

**“A CLINICAL STUDY TO EVALUATE THE EFFECT OF APAMARGA
TIKSHNA PRATISARNIYA KSHARA AND DANTYARISHTA IN GUDA
ARSHA (HAEMORRHOIDS)”**

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ABSTRACT

In *Samhitas Acharyas Charak, Sushruta and Vagbhata* have given great description about *Arsha* and their management but still there is need to evaluate an efficient therapy for management of *Arsha*. Haemorrhoids are caused by increased straining or intra-abdominal pressure or extended periods of sitting. Worldwide, the prevalence of symptomatic haemorrhoids is estimated at 4.4% in the general population. Its incidence increases with advancing age. In *Ayurveda*, *Sushruta* states four modalities i.e. *Bhaishaja chikitsa*, *Kshara karma*, *Agnikarma* and *Shastra karma*. Among these, *Kshara Karma* modality is the best one. Application of *Pratisarniya Tikshna Kshara* is a non-surgical procedure of *Ayurveda* indicated for the management of *Arshas*. This study was conducted clinical evaluation of *Apamarga Tikshna Pratisarniya Kshara and Dantyarishta in Guda Arