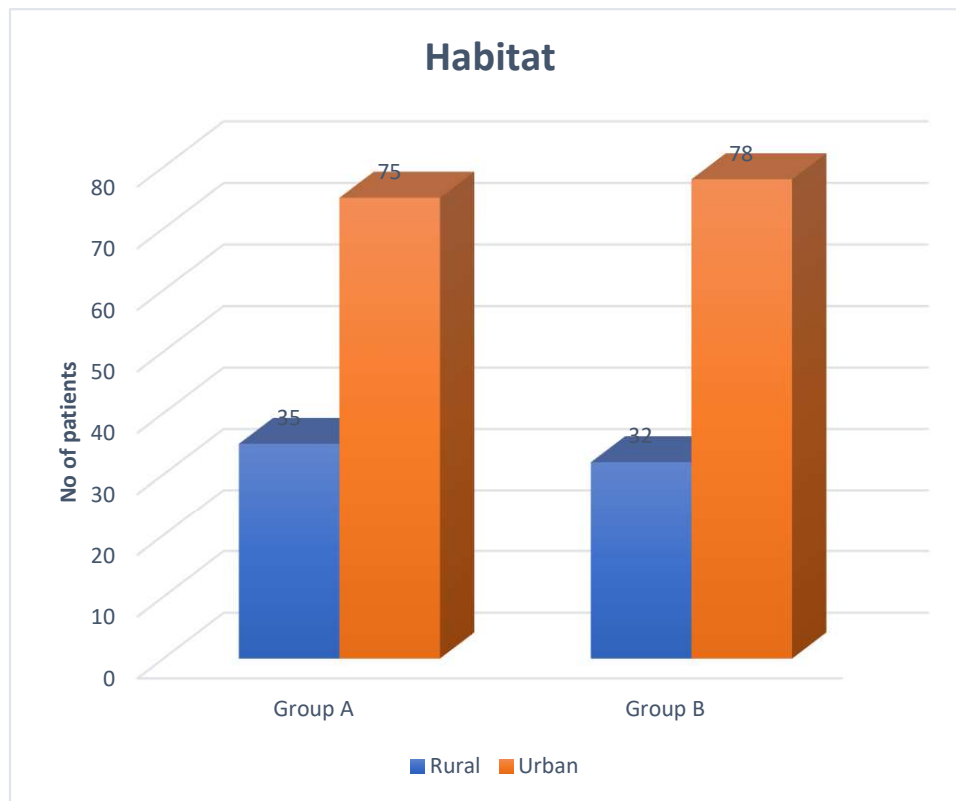


## F) Habitat

Table 4.6 Shows Habitat wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Habitat	Group A	Group B		Group A	Group B	Total
1	Rural	35	32	67	31.82	29.09	30.45
2	Urban	75	78	153	68.18	70.91	69.55
3	Total	110	110	220	100	100	100

Figure 4.6 Shows Habitat wise distributions in both groups

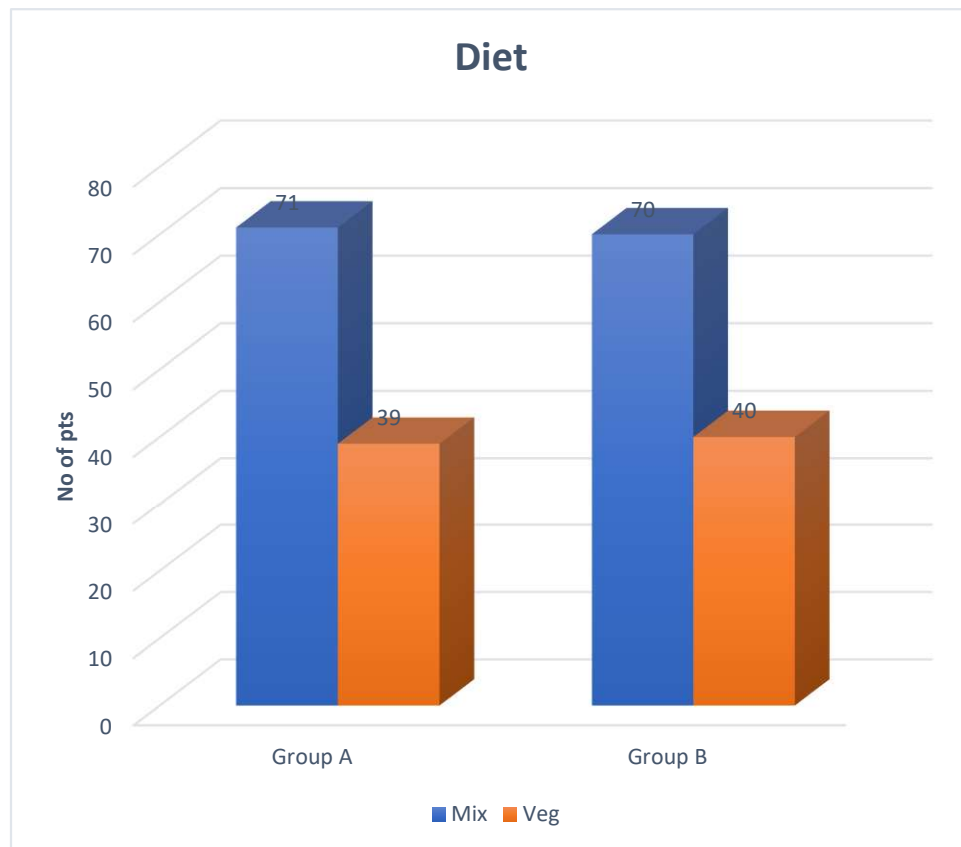


## G) Diet

Table 4.7 Shows Diet wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Diet	Group A	Group B		Group A	Group B	Total
1	Mix	71	70	141	64.55	63.64	64.09
2	Veg	39	40	79	35.45	36.36	35.91
3	Total	110	110	220	100	100	100

Figure 4.7 Shows Diet wise distributions in both groups

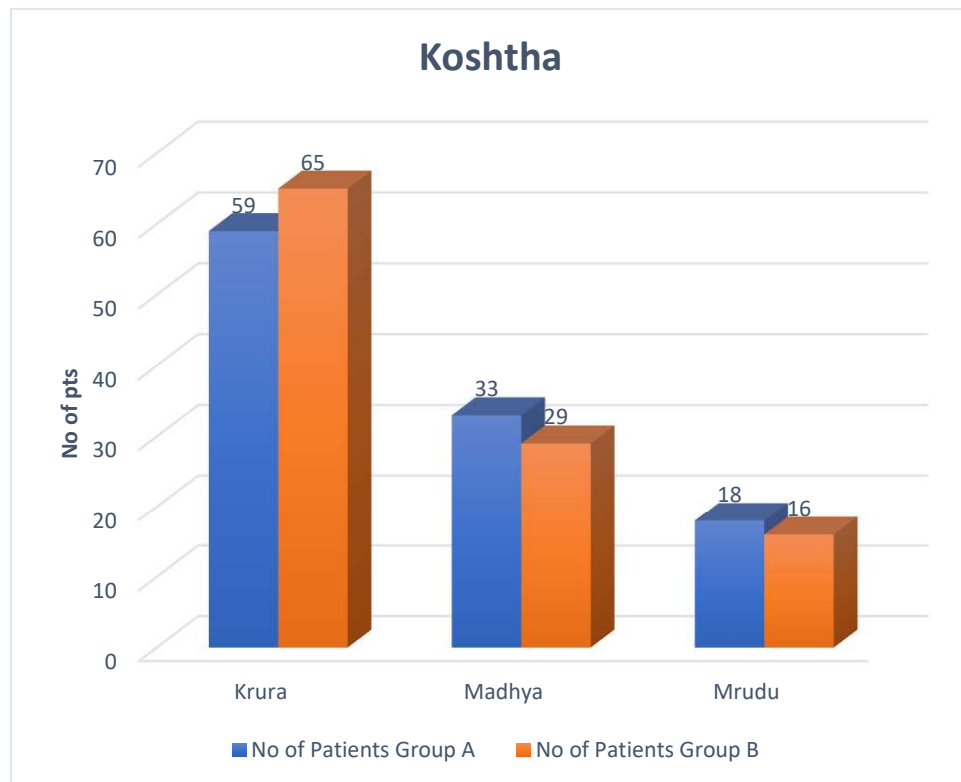


## H) Koshtha

Table 4.8 Shows Koshtha wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Koshtha	Group A	Group B		Group A	Group B	Total
1	Krura	59	65	124	53.64	59.09	56.36
2	Madhya	33	29	62	30	26.36	28.18
3	Mrudu	18	16	34	16.36	14.55	15.45
4	Total	110	110	220	100	100	100

Figure 4.8 Shows Koshtha wise distributions in both groups

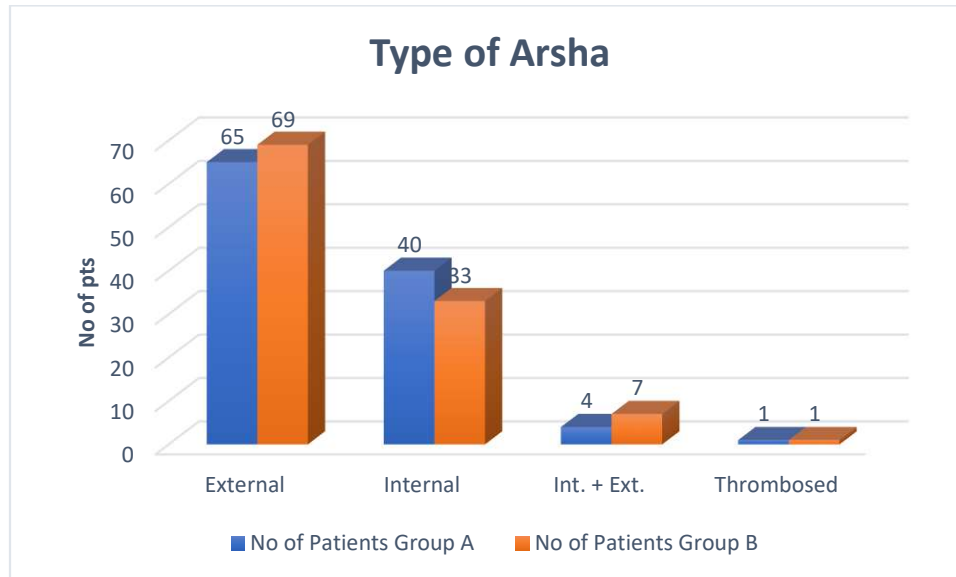


## D) Type of Arsha

Table 4.9 Shows Type of Arsha wise distribution in both groups

Sr. No.	No of Patients			Total	Percentage		
	Type	Group A	Group B		Group A	Group B	Total
1	External	65	69	134	59.09	62.73	60.91
2	Internal	40	33	73	36.36	30	33.18
3	Int. + Ext.	4	7	11	3.636	6.364	5
4	Thrombosed	1	1	2	0.909	0.909	0.909
5	<b>Total</b>	<b>110</b>	<b>110</b>	<b>220</b>	<b>100</b>	<b>100</b>	<b>100</b>

Figure 4.9 Shows Type of Arsha wise distributions in both groups



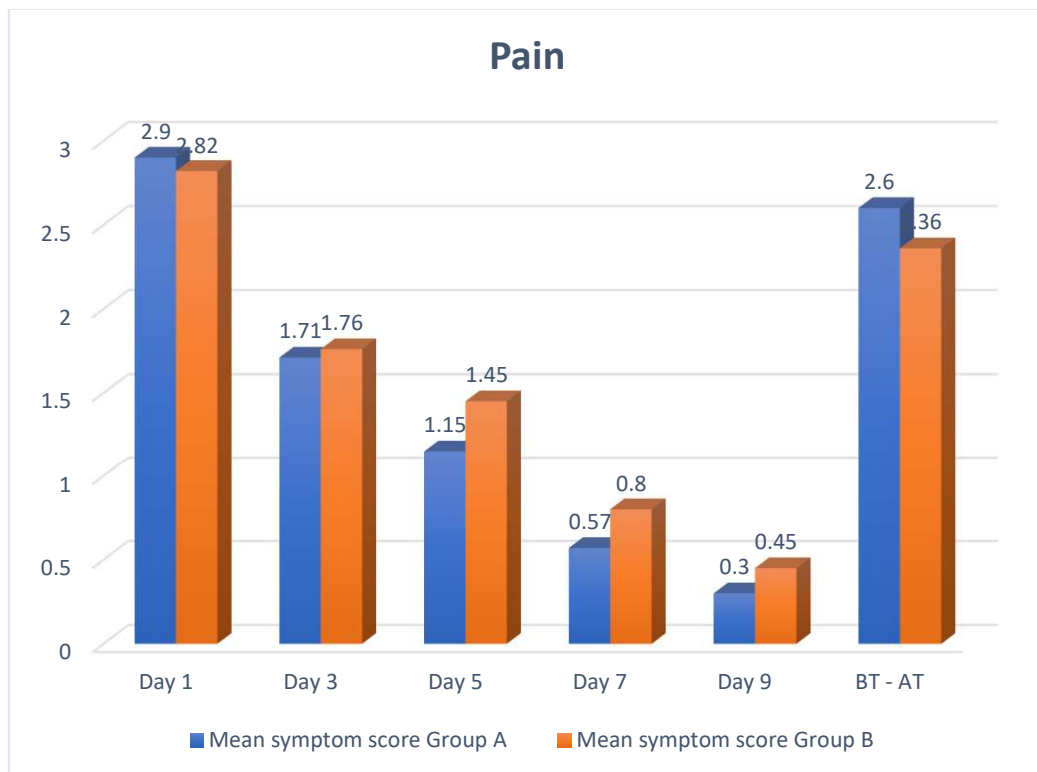
#### 4.1.2. Changes in Subjective parameters before and after treatment

##### A) Changes in Pain (BT and AT) in Group A and Group B

Table 4.10 Shows Changes in Pain in Group A and Group B

Follow Up	Mean symptom score	
	Group A	Group B
Day 1	2.9	2.82
Day 3	1.71	1.76
Day 5	1.15	1.45
Day 7	0.57	0.8
Day 9	0.3	0.45
BT – AT	2.6	2.36

Figure 4.10 Shows Changes in Pain in Group A and Group B



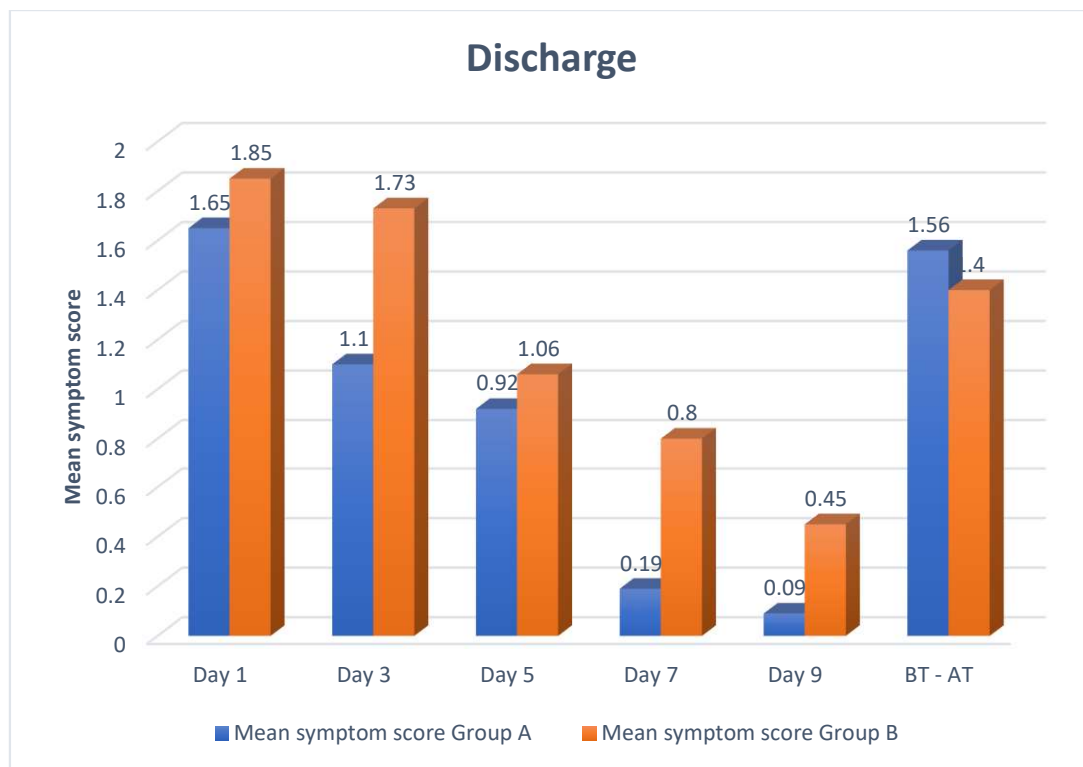
It was observed that, Pain has decreased more in Group A than in Group B.

## B) Changes in Discharge (BT and AT) in Group A and Group B

Table 4.11 Shows Changes in Discharge in Group A and Group B

Follow Up	Mean symptom score	
	Group A	Group B
Day 1	1.65	1.85
Day 3	1.1	1.73
Day 5	0.92	1.06
Day 7	0.19	0.8
Day 9	0.09	0.45
BT – AT	1.56	1.4

Figure 4.11 Shows Changes in Discharge in Group A and Group B



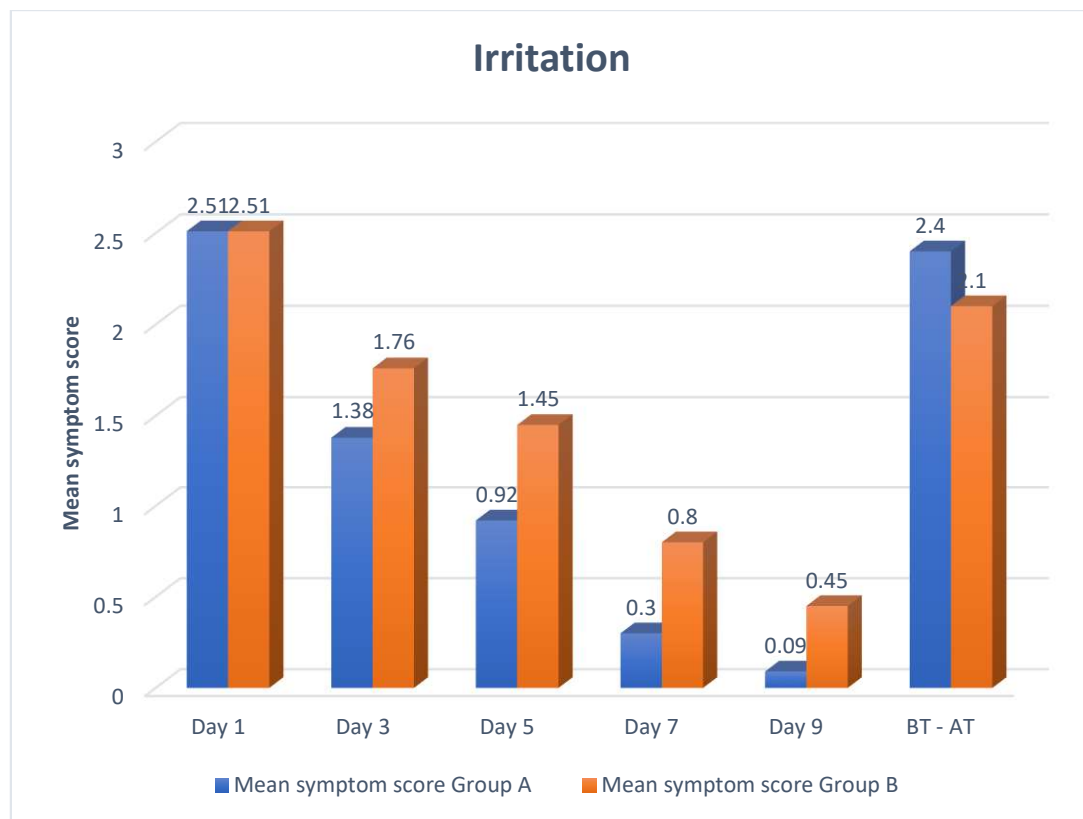
It was observed that, Discharge has decreased more in Group A than in Group B.

### C) Changes in Irritation (BT and AT) in Group A and Group B

Table 4.12 Shows Changes in Irritation in Group A and Group B

Follow Up	Mean symptom score	
	Group A	Group B
Day 1	2.51	2.51
Day 3	1.38	1.76
Day 5	0.92	1.45
Day 7	0.3	0.8
Day 9	0.09	0.45
BT – AT	2.4	2.1

Figure 4.12 Shows Changes in Irritation in Group A and Group B



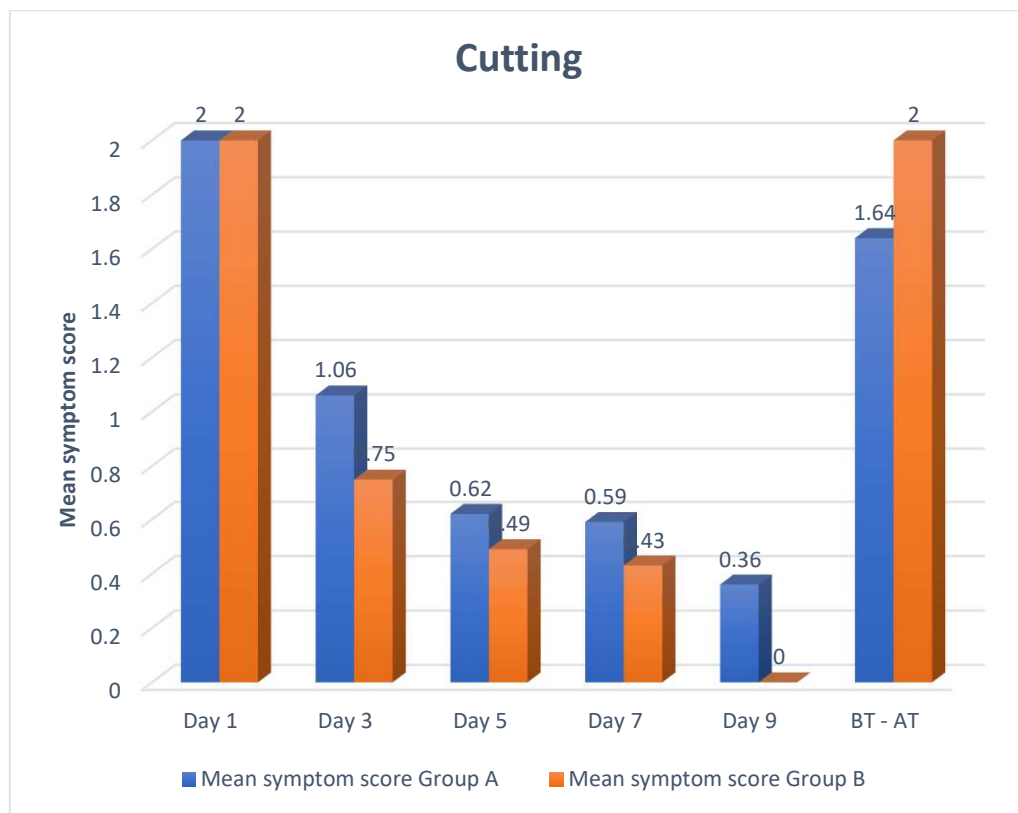
It was observed that, Irritation has decreased more in Group A than in Group B.

#### D) Changes in Cutting (BT and AT) in Group A and Group B

Table 4.13 Shows Changes in mean score of Cutting in Group A and Group B

Follow Up	Mean symptom score	
	Group A	Group B
Day 1	2	2
Day 3	1.06	0.75
Day 5	0.62	0.49
Day 7	0.59	0.43
Day 9	0.36	0
BT – AT	1.64	2

Figure 4.13 Shows Changes in mean score of Cutting in Group A and Group B



It was observed that, Cutting was more effective in Group B than in Group A.

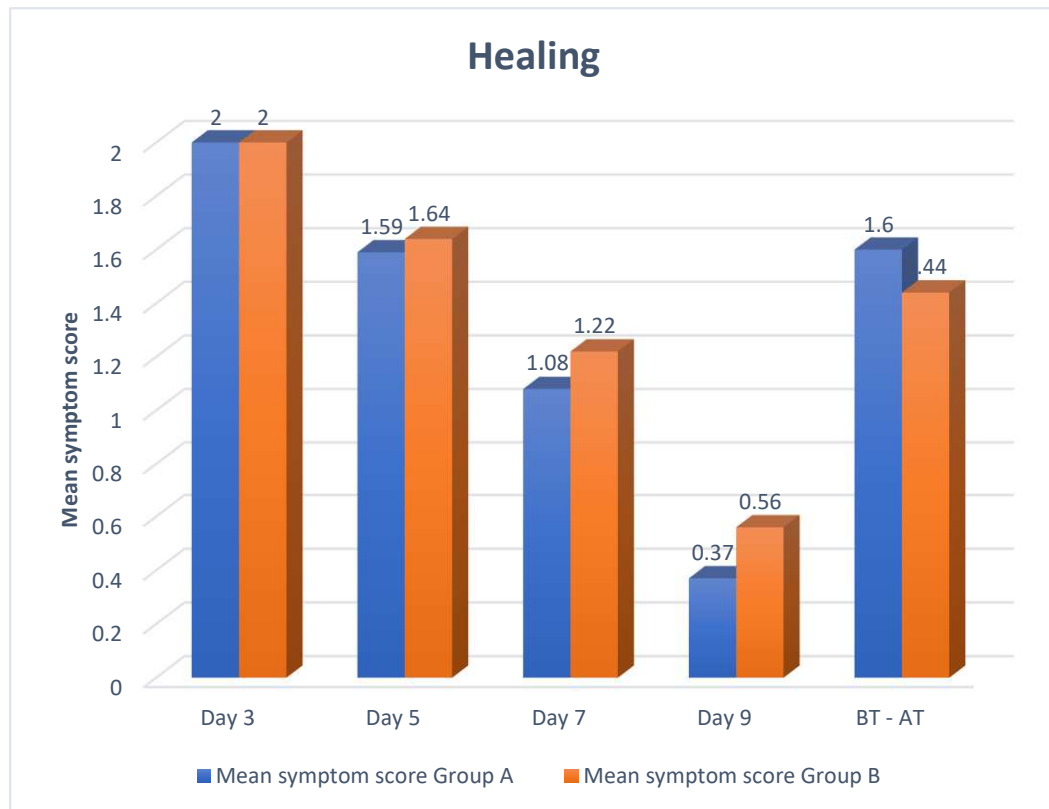


### E) Changes in Healing (BT and AT) in Group A and Group B

Table 4.14 Shows Changes in Healing in Group A and Group B

Follow Up	Mean symptom score	
	Group A	Group B
Day 3	2	2
Day 5	1.59	1.64
Day 7	1.08	1.22
Day 9	0.37	0.56
BT – AT	1.6	1.44

Figure 4.14 Shows Changes in Healing in Group A and Group B



It was observed that, Healing was more effective in Group A than in Group B.

### 4.1.3. Statistical Analysis within Group A and Group B (By Wilcoxon Signed Ranks Test)

#### A) Pain

Table 4.15 Wilcoxon Signed Ranks Test within the Group A and Group B

Group	BT/AT	N	Mean	SD	W	P
Group A	BT	110	2.900	0.301	6105	<0.0001
	AT	110	0.300	0.460		
Group B	BT	110	2.818	0.387	6105	<0.0001
	AT	110	0.454	0.500		

#### Group A

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Pain symptom. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective to reduce Pain in Arsha (Hemorrhoids) after Ksharasutra ligation.

#### Group B

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Pain symptom. Hence it is concluded that Snuhi Kshira Ksharasutra is significantly effective to reduce Pain in Arsha (Hemorrhoids) after Ksharasutra ligation.

#### B) Discharge

Table 4.16 Wilcoxon Signed Ranks Test within the Group A and Group B

Group	BT/AT	N	Mean	SD	W	P
Group A	BT	110	1.655	0.477	6105	<0.0001
	AT	110	0.092	0.288		
Group B	BT	110	1.855	0.345	5886	<0.0001
	AT	110	0.454	0.500		

### Group A

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Discharge symptom. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective to reduce Discharge in Arsha (Hemorrhoids) after Ksharasutra ligation.

### Group B

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Discharge symptom. Hence it is concluded that Snuhi Kshira Ksharasutra is significantly effective to reduce Discharge in Arsha (Hemorrhoids) after Ksharasutra ligation.

### C) Irritation

Table 4.17 Wilcoxon Signed Ranks Test within the Group A and Group B

Group	BT/AT	N	Mean	SD	W	P
Group A	BT	110	2.509	0.502	6105	<0.0001
	AT	110	0.090	0.288		
Group B	BT	110	2.509	0.502	6105	<0.0001
	AT	110	0.454	0.500		

### Group A

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Irritation symptom. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective to reduce Irritation in Arsha (Hemorrhoids) after Ksharasutra ligation.

### Group B

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Irritation symptom. Hence it is concluded that Snuhi Kshira

Ksharasutra is significantly effective to reduce Irritation in Arsha (Hemorrhoids) after Ksharasutra ligation.

#### D) Cutting

Table 4.18 Wilcoxon Signed Ranks Test within the Group A and Group B

Group	BT/AT	N	Mean	SD	W	P
Group A	BT	110	2.000	0.095	6105	<0.0001
	AT	110	0.109	0.313		
Group B	BT	110	2.000	0.095	6105	<0.0001
	AT	110	0.000	0.000		

#### Group A

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Cutting symptom. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective to cut the Arsha (Hemorrhoids) after Ksharasutra ligation.

#### Group B

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Cutting symptom. Hence it is concluded that Snuhi Kshira Ksharasutra is significantly effective to cut the Arsha (Hemorrhoids) after Ksharasutra ligation.

#### E) Healing

Table 4.19 Wilcoxon Signed Ranks Test within the Group A and Group B

Group	BT/AT	N	Mean	SD	W	P
Group A	BT	110	1.837	0.371	3081	<0.0001
	AT	110	0.367	0.632		
Group B	BT	110	2.000	0.095	4371	<0.0001
	AT	110	0.536	0.748		

### **Group A**

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Healing symptom. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective to heal wound on cutting the Arsha (Hemorrhoids) after Ksharasutra ligation.

### **Group B**

As value of p is far less than 0.05 extremely significant difference was observed between mean of BT and AT score in Healing symptom. Hence it is concluded that Snuhi Kshira Ksharasutra is significantly effective to heal wound on cutting the Arsha (Hemorrhoids) after Ksharasutra ligation.

**4.1.4. Statistical Analysis in between the Group A and Group B (By Mann Whitney's Test)**

**A) Pain**

Table 4.20 Mann Whitney's Test in between the Group A and Group B

<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>U</b>	<b>P</b>
<b>Group A</b>	<b>110</b>	2.600	0.510	4600	0.0018
<b>Group B</b>	<b>110</b>	2.364	0.483		

As value of p is less than 0.05, significant difference was observed between the mean of difference of Group A and Group B in Pain symptom. Mean score of Group A is more than that of Group B. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective than Snuhi Kshira Ksharasutra to reduce Pain in Arsha (Hemorrhoids) after Ksharasutra ligation.

**B) Discharge**

Table 4.21 Mann Whitney's Test in between the Group A and Group B

<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>U</b>	<b>P</b>
<b>Group A</b>	<b>110</b>	1.564	0.498	5122	0.0460
<b>Group B</b>	<b>110</b>	1.400	0.528		

As value of p is less than 0.05, significant difference was observed between the mean of difference of Group A and Group B in Pain symptom. Mean score of Group A is more than that of Group B. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective than Snuhi Kshira Ksharasutra to reduce Discharge in Arsha (Hemorrhoids) after Ksharasutra ligation.

### C) Irritation

Table 4.22 Mann Whitney's Test in between the Group A and Group B

<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>U</b>	<b>P</b>
<b>Group A</b>	<b>110</b>	2.418	0.548	4324	0.0002
<b>Group B</b>	<b>110</b>	2.055	0.661		

As value of p is less than 0.05, significant difference was observed between the mean of difference of Group A and Group B in Pain symptom. Mean score of Group A is more than that of Group B. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective than Snuhi Kshira Ksharasutra to reduce Irritation in Arsha (Hemorrhoids) after Ksharasutra ligation.

### D) Cutting

Table 4.23 Mann Whitney's Test in between the Group A and Group B

<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>U</b>	<b>P</b>
<b>Group A</b>	<b>110</b>	1.891	0.313	5145	0.0488
<b>Group B</b>	<b>110</b>	1.991	0.095		

As value of p is less than 0.05, significant difference was observed between the mean of difference of Group A and Group B in Pain symptom. Mean score of Group B is more than that of Group A. Hence it is concluded that Snuhi Kshira Ksharasutra is significantly effective than Aloe Vera Ksharasutra to cut the Arsha (Hemorrhoids) after Ksharasutra ligation.

### E) Healing

Table 4.24 Mann Whitney's Test in between the Group A and Group B

<b>Group</b>	<b>N</b>	<b>Mean</b>	<b>SD</b>	<b>U</b>	<b>P</b>
<b>Group A</b>	<b>110</b>	1.469	0.814	5153	0.0497
<b>Group B</b>	<b>110</b>	1.436	0.748		

As value of p is less than 0.05, significant difference was observed between the mean of difference of Group A and Group B in Pain symptom. Mean score of Group A is more than that of Group B. Hence it is concluded that Aloe Vera Ksharasutra is significantly effective than Snuhi Kshira Ksharasutra to heal wound on cutting the Arsha (Hemorrhoids) after Ksharasutra ligation.



#### 4.1.5. Effect of therapy

##### A. Effect of therapy according to % Relief in Patients

Table 4.25 Relieved score and % Relief in Patients of both groups

Pt. No.	Group A				Pt. No.	Group B			
	B	A	Relieved	% Relief		B	A	Relieved	% Relief
1	11	0	11	100	1	9	0	9	100
2	9	0	9	100	2	12	4	8	66.67
3	12	0	12	100	3	11	4	7	63.64
4	11	1	10	90.91	4	10	0	10	100
5	10	0	10	100	5	11	0	11	100
6	11	2	9	81.82	6	12	5	7	58.33
7	10	0	10	100	7	10	0	10	100
8	12	1	11	91.67	8	12	3	9	75
9	11	0	11	100	9	12	4	8	66.67
10	12	3	9	75	10	10	0	10	100
11	10	0	10	100	11	12	5	7	58.33
12	9	0	9	100	12	12	0	12	100
13	11	0	11	100	13	11	4	7	63.64
14	11	0	11	100	14	12	0	12	100
15	11	4	7	63.64	15	11	5	6	54.55
16	10	0	10	100	16	12	3	9	75
17	9	0	9	100	17	12	4	8	66.67
18	11	1	10	90.91	18	11	3	8	72.73
19	11	0	11	100	19	11	3	8	72.73
20	12	2	10	83.33	20	10	0	10	100
21	10	0	10	100	21	11	4	7	63.64
22	12	0	12	100	22	12	4	8	66.67
23	11	1	10	90.91	23	9	0	9	100
24	10	3	7	70	24	12	0	12	100
25	11	0	11	100	25	11	0	11	100
26	11	0	11	100	26	12	3	9	75
27	12	0	12	100	27	12	4	8	66.67
28	10	0	10	100	28	11	5	6	54.55
29	10	2	8	80	29	12	1	11	91.67
30	12	0	12	100	30	10	0	10	100
31	10	0	10	100	31	12	0	12	100
32	10	0	10	100	32	9	0	9	100
33	12	0	12	100	33	12	0	12	100
34	11	1	10	90.91	34	11	4	7	63.64
35	11	1	10	90.91	35	9	0	9	100
36	10	4	6	60	36	12	5	7	58.33
37	10	0	10	100	37	11	3	8	72.73

<b>38</b>	11	0	11	100	<b>38</b>	12	0	12	100
<b>39</b>	10	1	9	90	<b>39</b>	12	0	12	100
<b>40</b>	10	2	8	80	<b>40</b>	11	4	7	63.64
<b>41</b>	12	0	12	100	<b>41</b>	12	1	11	91.67
<b>42</b>	10	1	9	90	<b>42</b>	11	5	6	54.55
<b>43</b>	12	0	12	100	<b>43</b>	12	0	12	100
<b>44</b>	10	3	7	70	<b>44</b>	11	5	6	54.55
<b>45</b>	12	0	12	100	<b>45</b>	12	3	9	75
<b>46</b>	11	2	9	81.82	<b>46</b>	11	5	6	54.55
<b>47</b>	12	0	12	100	<b>47</b>	12	0	12	100
<b>48</b>	11	0	11	100	<b>48</b>	12	4	8	66.67
<b>49</b>	11	0	11	100	<b>49</b>	9	0	9	100
<b>50</b>	10	0	10	100	<b>50</b>	11	4	7	63.64
<b>51</b>	12	1	11	91.67	<b>51</b>	10	0	10	100
<b>52</b>	11	0	11	100	<b>52</b>	12	5	7	58.33
<b>53</b>	10	2	8	80	<b>53</b>	11	0	11	100
<b>54</b>	11	0	11	100	<b>54</b>	12	4	8	66.67
<b>55</b>	10	4	6	60	<b>55</b>	11	0	11	100
<b>56</b>	11	0	11	100	<b>56</b>	12	5	7	58.33
<b>57</b>	11	0	11	100	<b>57</b>	11	0	11	100
<b>58</b>	9	0	9	100	<b>58</b>	11	0	11	100
<b>59</b>	10	2	8	80	<b>59</b>	9	0	9	100
<b>60</b>	11	0	11	100	<b>60</b>	12	1	11	91.67
<b>61</b>	11	4	7	63.64	<b>61</b>	12	4	8	66.67
<b>62</b>	12	0	12	100	<b>62</b>	11	3	8	72.73
<b>63</b>	9	0	9	100	<b>63</b>	12	0	12	100
<b>64</b>	10	1	9	90	<b>64</b>	11	4	7	63.64
<b>65</b>	12	0	12	100	<b>65</b>	12	0	12	100
<b>66</b>	10	0	10	100	<b>66</b>	12	4	8	66.67
<b>67</b>	11	0	11	100	<b>67</b>	10	0	10	100
<b>68</b>	11	0	11	100	<b>68</b>	12	5	7	58.33
<b>69</b>	11	0	11	100	<b>69</b>	10	0	10	100
<b>70</b>	11	0	11	100	<b>70</b>	12	0	12	100
<b>71</b>	11	4	7	63.64	<b>71</b>	12	4	8	66.67
<b>72</b>	9	2	7	77.78	<b>72</b>	11	1	10	90.91
<b>73</b>	12	0	12	100	<b>73</b>	9	0	9	100
<b>74</b>	7	2	5	71.43	<b>74</b>	11	0	11	100
<b>75</b>	10	0	10	100	<b>75</b>	12	5	7	58.33
<b>76</b>	12	3	9	75	<b>76</b>	10	0	10	100
<b>77</b>	12	0	12	100	<b>77</b>	11	0	11	100
<b>78</b>	11	3	8	72.73	<b>78</b>	11	4	7	63.64
<b>79</b>	10	4	6	60	<b>79</b>	12	0	12	100
<b>80</b>	9	2	7	77.78	<b>80</b>	12	0	12	100
<b>81</b>	12	0	12	100	<b>81</b>	11	5	6	54.55
<b>82</b>	11	0	11	100	<b>82</b>	12	4	8	66.67

<b>83</b>	11	2	9	81.82	<b>83</b>	12	0	12	100
<b>84</b>	10	2	8	80	<b>84</b>	9	0	9	100
<b>85</b>	9	0	9	100	<b>85</b>	10	0	10	100
<b>86</b>	11	0	11	100	<b>86</b>	11	4	7	63.64
<b>87</b>	11	0	11	100	<b>87</b>	12	0	12	100
<b>88</b>	10	4	6	60	<b>88</b>	10	0	10	100
<b>89</b>	11	0	11	100	<b>89</b>	12	5	7	58.33
<b>90</b>	9	4	5	55.56	<b>90</b>	11	4	7	63.64
<b>91</b>	10	0	10	100	<b>91</b>	10	0	10	100
<b>92</b>	12	0	12	100	<b>92</b>	12	1	11	91.67
<b>93</b>	11	2	9	81.82	<b>93</b>	11	5	6	54.55
<b>94</b>	11	0	11	100	<b>94</b>	12	0	12	100
<b>95</b>	11	1	10	90.91	<b>95</b>	12	3	9	75
<b>96</b>	10	2	8	80	<b>96</b>	11	0	11	100
<b>97</b>	11	0	11	100	<b>97</b>	11	4	7	63.64
<b>98</b>	10	4	6	60	<b>98</b>	12	3	9	75
<b>99</b>	10	1	9	90	<b>99</b>	10	0	10	100
<b>100</b>	12	0	12	100	<b>100</b>	11	5	6	54.55
<b>101</b>	9	2	7	77.78	<b>101</b>	12	0	12	100
<b>102</b>	11	1	10	90.91	<b>102</b>	11	0	11	100
<b>103</b>	11	2	9	81.82	<b>103</b>	12	5	7	58.33
<b>104</b>	11	0	11	100	<b>104</b>	12	0	12	100
<b>105</b>	11	0	11	100	<b>105</b>	10	0	10	100
<b>106</b>	11	4	7	63.64	<b>106</b>	12	0	12	100
<b>107</b>	11	0	11	100	<b>107</b>	10	0	10	100
<b>108</b>	12	1	11	91.67	<b>108</b>	12	4	8	66.67
<b>109</b>	12	0	12	100	<b>109</b>	11	0	11	100
<b>110</b>	9	0	9	100	<b>110</b>	11	0	11	100
<b>111</b>	<b>Average % Relief (A)</b>			<b>91.10%</b>	<b>111</b>	<b>Average % Relief (B)</b>			<b>83.27%</b>

**Average % Relief** in Patients of Group A is **91.10%** and in Patients of Group B is **83.27%**. (Table 4.25)

## B. Effect of therapy according to % Relief in Symptoms

Table 4.26 Relieved score and % Relief in Symptoms of Group A

Symptom No.	Symptoms (Group A)	B.T.	A.T.	Relieved	% Relief
1	Pain	319	33	286	89.66
2	Discharge	182	10	172	94.51
3	Irritation	276	10	266	96.38
4	Cutting	220	12	208	94.55
5	Healing	180	36	144	80
6	Average Relief (A)				91.01%

Table 4.27 Relieved score and % Relief in Symptoms of Group B

Symptom No.	Symptoms (Group A)	B.T.	A.T.	Relieved	% Relief
1	Pain	310	50	260	83.87
2	Discharge	204	50	154	75.49
3	Irritation	276	50	226	81.88
4	Cutting	220	0	220	100
5	Healing	220	62	158	71.82
6	Average Relief (A)				82.61%

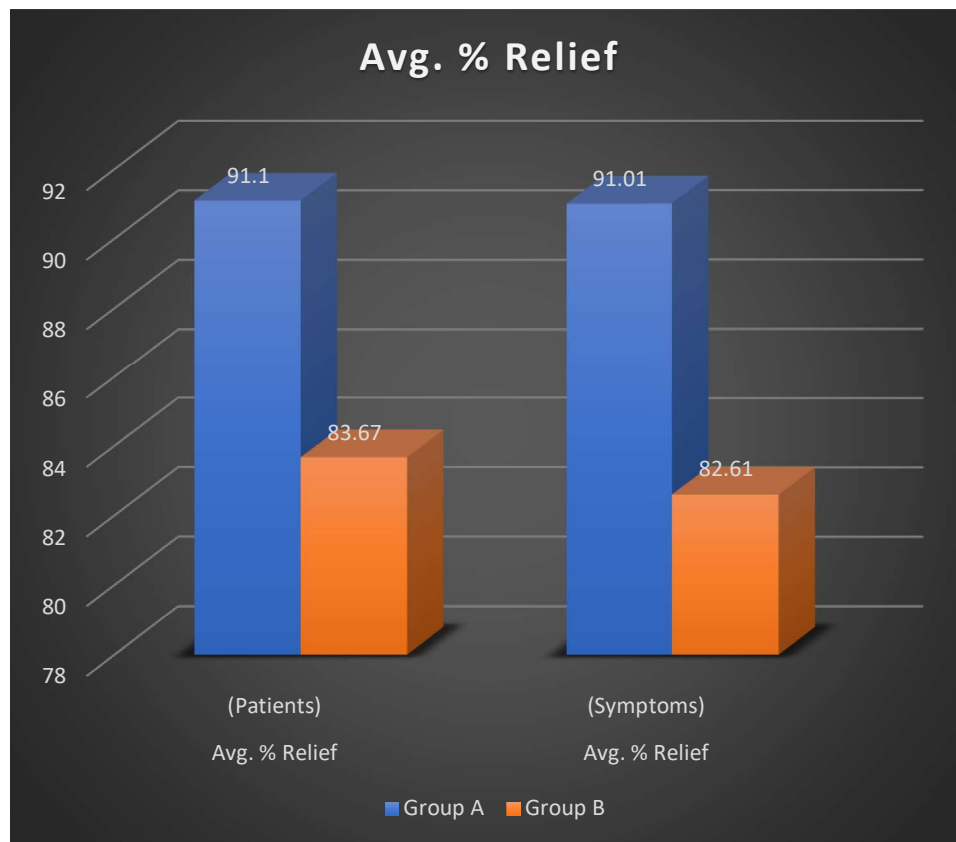
Average % Relief in Symptoms of Group A is **91.01%** (Table 4.26) and in Symptoms of Group is **82.61%** (Table 4.27).

### C. Average % Relief in Patients and in Symptoms

Table 4.28 Shows Average % Relief in Patients and in Symptoms

Sr. No.	Group	Avg. % Relief (Patients)	Avg. % Relief (Symptoms)
1	Group A	91.10	91.01
2	Group B	83.67	82.61

Figure 4.15 Shows Average % Relief in Patients and in Symptoms



It was observed that Average % Relief is more in Group A than Group B.

## 4.2. INTERPRETATION (DISCUSSION)

The present study type was Randomized Controlled Clinical study. Trial Group (Group A) and Control Group (Group B) comprised 110 patients each of Arsha (Hemorrhoids). Patients of Trial group were treated with Aloe Vera Ksharasutra ligation while Patients of Control group were treated with Snuhi Kshira Ksharasutra ligation. Research question and Hypothesis of the present study were defined as follows–

Collected data was tabulated, classified and presented in the forms of tables and graphs and finally analyzed statistically in order to draw interference and to accept/reject hypothesis. Interpretation and critical analysis are as follows.

### 4.2.1. Discussion on Arsha

Arsha is *Kastha sadhya / Shastrakarma sadhya vyadhi*. It troubles the patient like enemy (*Arivat*) and hence the name Arsha. Ayurveda describes the pathogenesis and emphasis of Arsha. It is disease of culmination of dosha prakopa. All Aacharayas have described it in separate chapters. Acharya Sushruta has included it under “Ashtamahagada” as it is *dirgha kalanubandhi*. Modern science believes it as a mere local process excessive and erroneous dietetic indulgence, erect posture which create pressure on anal region. According to WHO 40% of people worldwide suffer from it. In India approximately 80% of the sufferers are in age group of 21 to 50 yrs. As per the situation of piles, three types have been considered viz.–

- External piles
- Internal piles
- Intero–External piles

According to prolapse of piles, it is further divided into 4 degrees viz.–

- First degree
- Second degree.
- Third degree
- Fourth degree.

#### 4.2.2. Discussion on Treatment of Arsha

Acharya Charaka and Sushruta both have mentioned four types of treatments for Arsha viz.–

- Aushadha chikitsa
- Ksharakarma
- Agnikarma
- Shastrakarma

First two degrees are treated by medicine, whereas the next two degrees need some of the non–surgical or surgical procedures like, Kshar karma / Kshara Sutra, Agni karma and Shastra karma are mentioned by Sushruta. Modern conservative therapies include non–surgical modalities like viz. Injection of Sclerotherapy, Cryo–therapy, Manual dilatation of anus, Electro–coagulation, Rubber–band Ligation etc.

Kshara Sutra is one of the routinely applied procedures, especially in second and third degree of piles which is very simple, economic and convenient to patients. The proper management of this disease, according to their severity and degree stage, is very essential. Hence, we have decided to work on this disease, by inventing the Kshara Sutra through changing its content.

#### **4.2.3. Discussion on selection of Aloe Vera Ksharasutra**

Presently all over India Snuhi Kshira Ksharasutra is being used for ligation of Arsha (Hemorrhoids) as a standard treatment, it has well known good results no doubt. But patients many times complaints about the symptoms like Pain, Irritation etc. after ligation of snuhi Kshira Ksharasutra. Hence, the basic concept was to overcome these difficulties and find new drug which is effective likewise Snuhi Kshira. Aloe Vera (Kumari, Ghrutakumari) being sheeta was thought to be tried in Ksharasutra. Selection of Aloe Vera instead of Snuhi Kshira was done on basis of following principles. Aloe Vera does not hamper the properties of Apamarga Kshara rather it adds for the expected result of disease. Aloe Vera does not have characteristics of Kshara, although Sheet viryatmaka, but the expected qualities like Ushna & Tikshna are maintain well, which by adding to Apamarga kshara helps in removing of piles without Irritation as compare to Snuhi. Aloe Vera has very good properties viz. Shothahara, Bhedana, Vedanasthapaka and Vranaropana which are very essential in removing of Pile–mass with minimum or no pain. Much more work has been carried out on Aloe Vera regarding wound healing and curing, but not on Cutting. Aloe Vera is soft (Mrudu) & non–irritative as compared to Snuhi which troubles more. Aloe Vera acts as good as antibiotic, hence chances of post removal Infection and Sepsis are on remote. Aloe Vera is freely available everywhere at any season in India, where as Snuhi is seasonal & scarce. Aloe vera is very cheap, economic & easy to collect than that of Snuhi.



#### **4.2.4. General Observations**

##### **A. Distribution**

Total 220 patients of Arsha were included in the study which were further divided into two equal groups. (Table 4.1)

##### **B. Age**

Maximum patients (105, i.e. 47.73%) were found in age group 33 to 49. It can be said that Arsha is not the disease of old age at all. It can affect in age and most commonly in middle age specially 4<sup>th</sup> and 5<sup>th</sup> decade of life. Different studies also have shown that, in India approximately 80% of total patients of Arsha are from age 21 to 50 years. (Table 4.2)

##### **C. Gender**

Maximum patients (122, i.e. 55.45%) were males. Prevalence of Arsha was found more in males than in females. It may be because, 1. Commonly males have to do long time standing or sitting job, 2. Males have to eat more fast food, junk food, food in hotels than females due to many reasons, 3. Addictions like Tobacco, Alcohol, Smoking etc. are very much more in males than females. (Table 4.3)

##### **D. Occupation**

Housewives (49, i.e. 22.27%) were found maximum among all occupations. It was by chance only as patients were selected randomly. Among other occupations Shopkeeper (35, i.e. 15.91%), Driver (29, i.e. 13.18%), Clerk (26, i.e. 11.82) and Service (20, i.e. 9.09%) were found dominant. Common thing among all occupations is prolonged sitting. Hence it can be definitely said that, occupation is one of major impact factors of Arsha. Prolonged sitting is found as a causative factor of Arsha (Hemorrhoids) in Ayurvedic as well as Modern texts. (Table 4.4)

### **E. Prakruti**

Maximum patients (127, i.e. 57.73%) were found having Vata prakriti. Arsha is disease of Vatadushti and its adhisthana in Apana sthana. Hence incidence of Vata prakriti in Arsha might have been found maximum. (Table 4.5)

### **F. Habitat**

Maximum patients (153, i.e. 69.55%) were from Urban habitat. Hence Arsha can be called as common disease of Urban population. Urban people found more incident in Arsha because of changed and improper lifestyle, changed food habits, stress–strain and jobs. (Table 4.6)

### **G. Diet**

Maximum patients (141, i.e. 64.09%) were found having mixed diet. It is clear that mutton, chicken, fish, eggs etc. in diet may result in disease like Arsha. (Table 4.7)

### **H. Koshtha**

Maximum patients (124, i.e. 56.36%) were found Krura koshtha. Arsha is Agni dushtijanya vyadhi in which Malavstambha (constipation) is the major cause. Agni dushti results in Krura koshtha and malavastambha and it leads disease like Arsha. Hence, incidence of Krura Koshtha has been found more in Arsha. (Table 4.8)

### **I. Type of Arsha**

Maximum patients (134, i.e. 60.91%) were found with External Hemorrhoids, followed by 73 (33.18%) patients with Internal Hemorrhoids, 11 (5%) patients with both External plus Internal Hemorrhoids and 2 (0.9%) patients with Thrombosed Hemorrhoids. This was purely by chance as patients were selected randomly irrespective of type of Hemorrhoids. (Table 4.9)

#### 4.2.5. Changes in symptoms before and after treatment

##### A. Pain

**In Group A**, difference in mean symptom score on Day 1 and Day 9 is **2.6** (Table 4.10). Relief % in the symptom Pain was 89.66% (Table 4.26). **In Group B**, difference in mean symptom score on Day 1 and Day 9 is **2.36** (Table 4.10). Relief % in the symptom Pain was 83.87% (Table 4.27). **It means**, Pain has been reduced more in Group A than in Group B.

**It suggests that**, efficacy of Aloe Vera Ksharasutra is more than Snuhi Kshira Ksharasutra to reduce Pain after ligation.

##### B. Discharge

**In Group A**, difference in mean symptom score on Day 1 and Day 9 is **1.56** (Table 4.11). Relief % in the symptom Discharge was 94.51% (Table 4.26). **In Group B**, difference in mean symptom score on Day 1 and Day 9 is **1.4** (Table 4.11). Relief % in the symptom Discharge was 75.49% (Table 4.27). **It means**, Discharge has been reduced more in Group A than in Group B.

**It suggests that**, efficacy of Aloe Vera Ksharasutra is more than Snuhi Kshira Ksharasutra to reduce Discharge after ligation.

##### C. Irritation

**In Group A**, difference in mean symptom score on Day 1 and Day 9 is **2.4** (Table 4.12). Relief % in the symptom Irritation was 96.38% (Table 4.26). **In Group B**, difference in mean symptom score on Day 1 and Day 9 is **2.1** (Table 4.12). Relief % in the symptom Irritation was 81.88% (Table 4.27). **It means**, Irritation has been reduced more in Group A than in Group B.

**It suggests that**, efficacy of Aloe Vera Ksharasutra is more than Snuhi Kshira Ksharasutra to reduce Irritation after ligation.

#### **D. Cutting**

**In Group A**, difference in mean symptom score on Day 1 and Day 9 is **1.64** (Table 4.13). Relief % in the Cutting was 94.55% (Table 4.26). **In Group B**, difference in mean symptom score on Day 1 and Day 9 is **2** (Table 4.13). Relief % in the Cutting was **100%** (Table 4.27). **It means**, Cutting was more effective in Group B than in Group A.

**It suggests that**, efficacy of Snuhi Kshira Ksharasutra is more than Aloe Vera Ksharasutra to cut Hemorrhoids after ligation.

#### **E. Healing**

**In Group A**, difference in mean symptom score on Day 1 and Day 9 is **1.6** (Table 4.14). Relief % in the Healing was 80% (Table 4.26). **In Group B**, difference in mean symptom score on Day 1 and Day 9 is **1.44** (Table 4.14). Relief % in the Healing was 71.82% (Table 4.27). **It means**, Healing was more effective in Group A than in Group B.

**It suggests that**, efficacy of Aloe Vera Ksharasutra is more than Snuhi Kshira Ksharasutra to heal wound on cutting the Hemorrhoids after ligation.

#### 4.2.6. Statistical Analysis (Within the groups)

Table 4.29 Statistical analysis within the Group A and B by Wilcoxon Signed Ranks Test

Sr. No.	Symptoms	Gr.	W	P	Significance
1	Pain	A	6105	<0.0001	Significant
		B	6105	<0.0001	Significant
2	Discharge	A	6105	<0.0001	Significant
		B	5886	<0.0001	Significant
3	Irritation	A	6105	<0.0001	Significant
		B	6105	<0.0001	Significant
4	Cutting	A	6105	<0.0001	Significant
		B	6105	<0.0001	Significant
5	Healing	A	3081	<0.0001	Significant
		B	4371	<0.0001	Significant

Wilcoxon Signed Ranks test was applied to both groups separately to observe whether the difference between BT and AT score is significant or not.

#### Group A

In the case of all symptoms Pain, Discharge, Irritation, Cutting and Healing the test has shown highly significant difference between BT and AT symptom scores. It is hence concluded that **1.** Aloe Vera Ksharasutra ligation is significantly effective to reduce Pain, Discharge, Irritation in the management of Arsha. **2.** Aloe Vera Ksharasutra ligation is significantly effective to cut pile mass and to heal wound in the management of Arsha.

#### Group B

In the case of all symptoms Pain, Discharge, Irritation, Cutting and Healing the test has shown highly significant difference between BT and AT symptom scores. It is hence concluded that **1.** Snuhi Kshira Ksharasutra ligation is significantly effective to reduce Pain, Discharge, Irritation in the management of Arsha. **2.** Snuhi Kshira Ksharasutra ligation is significantly effective to cut pile mass and to heal wound in the management of Arsha.

#### 4.2.7. Statistical Analysis (Comparison between both groups)

Table 4.30 Mann Whitney's U Test in between the Group A and Group B

Sr. No.	Symptom	U	P	Significance	Efficacy
1	Pain	4600	0.0018	Significant	Trial > Control
2	Discharge	5122	0.0460	Significant	Trial > Control
3	Irritation	4324	0.0002	Significant	Trial > Control
4	Cutting	5145	0.0488	Significant	Control > Trial
5	Healing	5153	0.0497	Significant	Trial > Control

Both groups were compared and analyzed statistically by Mann–Whitney's U test.

In the case of symptoms Pain, Discharge, Irritation and Healing the test has shown **significant** difference between difference of means of Group A and Group B. **H<sub>1</sub>** is accepted and **H<sub>0</sub>** is rejected here **because difference of means of Group A is more than that of Group B**. It is hence concluded that Arsha Ligation with Aloe Vera Ksharasutra is significantly effective than Arsha Ligation with Snuhi Kshira Ksharasutra in Arsha vyadhi to reduce Pain, Discharge, Irritation and to Heal wound on cutting.

In the case of Cutting also, the test has shown **significant** difference between difference of means of Group A and Group B. Still **H<sub>0</sub>** is accepted and **H<sub>1</sub>** is rejected here **because difference of means of Group B is more than that of Group A**. It is hence concluded that Arsha Ligation with Aloe Vera Ksharasutra is not significantly effective than Arsha Ligation with Snuhi Kshira Ksharasutra in Arsha vyadhi to cut the pile mass.

#### 4.2.8. Overall Effect of Therapy

##### A. Effect of Therapy according % Relief in Patients and in Symptoms

Table 4.31 Effect of Therapy according % Relief in Patients and in Symptoms

Sr. No.	Improvement Grade	Criteria	No. of patients		No. of Symptoms	
			Gr. A	Gr. B	Gr. A	Gr. B
1	Cured	100%	65	55	00	01
2	Marked	75% – 99%	31	11	05	03
3	Moderate	50% – 74%	14	44	00	01
4	Mild	25% – 49%	00	00	00	00
5	Poor	00% – 24%	00	00	00	00

##### Relief in Patients

**In Group A**, 65 patients completely Cured, 31 patients have shown Marked improvement, 14 patients have shown Moderate improvement. **In Group B**, 55 patients completely Cured, 11 patients have shown Marked improvement, 44 patients have shown Moderate improvement.

##### Relief in Symptoms

**In Group A**, all 05 symptoms have shown Marked improvement. **In Group B**, 01 symptom (Cutting of pile mass) has been Cured completely, 3 symptoms have shown Marked improvement, 01 symptom has shown Moderate improvement.

**Group A** has shown better effect than **Group B** to reduce score **in Patients and in Symptoms**. (Table 6.3) Hence **according to % Relief**, Aloe Vera Ksharasutra ligation is effective than Snuhi Kshira Kasharasutra ligation in Arsha to reduce score in Patients and in Symptoms.

#### 6.8.2. Effect of therapy according to Average % Relief

Average % Relief in Patients of **Group A** is **91.10%** and Average % Relief in Patients of **Group B** is **83.67%**. Average % Relief in Symptoms of **Group A** is **91.01%** and Average % Relief in Symptoms of **Group B** is **82.61%**. (Table 5.28)

Hence **according to average % relief**, Aloe Vera Ksharasutra ligation is effective than Snuhi Kshira Kasharasutra ligation in Arsha to reduce score in Patients and in Symptoms.

#### **4.2.9. Mode of Action of Aloe Vera Ksharsutra**

- The cutting of piles by Aloe Vera Ksharasutra is by process of Chemical cauterization due to chemical properties of its contents.
- After ligation the pressure is created on muscle mass by the Ksharasutra and due to chemical properties chemical cauterization occurs. During this Cutting and Healing processes take place at a time. Infection / Sepsis does not take place due to following properties –
- Aloe Vera does not hamper the properties of Apamarga Kshara rather it adds for the expected result of disease.
- Aloe Vera does not have characteristics of Kshara, although Sheet viryatmaka, but the expected qualities like Ushna & Tikshna are maintain well, which by adding to Apamarga kshara helps in removing of piles without Irritation as compare to Snuhi.
- Aloe Vera has very good properties viz. Shothahara, Bhedana, Vedanasthapaka and Vranaropana which are very essential in removing of Pile–mass with minimum or no pain.
- Much more work has been carried out on Aloe Vera regarding wound healing and curing, but not on Cutting.
- Aloe Vera is soft (Mrudu) & non–irritative as compared to Snuhi which troubles more.
- Aloe Vera acts as good as antibiotic, hence chances of post removal Infection and Sepsis are on remote.



## 5. CONCLUSION, FINDINGS AND RECOMMENDATION

After literary study, clinical trials, data collection, data classification, data presentation and data analysis in the Thesis work on “**Aloe Vera Ksharasutra and Arsha**” we came across following conclusions and finding.

### 5.1. CONCLUSION

1. Wilcoxon Signed Ranks Test proved that Aloe Vera Ksharasutra ( $P < 0.0001$ ) and Snuhi Kshira Ksharasutra ( $P < 0.0001$ ) both effectively relieved all symptoms in Arsha.
2. After comparison of both groups by Mann–Whitney’s U test – Aloe Vera Ksharasutra was found better in relieving Pain, Discharge, Irritation and Healing than Snuhi Kshira Ksharasutra in Arsha. ( $P < 0.05$ )
3. Mann–Whitney’s U test also reveals that Snuhi Kshira Ksharasutra was found better in Cutting than Aloe Vera Ksharasutra in Arsha. ( $P < 0.05$ )
4. Aloe Vera Ksharasutra is safe in Arsha management, it is easily available everywhere and its cost is less so that poor patients can afford it.
5. Present Study was without any complications and side effects.

**Finally, conclusion can be made,**

- **Overall, Aloe Vera Ksharasutra ligation in Arsha is effective specially in Pain, Discharge, Irritation and Healing without any complications.**
- **Aloe Vera Ksharasutra ligation is effective than Snuhi Kshira Ksharasutra ligation specially in Pain, Discharge, Irritation and Healing in Arsha patients.**
- **Snuhi Kshira Ksharasutra ligation is effective than Aloe Vera Ksharasutra ligation specially in Cutting of Hemorrhoidal mass in Arsha patients.**

## 5.2. FINDINGS

1. Arsha prevalence is more now a days as compared to past.
2. Middle aged persons (33 to 49 yrs.) and males were affected more.
3. Arsha incidences found more in Vata Prakruti, Urban habitat and patients with Krura Koshtha.
4. Long standing, sitting and frequent Non-vegetarian diet may be the causative factors of Arsha as more incidences found in such persons.
5. Effect of Aloe Vera Ksharasutra,
  - a. 65 patients: Complete cure
  - b. 31 patients: Marked improvement
  - c. 14 patients: Moderate improvement.
6. Effect of Snuhi Kshira Ksharasutra,
  - a. 55 patients: Complete cure
  - b. 11 patients: Marked improvement
  - c. 44 patients: Moderate improvement.

### **5.3. RECOMMENDATION**

#### **5.3.1. Limitations of Study**

1. Sample size was very less.
2. Population was limited, only the patients in the periphery of Ayurved College were considered.
3. Study duration was very short.
4. Shaman chikitsa with Ayurveda medicine was not given.

#### **5.3.2. Further Scope & Recommendations**

1. Larger sample size from larger population may give more correct results.
2. By taking longer duration studies one can conclude about late complications and recurrence of disease.
3. New researchers may study Aloe Vera Ksharasutra in diseases like Sinus and Fistula also.
4. A new method of preparation of Ksharasutra by adding specific content which can increase the cutting effect of Aloe Vera Ksharasutra further more.
5. New drug can be tested in Ksharasutra to compare with Aloe Vera Ksharasutra.

## ANNEXURES

### 1. MASTER CHARTS

#### 1.1. Demographic Data

##### A. Demographic Data (Trial Group)

MASTER CHART 1-A (DEMOGRAPHIC DATA)										
Sr. No.	OPD No.	Age	Sex	Occupation	Habitat	Agni	Koshtha	Prakruti	Diet	Type
1	22921	60	M	FR	R	M	Kr	V	M	I
2	23079	31	M	CL	U	V	Md	P	V	E
3	23177	54	M	SK	U	M	Kr	V	M	E
4	24267	29	F	HW	R	M	Kr	P	M	I
5	25022	60	M	RT	U	M	Kr	V	M	I
6	25005	36	M	FR	R	T	Kr	V	M	E
7	25189	26	F	HW	U	V	Mr	K	M	E
8	25807	26	M	SK	U	V	Md	V	M	I
9	25709	42	M	SK	U	M	Kr	V	V	I
10	25823	27	F	HW	R	M	Kr	P	V	I
11	27268	60	F	HW	R	M	Kr	V	M	E
12	27206	35	M	DR	U	M	Kr	V	M	E
13	27947	48	M	SR	U	V	Mr	V	M	E
14	28947	65	M	RT	U	T	Kr	K	M	I
15	29074	40	F	CL	U	V	Kr	P	M	I
16	29653	42	M	CJ	U	M	Kr	V	M	I+E
17	29695	65	F	HW	U	V	Md	V	M	I
18	30355	31	M	CJ	U	T	Mr	V	M	E
19	30524	35	M	CL	U	M	Kr	V	M	T
20	30858	38	F	CJ	R	V	Kr	V	M	E
21	33150	23	M	ST	U	T	Kr	P	M	E
22	30529	40	F	FR	R	M	Mr	K	M	E
23	28088	50	M	SK	U	V	Kr	V	V	E
24	33699	44	M	DR	U	T	Md	V	V	E
25	33893	31	M	CL	R	V	Kr	V	M	I

26	34249	32	F	SR	U	M	Mr	V	M	I
27	34112	30	M	CJ	U	V	Kr	K	M	E
28	34267	40	F	SK	U	V	Md	P	M	E
29	34641	35	M	FR	R	T	Md	V	V	E
30	35037	32	M	DR	U	M	Kr	P	V	I
31	36203	40	F	HW	U	T	Md	V	M	E
32	37340	60	M	RT	U	V	Mr	V	M	E
33	37782	48	M	SK	R	M	Kr	V	M	E
34	38352	60	M	FR	R	M	Kr	P	M	I
35	38245	35	F	HW	U	M	Kr	V	V	E
36	39044	37	F	CL	U	T	Kr	V	V	E
37	31973	32	F	SK	U	V	Kr	K	M	E
38	30656	42	F	HW	R	V	Md	P	V	E
39	40055	17	F	ST	U	M	Mr	V	M	E
40	37634	65	M	CJ	U	M	Kr	V	M	E
41	8490	30	F	HW	R	M	Md	V	M	E
42	3492	52	M	DR	U	M	Kr	V	V	E
43	2123	27	F	SR	U	V	Kr	P	V	E
44	3409	29	F	FR	R	M	Md	K	M	E
45	3990	28	F	HW	U	M	Md	V	M	E
46	1042	60	M	RT	U	V	Mr	V	M	I
47	1068	65	F	HW	R	V	Kr	V	M	I
48	5033	23	M	DR	R	M	Md	P	M	I
49	5283	34	F	CL	U	V	Mr	P	M	I
50	6199	62	F	SK	U	V	Kr	K	M	E
51	5996	25	M	ST	U	M	Kr	V	M	I
52	6930	27	M	SK	U	M	Kr	V	M	E
53	7750	42	F	CL	U	M	Md	V	M	E
54	8684	35	M	SR	R	T	Mr	V	M	I+E
55	8789	28	M	DR	R	V	Md	K	V	I
56	8744	55	M	SR	U	M	Kr	P	V	E
57	8593	50	M	SK	U	M	Kr	K	M	I
58	9833	55	F	FR	R	M	Kr	V	V	I
59	10119	65	F	HW	U	M	Kr	V	M	E
60	9766	45	M	CJ	U	V	Md	V	V	I+E
61	10253	26	F	HW	R	M	Md	P	V	E
62	9477	20	M	ST	U	V	Mr	P	M	I+E
63	8480	42	M	CL	U	M	Md	V	V	I
64	10812	39	F	FR	R	T	Mr	K	M	E

65	10916	35	M	DR	U	M	Kr	P	V	E
66	10898	45	M	DR	R	T	Kr	V	V	I
67	11166	34	F	CL	U	M	Kr	K	M	E
68	10920	65	F	HW	U	V	Md	V	V	I
69	10760	20	F	ST	U	M	Md	V	V	E
70	12770	40	M	SR	U	T	Md	P	M	I
71	13589	36	F	HW	R	M	Kr	P	V	E
72	13841	50	F	FR	R	T	Md	V	M	E
73	13809	29	M	DR	R	V	Kr	V	V	E
74	13811	48	M	SR	U	T	Md	K	M	E
75	13817	43	M	CL	U	M	Mr	P	M	I
76	12272	37	M	DR	U	M	Kr	V	M	E
77	13822	35	F	SK	U	M	Kr	P	M	E
78	13954	32	F	HW	U	V	Kr	V	M	I
79	13997	28	M	SK	U	T	Md	P	V	E
80	12929	36	M	FR	R	V	Md	K	V	I
81	14034	32	F	SK	U	M	Kr	V	M	E
82	14400	24	F	HW	U	M	Kr	V	V	E
83	16372	35	F	HW	R	M	Md	V	V	E
84	15119	27	M	DR	U	M	Mr	P	M	E
85	17051	23	M	ST	U	T	Kr	K	V	E
86	3411	40	M	SK	U	V	Kr	V	M	I
87	17303	25	F	HW	U	M	Md	K	M	E
88	17004	50	F	SK	U	M	Md	P	M	E
89	18949	36	F	FR	R	M	Mr	K	M	I
90	19508	28	M	DR	R	T	Kr	V	V	I
91	14589	40	M	CJ	U	V	Kr	V	V	E
92	21052	42	M	CL	U	M	Kr	V	M	E
93	20180	42	M	SR	R	V	Mr	V	V	E
94	20458	34	F	HW	U	V	Md	K	V	I
95	20669	30	M	CL	U	M	Kr	P	M	E
96	21336	28	F	HW	U	V	Kr	V	V	E
97	21453	50	M	FR	R	T	Mr	V	M	E
98	18529	65	F	RT	U	M	Kr	V	V	E
99	22824	35	F	SK	U	V	Md	P	M	I
100	22867	38	M	CJ	U	V	Kr	P	V	I
101	23341	29	M	DR	U	M	Mr	K	M	E
102	22897	45	M	FR	R	V	Kr	K	M	I
103	22642	28	M	DR	R	M	Md	V	M	I

<b>104</b>	22492	41	M	SR	U	M	Mr	V	M	E
<b>105</b>	24757	36	M	CJ	U	M	Kr	V	V	E
<b>106</b>	26185	65	M	RT	U	V	Md	P	V	I
<b>107</b>	26178	65	M	RT	U	T	Kr	K	V	I
<b>108</b>	26404	30	F	HW	R	V	Kr	V	M	E
<b>109</b>	26801	48	M	DR	U	M	Kr	V	M	I
<b>110</b>	26831	65	M	RT	R	M	Md	P	M	I

### B. Demographic Data (Control Group)

<b>MASTER CHART 1-B (DEMOGRAPHIC DATA)</b>										
<b>Sr. No.</b>	<b>OPD No.</b>	<b>Age</b>	<b>Sex</b>	<b>Occupation</b>	<b>Habitat</b>	<b>Agni</b>	<b>Koshtha</b>	<b>Prakruti</b>	<b>Diet</b>	<b>Type</b>
<b>1</b>	25914	50	M	CJ	U	V	Md	K	V	I
<b>2</b>	26169	41	M	SK	U	M	Kr	V	M	I
<b>3</b>	26257	36	M	CL	U	T	Mr	P	V	I
<b>4</b>	25758	52	M	FR	R	M	Kr	P	V	I+E
<b>5</b>	26738	37	F	CL	U	M	Kr	V	M	I
<b>6</b>	26736	40	F	SK	R	V	Kr	V	M	I
<b>7</b>	27161	39	M	CL	U	M	Md	V	M	I
<b>8</b>	27329	65	M	RT	U	M	Md	V	M	I
<b>9</b>	29265	60	M	SK	U	M	Kr	V	M	I
<b>10</b>	29276	28	M	FR	R	M	Kr	V	M	I
<b>11</b>	29524	40	M	HW	U	V	Kr	P	V	I
<b>12</b>	30204	27	M	DR	U	T	Md	K	V	I
<b>13</b>	30583	60	M	RT	R	M	Mr	V	M	I
<b>14</b>	30739	35	F	SR	U	M	Md	V	M	E
<b>15</b>	31152	50	M	CL	U	M	Kr	P	M	I+E
<b>16</b>	31459	50	F	SR	U	V	Kr	P	M	E
<b>17</b>	29266	16	F	ST	R	V	Kr	V	M	E
<b>18</b>	32255	40	F	CL	U	M	Kr	V	M	I
<b>19</b>	32529	40	M	DR	U	M	Kr	V	V	E
<b>20</b>	32217	52	M	CJ	U	T	Kr	P	M	I+E
<b>21</b>	33184	24	F	HW	R	M	Kr	K	V	I+E
<b>22</b>	33696	30	M	DR	R	T	Kr	V	M	E
<b>23</b>	34199	40	F	SK	U	M	Md	V	V	I

24	34415	38	F	SR	U	V	Mr	P	M	E
25	34975	65	M	RT	U	M	Mr	V	V	I
26	35226	40	F	SR	U	V	Kr	P	M	E
27	35378	33	F	HW	U	M	Kr	K	M	E
28	30300	60	F	HW	R	T	Kr	V	V	E
29	36386	40	M	FR	R	V	Kr	P	V	E
30	37169	30	M	DR	U	M	Kr	V	V	E
31	37608	45	F	HW	U	M	Kr	P	M	E
32	36872	38	F	CL	U	M	Kr	V	M	E
33	37740	39	F	SK	R	M	Kr	K	M	E
34	38274	27	M	FR	R	M	Md	V	M	E
35	38276	26	M	SR	U	M	Mr	P	V	E
36	17881	49	F	HW	R	M	Kr	V	M	E
37	39607	35	F	SK	U	T	Kr	P	M	E
38	39600	35	M	DR	U	V	Kr	V	V	I+E
39	40211	20	M	ST	U	V	Md	K	V	E
40	40227	30	M	CJ	U	M	Md	P	V	I
41	39858	17	M	ST	R	M	Kr	V	M	T
42	40880	35	M	CJ	U	M	Kr	V	M	I
43	31310	35	F	CL	U	M	Mr	V	M	I
44	42099	40	M	SK	U	M	Kr	V	M	E
45	41521	30	M	FR	R	M	Md	V	V	E
46	49943	35	M	DR	U	M	Kr	V	M	E
47	42985	50	M	SR	U	M	Md	V	V	E
48	42856	37	M	DR	U	V	Kr	V	V	E
49	42415	36	M	FR	R	T	Mr	P	M	E
50	43134	35	M	SK	U	M	Kr	K	M	E
51	1116	38	F	HW	U	V	Md	P	M	E
52	421	43	M	SK	U	T	Kr	V	V	I
53	1124	55	M	DR	R	V	Md	V	V	E
54	1276	40	M	SK	U	M	Kr	P	M	I+E
55	2062	30	M	DR	R	V	Mr	K	M	E
56	2629	30	F	HW	R	M	Kr	V	M	I+E
57	2419	40	M	SK	U	T	Kr	V	M	E
58	2271	35	F	SR	U	M	Md	V	M	E
59	2122	43	F	HW	U	V	Mr	V	M	E
60	3592	50	F	CL	U	M	Md	V	V	E
61	4012	25	F	HW	U	V	Kr	V	M	E
62	4363	38	M	CJ	U	T	Kr	V	V	I



63	4379	40	F	CL	U	M	Kr	V	V	E
64	5455	40	F	DR	U	V	Kr	P	M	E
65	5579	35	F	HW	R	V	Kr	V	M	E
66	5987	50	F	SK	U	T	Kr	V	M	E
67	5886	25	F	FR	R	M	Md	P	M	E
68	6500	28	M	DR	U	V	Md	V	M	E
69	7635	42	M	SR	U	M	Kr	P	V	I
70	8261	30	F	HW	R	M	Kr	V	V	E
71	8654	56	F	CL	U	M	Kr	K	V	E
72	8698	65	M	HW	R	M	Kr	V	V	I
73	6396	32	F	HW	U	M	Mr	P	M	E
74	8738	35	M	SK	U	M	Md	V	M	I
75	9433	34	M	CL	U	M	Kr	K	M	E
76	9537	28	F	HW	U	M	Kr	V	M	E
77	10087	30	M	SK	R	M	Mr	V	M	E
78	11581	32	F	HW	R	M	Md	P	M	E
79	11534	35	F	HW	R	V	Kr	V	V	E
80	245	42	F	SR	U	M	Kr	V	M	E
81	2486	28	F	HW	U	M	Md	P	M	E
82	13197	65	M	RT	R	M	Mr	V	V	E
83	14148	36	F	HW	U	V	Kr	V	M	I
84	14720	28	F	HW	U	T	Kr	V	M	E
85	14842	40	F	SK	U	M	Kr	V	M	E
86	14730	36	F	CL	U	M	Md	P	M	E
87	18450	35	F	HW	R	M	Md	K	V	E
88	18346	45	M	SK	U	V	Mr	P	V	I
89	15715	44	M	CJ	U	M	Kr	V	M	I
90	14526	22	F	ST	U	M	Mr	V	M	E
91	16914	40	M	DR	R	V	Kr	V	M	E
92	17770	62	M	RT	U	M	Md	P	M	E
93	17893	50	F	HW	U	M	Kr	P	V	E
94	17940	42	M	SK	U	V	Md	V	M	I
95	18509	40	M	CL	R	M	Kr	V	V	E
96	18300	40	F	HW	U	T	Mr	V	M	E
97	19412	55	M	DSR	U	M	Kr	K	V	I
98	20111	40	M	SK	U	M	Kr	P	V	I
99	18518	40	M	SK	U	T	Kr	P	V	E
100	20551	35	F	HW	R	V	Kr	V	M	E
101	20929	55	F	HW	U	M	Md	V	M	I

<b>102</b>	20847	50	F	SR	U	M	Mr	P	M	E
<b>103</b>	20969	65	F	RT	U	M	Kr	P	M	E
<b>104</b>	20635	36	F	SR	U	V	Md	V	M	E
<b>105</b>	20593	35	F	CL	U	M	Kr	V	M	E
<b>106</b>	20543	30	F	HW	R	T	Md	K	V	E
<b>107</b>	21297	45	M	CJ	U	M	Kr	V	V	I
<b>108</b>	21478	32	F	HW	U	V	Md	P	V	E
<b>109</b>	22713	36	M	DR	R	M	Kr	V	M	I
<b>110</b>	22130	24	M	ST	U	V	Md	P	M	I

## 1.2. Data related to Parameters

### A. Parameters (Trial Group)

MASTER CHART 2-A (Subjective Parameters)																									
Sr. No.	Pain					Discharge					Irritation					Cutting					Healing				
	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9
1	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
2	2	1	1	1	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
3	3	1	1	0	0	2	1	0	0	0	3	1	0	0	0	2	0	*	*	*	●	2	1	0	0
4	3	2	1	1	0	2	1	1	1	0	2	1	1	1	0	2	2	1	0	*	●	●	●	2	1
5	3	2	1	0	0	1	1	0	0	0	2	1	0	0	0	2	1	0	*	*	●	●	2	1	0
6	3	2	1	1	0	1	1	1	0	0	3	1	1	0	0	2	2	1	1	0	●	●	●	●	2
7	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
8	3	2	1	0	0	2	1	1	0	0	3	1	1	0	0	2	1	1	0	*	●	●	●	2	1
9	3	2	1	0	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
10	3	2	1	1	1	2	1	1	1	0	3	1	1	1	0	2	2	1	1	0	●	●	●	●	2
11	3	2	1	0	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
12	2	1	1	0	0	1	1	0	0	0	2	1	0	0	0	2	0	*	*	*	●	2	1	0	0
13	3	2	1	1	0	1	1	1	0	0	3	2	1	1	0	2	2	1	0	*	●	●	●	2	0
14	3	2	1	0	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
15	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	0	●	●	●	●	1
16	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
17	2	1	0	0	0	1	1	0	0	0	2	1	0	0	0	2	0	*	*	*	●	2	1	0	0
18	3	2	1	1	1	2	1	1	1	0	3	1	1	1	0	2	1	1	0	*	●	●	●	1	0
19	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
20	3	2	1	1	0	2	1	1	0	0	3	1	1	0	0	2	2	1	1	0	●	●	●	●	2
21	3	2	1	0	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0

22	3	2	1	0	0	2	2	1	0	0	3	2	1	0	0	2	0	*	*	*	●	2	1	0	0
23	3	2	2	1	1	1	1	1	0	0	3	2	1	1	0	2	1	1	0	*	●	●	●	2	0
24	3	2	1	1	1	1	1	1	0	0	2	1	1	0	0	2	2	1	1	0	●	●	●	●	2
25	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	1	0	*	*	●	●	2	1	0
26	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
27	3	2	1	0	0	2	1	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
28	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	0	0
29	3	2	2	1	1	1	1	1	0	0	3	2	1	1	0	2	2	1	1	0	●	●	●	●	1
30	3	2	1	1	0	2	1	1	0	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
31	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	1	0
32	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
33	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	0	0
34	3	2	2	1	1	2	1	1	1	0	2	1	1	1	0	2	1	1	0	*	●	●	●	2	0
35	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	1	0	*	*	●	●	2	1	1
36	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	1	●	●	●	●	●
37	3	2	1	1	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
38	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
39	2	2	1	1	0	2	1	1	1	0	2	1	1	1	0	2	1	1	0	*	●	●	●	2	1
40	3	2	2	1	1	2	1	1	1	0	2	1	1	1	0	2	2	1	1	0	●	●	●	●	1
41	3	2	1	1	0	2	1	1	0	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
42	3	2	2	1	1	1	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
43	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	0	0
44	3	2	2	1	1	1	1	1	1	0	2	1	1	1	0	2	2	1	1	0	●	●	●	●	2
45	3	2	1	1	0	2	1	1	0	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
46	3	2	2	1	1	2	1	1	1	0	2	1	1	1	0	2	1	1	0	*	●	●	●	2	1
47	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	0	0
48	3	2	1	0	0	2	1	1	0	0	2	2	1	0	0	2	1	0	*	*	●	●	0	1	0
49	3	2	2	1	0	1	1	1	0	0	3	2	1	0	0	2	1	1	0	*	●	●	●	2	0
50	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	0	0
51	3	2	1	1	0	2	1	1	0	0	3	2	1	1	0	2	1	1	0	*	●	●	●	2	1
52	3	2	1	1	0	2	1	1	0	0	2	2	1	1	0	2	1	0	*	*	●	●	2	1	0
53	3	2	2	1	1	2	1	1	0	0	3	2	1	1	0	2	2	1	1	1	●	●	●	●	●
54	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	0	0
55	3	2	2	1	1	2	1	1	1	1	2	1	1	1	1	2	2	1	1	0	●	●	●	●	1
56	3	2	1	1	0	1	1	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
57	3	2	2	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
58	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	0	0
59	3	2	2	1	1	2	1	1	0	0	3	2	1	1	0	2	2	1	1	1	●	●	●	●	●
60	3	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0

61	3	2	2	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	0	●	●	●	●	1
62	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
63	2	1	1	0	0	1	1	0	0	0	2	1	0	0	0	2	1	0	*	*	●	●	2	1	0
64	3	2	2	1	1	1	1	1	0	0	3	2	1	0	0	2	1	1	1	0	●	●	●	●	0
65	3	2	2	1	0	2	1	1	0	0	3	2	1	0	0	2	1	1	0	*	●	●	●	2	0
66	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
67	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
68	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
69	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	0	0
70	3	2	1	0	0	1	1	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
71	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	0	●	●	●	●	1
72	3	2	1	1	1	2	1	1	0	0	2	1	1	0	0	2	2	1	1	1	●	●	●	●	●
73	3	2	1	0	0	2	1	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
74	2	1	1	1	1	1	1	1	0	0	2	1	1	0	0	2	1	1	1	1	●	●	●	●	●
75	3	2	1	1	0	1	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	0
76	3	2	1	1	1	2	2	1	1	0	3	2	1	1	0	2	2	1	1	0	●	●	●	●	2
77	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	1	0	*	*	●	●	2	1	0
78	3	2	2	1	1	2	1	1	0	0	2	1	1	0	0	2	2	1	1	0	●	●	●	●	2
79	3	2	1	1	1	2	1	1	1	1	3	2	1	1	1	2	2	1	1	1	●	●	●	●	●
80	3	2	1	1	1	2	1	1	0	0	2	1	1	0	0	2	1	1	1	1	●	●	●	●	●
81	3	2	1	0	0	2	1	1	0	0	3	1	1	0	0	2	1	0	*	*	●	●	2	1	0
82	3	1	0	0	0	2	1	0	0	0	2	1	0	0	0	2	0	*	*	*	●	2	1	1	0
83	3	2	1	1	1	2	1	1	0	0	3	2	1	0	0	2	1	1	1	0	●	●	●	●	1
84	3	2	2	1	1	2	1	1	0	0	3	2	1	1	0	2	2	1	1	1	●	●	●	●	●
85	2	1	1	0	0	1	1	0	0	0	2	1	0	0	0	2	1	0	*	*	●	●	2	1	0
86	3	1	0	0	0	2	1	0	0	0	2	1	0	0	0	2	0	*	*	*	●	2	1	0	0
87	3	2	1	1	0	1	1	1	0	0	3	2	1	1	0	2	1	1	0	*	●	●	●	2	0
88	3	2	2	1	1	2	1	1	1	1	2	1	1	1	1	2	2	1	1	0	●	●	●	●	1
89	3	2	1	0	0	1	1	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
90	3	2	2	1	1	2	1	1	1	1	2	1	1	1	1	2	2	1	1	1	●	●	●	●	●
91	3	2	1	0	0	1	1	1	0	0	2	2	1	0	0	2	1	0	*	*	●	●	2	1	0
92	3	2	1	1	0	2	1	1	1	0	3	2	1	1	0	2	1	1	0	*	●	●	●	2	0
93	3	1	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	1	0	●	●	●	●	2
94	3	2	1	0	0	2	2	1	0	0	2	2	1	0	0	2	1	0	*	*	●	●	2	1	0
95	3	2	2	1	0	2	1	1	0	0	3	2	1	0	0	2	1	1	1	0	●	●	●	●	1
96	3	2	1	1	1	2	1	1	0	0	3	2	1	0	0	2	2	1	1	1	●	●	●	●	●
97	3	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	1	0	*	*	●	●	2	1	0
98	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	1	●	●	●	●	●
99	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	1	0	●	●	●	●	1

100	3	2	1	0	0	2	2	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
101	3	2	1	1	1	1	1	1	0	0	3	1	1	0	0	2	2	1	1	1	●	●	●	●	●
102	3	2	1	1	0	2	1	1	0	0	2	1	1	0	0	2	1	1	0	*	●	●	●	2	1
103	3	2	1	1	1	2	1	1	0	0	3	2	1	0	0	2	2	1	1	0	●	●	●	●	1
104	3	2	1	0	0	2	1	1	0	0	2	2	1	0	0	2	1	0	*	*	●	●	2	1	0
105	3	2	2	1	0	2	1	1	0	0	3	2	1	0	0	2	1	1	0	*	●	●	●	1	0
106	3	2	1	1	1	2	1	1	1	1	3	2	1	1	1	2	1	1	1	0	●	●	●	●	1
107	3	1	0	0	0	2	1	0	0	0	2	1	0	0	0	2	0	*	*	*	●	2	1	0	0
108	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	1	0	*	●	●	●	2	1
109	3	2	1	0	0	2	2	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
110	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
*Follow ups after cutting of pile mass. ●Follow ups before cutting of pile mass.																									

**B. Parameters (Control Group)**

MASTER CHART 2-B (Subjective Parameters)																									
Sr. No.	Pain					Discharge					Irritation					Cutting					Healing				
	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9	D 1	D 3	D 5	D 7	D 9
1	2	1	1	1	0	1	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	2	1	0
2	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	0	*	●	●	●	2	1
3	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	0	*	*	●	●	2	1	1
4	2	1	1	1	0	2	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
5	3	2	2	1	0	2	2	1	1	0	2	2	2	1	0	2	1	0	*	*	●	●	2	1	0
6	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	1	0	*	●	●	●	2	2
7	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	2	1	0
8	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	0
9	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	0	*	●	●	●	2	1
10	2	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	0	*	*	*	●	2	1	1	0
11	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	0	●	●	●	●	2
12	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
13	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	0	*	●	●	●	2	1
14	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	0	*	*	*	●	2	2	1	0
15	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	0	*	●	●	●	2	2
16	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	0	*	*	●	●	2	1	0
17	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	0	*	●	●	●	2	1

18	3	2	2	1	1	2	2	2	1	1	2	2	2	1	1	2	1	0	*	*	●	●	2	1	0
19	3	2	2	1	1	1	2	2	1	1	3	2	2	1	1	2	2	1	1	0	●	●	●	●	0
20	2	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	0	*	*	*	●	2	1	1	0
21	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	0	*	●	●	●	2	1
22	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	0	*	*	●	●	2	1	1
23	2	1	1	1	0	1	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
24	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
25	3	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	0	*	*	*	●	2	1	1	0
26	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	0
27	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	1	0	*	●	●	●	2	1
28	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	1	0	●	●	●	●	2
29	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	1
30	2	1	1	1	0	2	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
31	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
32	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
33	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
34	3	2	1	0	1	2	2	1	0	1	2	2	1	0	1	2	1	1	0	*	●	●	●	2	1
35	2	1	1	1	0	1	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
36	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	2	1	1	0	●	●	●	●	2
37	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	0	*	*	●	●	2	1	0
38	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	0	*	*	*	●	2	1	1	0
39	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
40	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	0	*	●	●	●	2	1
41	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	1
42	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	1	1	0	●	●	●	●	2
43	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	0	*	*	*	●	2	2	1	0
44	3	2	1	1	1	2	2	1	1	1	2	2	1	1	1	2	1	1	1	0	●	●	●	●	2
45	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	0
46	3	2	1	1	1	2	2	1	1	1	2	2	1	1	1	2	1	1	1	0	●	●	●	●	2
47	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
48	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	0	*	●	●	●	2	1
49	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
50	3	2	2	1	1	2	2	2	1	1	2	2	2	1	1	2	1	1	0	*	●	●	●	2	1
51	2	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	1	0	*	*	●	●	2	1	0
52	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	2	1	1	0	●	●	●	●	2
53	3	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	0	*	*	*	●	2	1	1	0
54	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	1	0	*	●	●	●	2	1
55	3	2	2	1	0	2	2	1	1	0	2	2	2	1	0	2	1	0	*	*	●	●	2	1	0
56	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	1	0	●	●	●	●	2

57	3	2	1	2	0	2	2	1	2	0	2	2	1	2	0	2	1	0	*	*	●	●	2	1	0
58	3	1	1	0	0	1	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	2	1	0
59	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
60	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	1
61	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	0	*	●	●	●	2	1
62	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	1	0	*	*	●	●	2	1	0
63	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
64	3	2	1	1	1	2	2	1	1	1	2	2	1	1	1	2	1	1	0	*	●	●	●	2	1
65	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
66	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	1	0	*	●	●	●	2	1
67	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	2	1	0
68	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	2	1	1	0	●	●	●	●	2
69	2	2	1	0	0	2	2	1	0	0	2	2	1	0	0	2	1	0	*	*	●	●	2	1	0
70	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	0	*	*	*	●	2	2	1	0
71	3	2	1	0	1	2	2	1	0	1	3	2	1	0	1	2	1	1	0	*	●	●	●	2	1
72	3	2	2	1	0	2	2	1	1	0	2	2	2	1	0	2	1	0	*	*	●	●	2	1	1
73	2	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	2	1	0
74	3	2	2	1	0	1	1	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
75	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	1	0	●	●	●	●	2
76	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
77	3	2	2	1	0	1	1	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
78	3	2	1	1	1	2	2	1	1	1	2	2	1	1	1	2	1	1	0	*	●	●	●	2	1
79	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
80	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	0
81	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	2	1	1	0	●	●	●	●	2
82	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	1
83	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
84	2	2	1	1	0	1	1	1	1	0	2	2	1	1	0	2	1	0	*	*	●	●	2	1	0
85	3	1	1	1	0	1	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	2	1	0
86	3	2	1	1	1	2	2	1	1	1	2	2	1	1	1	2	1	1	0	*	●	●	●	2	1
87	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
88	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
89	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	1	1	0	●	●	●	●	2
90	3	2	2	1	1	2	2	2	1	1	2	2	2	1	1	2	1	0	*	*	●	●	2	1	1
91	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
92	3	2	1	1	0	2	2	1	1	0	3	2	1	1	0	2	1	0	*	*	●	●	2	1	1
93	3	2	2	1	1	2	2	1	1	1	2	2	2	1	1	2	2	1	1	0	●	●	●	●	2
94	3	1	1	0	0	2	1	1	0	0	3	1	1	0	0	2	0	*	*	*	●	2	1	1	0
95	3	2	2	1	1	2	2	2	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	0

96	3	1	1	1	0	2	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
97	3	2	1	1	1	1	1	1	1	1	3	2	1	1	1	2	1	1	0	*	●	●	●	2	1
98	3	2	2	1	1	2	2	1	1	1	3	2	2	1	1	2	1	0	*	*	●	●	2	1	0
99	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
100	3	2	2	1	1	2	2	2	1	1	2	2	2	1	1	2	1	1	1	0	●	●	●	●	2
101	3	2	1	0	0	2	2	1	0	0	3	2	1	0	0	2	1	0	*	*	●	●	2	1	0
102	3	1	1	1	0	2	1	1	1	0	2	1	1	1	0	2	0	*	*	*	●	2	1	1	0
103	3	2	1	1	1	2	2	1	1	1	3	2	1	1	1	2	1	1	1	0	●	●	●	●	2
104	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
105	3	1	1	0	0	1	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
106	3	2	2	1	0	2	2	1	1	0	3	2	2	1	0	2	1	0	*	*	●	●	2	1	0
107	2	1	1	0	0	2	1	1	0	0	2	1	1	0	0	2	0	*	*	*	●	2	1	1	0
108	3	2	1	0	1	2	2	1	0	1	3	2	1	0	1	2	1	1	0	*	●	●	●	2	1
109	3	2	1	1	0	2	2	1	1	0	2	2	1	1	0	2	1	0	*	*	●	●	2	1	0
110	3	2	2	1	0	2	2	2	1	0	2	2	2	1	0	2	0	*	*	*	●	2	1	1	0
*Follow ups after cutting of pile mass.                      ●Follow ups before cutting of pile mass.																									



### **1.3. Abbreviations for Master Charts**

#### **A. General**

**Sr. No.:** Serial number, **OPD:** Out Patient Department.

#### **B. Occupation**

**HW:** Housewife, **DR:** Driver, **SR:** Service, **SK:** Shop keeper, **ST:** Student, **FR:** Farmer, **RT:** Retired, **CL:** Clerk, **CJ:** Computer Job.

#### **C. Sex**

**M:** Male, **F:** Female.

#### **D. Prakruti**

**V:** Vata pradhana, **P:** Pitta pradhana, **K:** Kapha pradhana.

#### **F. Habitat**

**R:** Rural, **U:** Urban.

#### **G. Koshtha**

**Mr:** Mrudu, **Md:** Madhya, **Kr:** Krura.

#### **H. Agni**

**M:** Manda, **V:** Vishama, **T:** Tikshna, **S:** Sama.

#### **H. Diet**

**M:** Mixed diet, **V:** Vegetarian diet.

#### **I. Type of piles**

**I:** Internal, **E:** External, **I+E:** Internal + External, **T:** Thrombosed.

## 2. WRITTEN CONSENT (English)

**Written Consent Form**

**Ph.D. Training & Research TMV, Pune.**

Myself Mr. / Mrs. \_\_\_\_\_

Here by give my full consent for participation in the research project titled “**Role of Aloe Vera Ksharasutra in the management Arsha.**” The attending Surgeon has explained me the purpose of the clinical trial and the nature of procedure to my satisfaction.

I am also aware of my right to refuse the trial at any time during the course of the trial without having to give reasons for doing so. I am willing to undergo any risk for inclusion in this study.

All the benefits involved; possible dangers & side effects have been explained to me by doctor in easy terminology. I am also aware of my right to discontinue the trial at any stage during the course of study without giving any reasoning.

I am giving this consent without any burden or compulsion.

**Signature**

**Name**

**Date**

**Place**

## WRITTEN CONSENT (Marathi)

संमति पत्रक

Ph.D. Training & Research TMV, Pune.

मी खाली सही करणार .- - - - -

असे लिहून देत आहे की, या संशोधनाचा विषय “**Role of Aloe Vera Ksharasutra in the management Arsha.**” याच्याशी संबंधित आहे. सदर संशोधन अभ्यासक्रमातील माझा सहभाग पूर्णपणे माझ्या इच्छेवर अवलंबून आहे. त्या बाबतीत मी पूर्णपणे स्वतंत्र आहे. याची माहिती मला पूर्णपणे समजावून सांगितली आहे व ती मला मान्य आहे.

यासाठी आवश्यक असणारी वैयक्तिक माहिती मी कुठल्याही अटी विना देण्यास तयार आहे. सदर संशोधनातून प्राप्त होणारे परिणाम आणि निकाल हे संशोधनासाठीच वापरले जातील. सदर सहभागासंबंधीची संपूर्ण माहिती गुप्त ठेवली जाईल, याची मला व माझ्या कुटुंबियांना खात्री आहे.

सदर संशोधनाच्या मला कुठल्याही प्रकारची इजा झाल्यास अथवा धोका निर्माण झाल्यास माझी किंवा माझ्या कुटुंबियांची संशोधन अभ्यासक्रमात सहभागी असणाऱ्या कुठल्याही डॉक्टर, नर्स किंवा हॉस्पिटल मॅनेजमेंट यांच्या विरुद्ध कुठल्याही प्रकारची तक्रार नसेल.

या संशोधन अभ्यासामध्ये सहभागी होण्यास मला किंवा माझ्या कुटुंबियांना कोणताही आर्थिक मोबदला दिला जाणार नाही.

या संशोधनात सहभागी होण्यास माझी कोणत्याही दबावाशिवाय पूर्णपणे सहमती आहे.

सही

नाव

दिनांक

ठिकाण

### 3. CASE RECORD FORM

#### DEPARTMENT OF SHALYATANTRA

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#### TILAK MAHARASHTRA UNIVERSITY

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#### “Role of Aloe Vera Ksharasutra in the Management of Arsha.”

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Case No.

Group: A / B

Date: / /201

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#### A. BASIC INFORMATION

**Name:**

**Age: Gender:** Male/Female

**Address:**

**Contact No.**

**Occupation:** CJ/CL/DR/FR/HW/RT/SK/SR/ST

**Habitat:** Rural / Urban

**DOA:** / /201

**DOD:** / /201

**OPD No.**

**IPD No.**

---

#### B. HISTORY OF PATIENT:

##### B.1. Chief Complaints: (along with grade)

- **Pain** : Yes / No (If yes, Grade – 0 / 1 / 2 / 3)
- **Discharge** : Yes / No (If yes, Grade – 0 / 1 / 2 / 3)
- **Irritation** : Yes / No (If yes, Grade – 0 / 1 / 2 / 3)

##### B.2. H/O Present illness:

##### B.3. H/O Past illness:

**B.3. Kulaj vritta:**

- Matruj –
- Pitruj –
- Swa –

**B.4. History of Treatment:**

**A. Medical –**

**B. Surgical –**

**B.5. Personal History:**

- **Diet:** Vegetarian / Mixed Diet
- **Sleep:** Sound / Good / Disturbed
- **Nature of Job:** Sedentary / Moderate / Hard / Travelling
- **Addiction:** Smoking / Alcohol / Tobacco / Gutakha / Other
- **Allergies:**
- **Hobbies:**

---

**C. EXAMINATION OF PATIENT**

**C.1. General Examination**

**Weight:**      **Kg**      **BP:**      /      **mm of Hg**      **Pulse:**      /**min**

**Temperature:**      <sup>0</sup>**F**      **Prakruti:**      **Koshtha:**      **Agni:**

**Other:** Koilonychia / Pallor / Icterus / Clubbing / Cyanosis / Edema / NAD

## **C.2. Ashtavidha Parikshana**

**Nadi:**

**Mala:**

**Mutra:**

**Jivha:**

**Shabda:**

**Sparsha:**

**Druk:**

**Akruti:**

## **C.3. Dashavidha Parikshana**

### **1. Parkruti**

**Sharira:** Vata pradhana / Pitta pradhana / Kapha pradhana

**Manasa:** Satvik / Rajas / Tamas

### **2. Sara**

a) Pravar                      b) Madhyam                      c) Avar

### **3. Samhanan**

a) Pravar                      b) Madhyam                      c) Avar

### **4. Satva**

a) Pravar                      b) Madhyam                      c) Avar

### **5. Aahar Shakti**

a) Pravar                      b) Madhyam                      c) Avar

### **6. Satmya**

a) Pravar                      b) Madhyam                      c) Avar

### **7. Vaya**

a) Bala                      b) Yuva                      c) Vruddha

### **8. Agni**

a) Sama b) Vishma c) Tiksha d) Mandha

### **9. Vyayam shakti**

a) Parvar                      b) Madhyam                      c) Avar

### **10. Vikruti**

#### **C.4. Systemic Examination:**

- CNS –**
- CVS –**
- RS –**
- Ano–recatal –**
- P/A –**

#### **C.5. Local Examination:**

1. Position of piles
2. No of piles
3. Bleeding
4. Itching
5. Tenderness
6. Size & shape of piles
7. Color of piles
8. Bleeding on Touch

#### **C.6. INVESTIGATIONS**

1. Hemoglobin:
2. Total WBC count:
3. Differential count: N:            B:            E:            L:            M:
4. ESR:
5. B.T.:                                    C.T.:
6. BSL (R):                                USL (R):
7. H.I.V. Test:
8. HBsAg:
9. Sr. Creatinine:
10. Urine (R & M):
11. Stool (R & M):

**D. VYADHI NIDAN: Arsha (Hemorrhoids)**

**Type:** Internal / External / Both / Thrombosed

---

**E. CHIKITSA**

<b>Sr. No.</b>	<b>Subject</b>	<b>Group A</b>	<b>Group B</b>
<b>1.</b>	<b>Group Type</b>	<b>Trial Group</b>	<b>Control Group</b>
<b>2.</b>	<b>Name of Drug</b>	Aloe Vera Ksharasutra	Snuhi Kshira Ksharasutra
<b>3.</b>	<b>Method</b>	Ligation	Ligation
<b>4.</b>	<b>Follow up</b>	Day: 1, 3, 5, 7, 9	Day: 1, 3, 5, 7, 9

---

**F. OBSERVATION TABLES**

<b>Sr. No.</b>	<b>Subjective Parameter</b>	<b>Follow Up (Day)</b>				
		<b>D1</b>	<b>D3</b>	<b>D5</b>	<b>D7</b>	<b>D9</b>
<b>1</b>	<b>Pain</b>					
<b>2</b>	<b>Discharge</b>					
<b>3</b>	<b>Irritation</b>					
<b>4</b>	<b>Cutting</b>					
<b>5</b>	<b>Healing*</b>					

---

**STUDENT SIGN**

**GUIDE SIGN**

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## 5. DRUG AUTHENTICATION REPORTS

### REPORT 1

#### AUTHENTIFICATION OF KUMARI

**Latin Name:** - Aloe vera

**Family:** - Liliaceae

**Synonyms:** - Kanya, Gruhkanya, Gruhkumari, Ghrutkumari, Deerghapatrika, Sthleruha, Bahupatra, Sukantaka, Mrudu, Kapila etc.

**Vernacular Names:** -

English: - Common Indian Aloe, Musabbar.

Hindi: - Ghikuaar, Gwar patha, Ghigwar.

Marathi: - Korphad.

Gujarati: - Kunwar.

**Parts Used:** - Patra

**Properties:**

**Rasa** – Tikta, Madhur

**Vipak** – Madhur

**Veerya** - Sheeta

**Guna** – Guru, Snigdha, Picchila.

**Doshghnata** – Tridoshashamak.

**Karma** –

Vedanasthapana, Shothahar, Vranashodhan, Ropana, Deepana, Pachana, Bhedana, Balya, Bruhan etc.

**Chemical Constituents:** -

All Aloe species contain anthraquinone glycosides. Barbaloin (aloe-emodin anthrone C-10 glucoside) is the major active constituent. Aloes also contain isobarbalin, aloe-emodin, resins, aloetic acid, homonataloin aloe-sone, chrysophanic acid, chrysamminic acid, galactouronic acid, choline choline salicylate, saponins, mucopolysacchrides, glucosamines, hexuronic acid, coniferyl alcohol.

**Identified By: Dr. Maruti Narhare**  
**(MD Rasashastra)**

  
**READER**  
Rasa Shastra Evum Ghaishajya Kalpana Dept.  
Late. Babruwan Vitthalrao Kale  
Ayurved Medical College  
& Hospital Latur

## REPORT 2

### AUTHENTICATION OF SNUHI

**Latin Name:** Euphorbia nerifolia Linn.

**Family:** Euphorbiaceae

**Gana:** Charak – Virechana, Shatshodhan Vruksha

**Sushruta –** Adhobhaghar, Shyamadi etc.

**Synonym:** Snuhi, Vajra, Vijari, Snuk, Sudha.

**English:** - Common milkhedge.

**Hindi:** - Thuhar, Sehund, sij.

#### **Morphology:**

It is large succulent shrub or small tree up to 20 ft. The stem and branches are of the shape of round and covered with thorns. Its leaves are fleshy, deciduous, ovate- oblong 6-12 inches long. The flowers are yellow in colour. Its seeds are flat and consisting of hairs.

**Part used:** Latex and root

#### **Properties:**

**Ras:** Katu, Tikta

**Virya:** Ushna

**Vipaka:** Katu

**Guna:** Laghu, Ruksha

**Doshaghna:** Kaphavataghna

**Karm:** Lekhan, Vedanasthapana, Shothahar, Raktashodhana, Vishaghna etc.

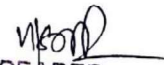
#### **Chemical Constituents:**

Euphorban, resin, gum, malate of calcium etc.

#### **Chemical Constituents of Latex:**

1. Totalsolid	:	29.57%w/w
2. Watersoluble substance	:	8.14%w/w
3. Dryrubber content	:	21.43%w/w
4. Resincontent	:	13.81%w/w
5. Ashvalue	:	1.17%w/w
6. Acidinsolubleash	:	trace
7. Caoutchouc (rubberhydrocarbon)	:	0.42%w/w

**Identified By: Dr. Maruti Narhare**  
(MD Rasashastra)

  
READER  
Asst. Shastra Evum Bhaishajya Kalpana Dept.  
Late. Babruwan Vitthalrao Kale  
Ayurved Medical College  
& Hospital, Latur

## REPORT 3

### AUTHENTICATION OF APAMARGA

**Botanical name:** Achyranthus aspera Linn

**Family:** Amaranthaceae.

**Gana – Charak –** Shirovirechana, Krumighna, Vamanopaga.

**Sushrut –** Arkadi.

**Sansrit Name –** AdhaShalya, Kharamanjari, Mayuraka, Markati, Durgraha, Pratyakpushpee, Shikhari, Kiniha, Kandakanta, Markatpippali.

**English –** Prickly-chaff flower, rough chafftree.

**Hindi –** Chirchira, Chirchitta, Latjira, Chirachiri

**Morphology:** Throughout India, up to an altitude of 2100 meters and in the south Andaman Island, commonly found as a weed on waysides and waste places.

**Parts used –** Whole plant

**Properties:**

**Rasa –** Katu, Tikta

**Veerya -** Ushna

**Vipaka -** Katu

**Guna –** Laghu, Ruksha

**Doshghnata –** Kaphavataghna

**Karma –** Deepana, Pachana, Vatanulomana, Kaphavilayan, Srotorodhnashak, Mootral, Lekhan, Vishaghna etc.

Achyranthes aspera contains triterpenoid saponins which possess oleanolic acid as the aglycone. Ecdysterone, an insect moulting hormone, and long chain alcohols are also found in Achyranthes aspera.

Other chemical constituents such as achyranthine, betaine, pentatriacontane, 6-pentatriacontanone, hexatriacontane, and tritriacontane are also present.

**Identified By: Dr. Maruti Narhare**  
**(MD Rasashastra)**

  
**READER**  
Rasa Shastra Evam Bhaishajya Kalpana Dept  
Late. Babruwan Vitthalrao Kale  
Ayurved Medical College  
& Hospital, Latur

## REPORT 4

### AUTHENTICATION OF HARIDRA

**Latin name:** Curcuma longalinn.

**Family:** Sciataminaceae

**Gana:** Charak – Kushthaghna, Kandughna, Vishghna, Tiktaskandha, Shirovirechana,

**Sushrut** – Haridradi, Mustadi, Shleshmasanshamana etc.

**Synonyms:** Rajani, Gauri, Varnavat, Haridra, Nisha, Kanchani, Varvarmini, Krumighna, Yoshitapriy Hattavilasinee etc.

**English:** - Indian Saffron, Turmeric

**Hindi:** - Haldi

**Morphology:**

It is a tall herb and leaves are very large, flowers are half inch in length. Its seeds are round and knott and root stalks are large, cylindrical tubers and orange coloured inside. It is extensively cultivated all over In and south Asian countries.

**Part used:** Tubers

**Properties:**

**Rasa:** Tikta, Katu

**Veerya:** Ushna

**Vipaka:** Katu

**Guna:** Ruksha, Laghu

**Doshagnata:** Kaphapittashamak

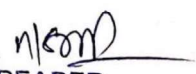
**Karma:**

Shothahar, Vedanasthapana, Vranapachana, Shodhana, Ropana, Sadnyasthapana, Rochana, Deepa Garbhashayshodhan, Vishaghna etc.

**Chemical Constituents:**

Essential oils, alkaloids and a colouring matter (curcumin). Oil does not contain any phenol, aldehyde or ketones. Caproic acid and valeric acid are found.

**Identified By: Dr. Maruti Narhare**  
(MD Rasashastra)

  
**READER**  
Rasa Shastra Evam Ghaishajya Kalpana Dept.  
Late. Babruwan Vitthalrao Kale  
Ayurved Medical College  
& Hospital, Latur

## 6. DRUG STANDARDIZATION REPORTS

### REPORT 1



## हाफकिन प्रशिक्षण, संशोधन व चाचणी संस्था

महाराष्ट्र शासन अनुदानित सोसायटीज् रजिस्ट्रेशन अंकेट १८६० अधिनियमान्वये नोंदणी कृत स्वायत्त संस्था  
भारत सरकार, विज्ञान व प्रौद्योगिक मंत्रालय, मान्यताप्राप्त "वैज्ञानिक आणि औद्योगिक संशोधन संस्था"

## Haffkine Institute for Training, Research & Testing

An Autonomous Institute of Govt. of Maharashtra Registered under Societies Registration Act 1860

Recognised as "Scientific & Industrial Research Organisation" (SIRO) by Govt. of India, Ministry of Science & Technology.



Date: 12.06.2018

To,  
Vd. Dr. Dharmapal Patil,

### Subject: Gas Chromatography analysis of samples

All samples provided by you were analyzed on Agilent Gas chromatography  
(Model: 7890) equipped with Auto sampler system as per your requirement.

Test Name: GC analysis

GC Conditions			
Column section	HP-5MS column(30m X 250µm X 0.25µM)		
Oven temperature	Rate(°C/min)	Temperature(°C)	Hold time (min)
	0	50	2
	10	300	3
Injection mode	Split mode, split ratio 90:1		
Injection temperature	300°C		
Injection volume	1.5µl		
Carrier gas	1.5µl		
Detector temperature	300°C		

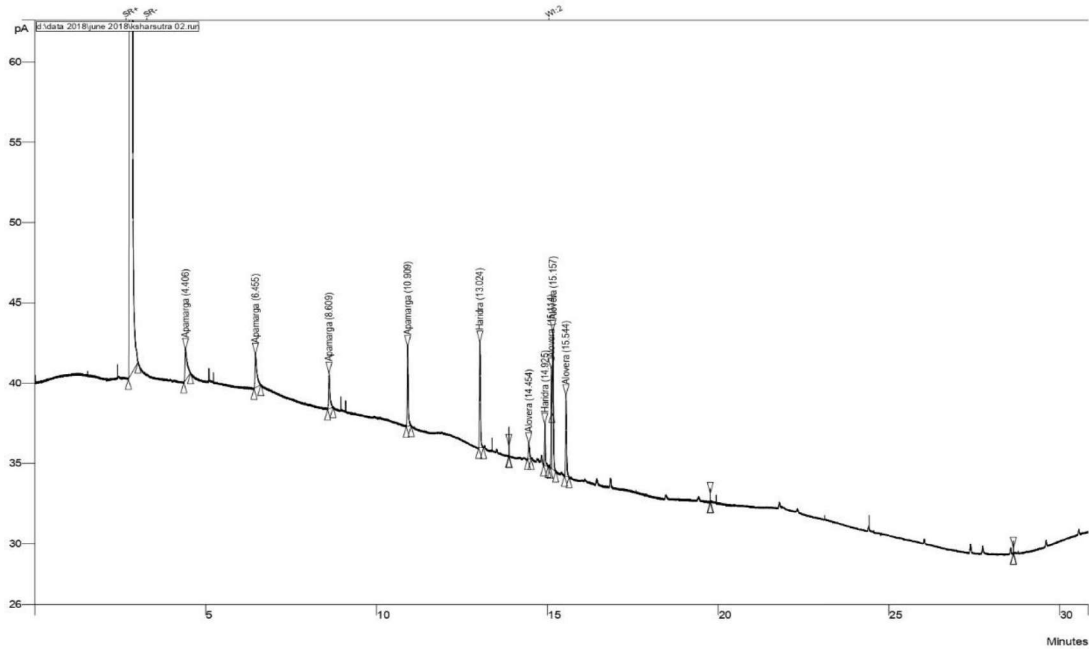
Results: Results attached.

The entire are test performs according to standard method. In case of any query regarding results please contact us at [ashish@haffkineinstitute.org](mailto:ashish@haffkineinstitute.org)

पत्ता : आचार्य दोंडे मार्ग, परळ, मुंबई - ४०० ०१२. दूरध्वनी क्र. ०२२-२४१६०९४७, २४१६०९६१, २४१६०९६२, फॅक्स - ०२२-२४१६१७८७  
Address : Acharya Donde Marg, Parel, Mumbai - 400 012. Tel: 022 - 24160947, 24160961, 24160962. Fax : 022 - 24161787  
email : [haffkineinstitute@gmail.com](mailto:haffkineinstitute@gmail.com), website: [www.haffkineinstitute.org](http://www.haffkineinstitute.org)



# REPORT 2



Print Date: Tue Jul 03 10:58:25 2018 Page 1 of 1

Title :  
 Run File : d:\data 2018\june 2018\ksharsutra 02.run  
 Method File : c:\users\admin\desktop\ksharsutra 02-1.mth  
 Sample ID : Ksharsutra 02

Injection Date: 02-07-2018 16:44 Calculation Date: 03-07-2018 10:56

Operator : CHEMO Detector Type: 7890A GC  
 Workstation: DATA Bus Address : 44  
 Instrument : 7890 GCMS Sample Rate : 50.00 Hz  
 Channel : 1 = Front FID Run Time : 30.837 min

\*\* MS Workstation Version 7.0.1 \*\* 10002-6A85-369-47D0 \*\*

Run Mode : Analysis  
 Peak Measurement: Peak Area  
 Calculation Type: Percent

Peak No.	Peak Name	Result ( )	Ret. Time (min)	Time Offset (min)	Area (counts)	Sep. Code	Width 1/2 (sec)	Status Codes
1	Apamarga	9.3267	4.406	0.000	8597	BB	0.0	
2	Apamarga	8.6087	6.455	-0.001	7935	BB	3.2	
3	Apamarga	6.5602	8.609	-0.000	6047	BB	2.2	
4	Apamarga	10.8639	10.909	-0.000	10014	BB	1.7	
5	Haridra	13.5736	13.024	-0.000	12512	BB	1.7	
6	Alovera	2.6723	14.454	0.000	2463	BB	2.3	
7	Haridra	5.1643	14.925	-0.000	4760	BB	1.6	
8	Alovera	11.8575	15.114	0.000	10930	BV	1.6	
9	Alovera	19.5866	15.157	0.000	18054	VB	2.0	
10	Alovera	11.7861	15.544	0.000	10864	BB	1.9	
Totals:		99.9999		-0.001	92176			

Total Unidentified Counts : 0 counts

Detected Peaks: 13 Rejected Peaks: 3 Identified Peaks: 10

Multiplier: 1 Divisor: 1 Unidentified Peak Factor: 0

Baseline Offset: 40.041 pA LSB: 1 fA

Noise (used): 385 fA - monitored before this run

Vial: 1 Injection Number: 1 Volume: 1.00 uL Position: Front

\*\*\*\*\*

## REPORT 3



### हाफकिन प्रशिक्षण, संशोधन व चाचणी संस्था

महाराष्ट्र शासन अमुदायित सोसायटीज् एजिट्रेशन अॅक्ट १८६० अधिनियमान्त्ये मोंदणी कृत स्वायत्त संस्था  
भारत सरकार, विज्ञान व प्रौद्योगिक मंत्रालय, मान्यताप्राप्त "वैज्ञानिक आणि औद्योगिक संशोधन संस्था"

### Haffkine Institute for Training, Research & Testing

An Autonomous Institute of Govt. of Maharashtra Registered under Societies Registration Act 1960  
Recognised as "Scientific & Industrial Research Organisation" (SIRO) by Govt. of India, Ministry of Science & Technology.



Date: 17.07.2018

To,  
Ph.D. Scholar - Dr. DHARMPAL T. PATIL,

#### Subject: Physicochemical analysis of samples

Project Title - Role of Aloe vera, Ksharsutra in the management of Arsha.

All samples provided by you were analyzed for Physico-chemical properties.




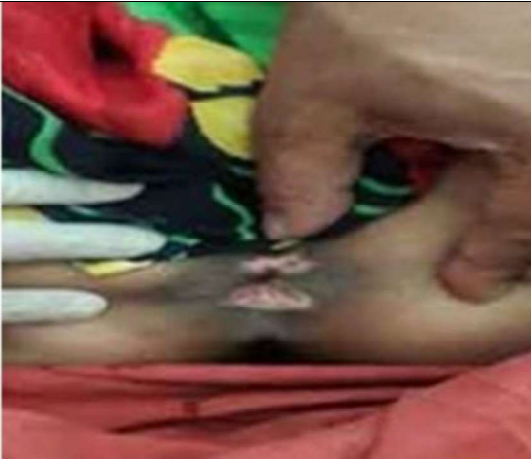


Test Name: Physico-chemical test report

Name of Test	Results
Loss on Drying	Moisture content – 11.12%
% Acid-insoluble ash	30.95%
pH value	pH- 7.65
Solubility	Water- 7.356% Methanol-20.300% DMSO- 35.958%
Presence Na, K etc.	Absent

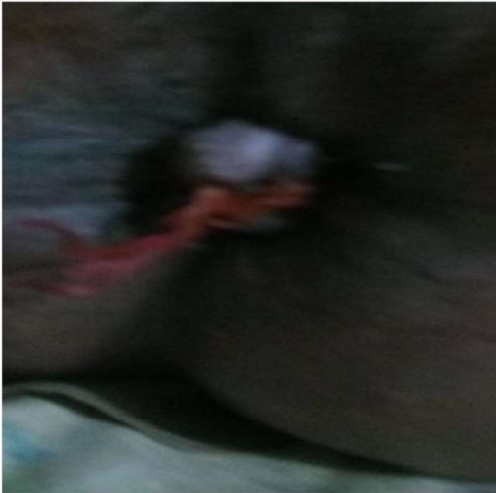



पत्ता : आचार्य दोंदे मार्ग, परळ, मुंबई - ४०० ०१२. दूरध्वनी क्र. ०२२-२४१६०९४७, २४१६०९६१, २४१६०९६२, फॅक्स - ०२२-२४१६१७८७  
Address : Acharya Donde Marg, Parel, Mumbai - 400 012. Tel: 022 - 24160947, 24160961, 24160962. Fax : 022 - 24161787  
email : haffkineinstitute@gmail.com, website: www.haffkineinstitute.org

## 7. SAMPLE PHOTOGRAPHS

### A. Trial Group

<p><b>Case No. 7.</b> <b>(BT &amp; AT)</b></p>		
<p><b>Case No. 20.</b> <b>(BT &amp; AT)</b></p>		
<p><b>Case No. 42.</b> <b>(BT &amp; AT)</b></p>		

**B. Control Group**

<p><b>Case No. 75.</b>  <b>(BT &amp; AT)</b></p>		
<p><b>Case No. 93.</b>  <b>(BT &amp; AT)</b></p>		
<p><b>Case No. 101.</b>  <b>(BT &amp; AT)</b></p>	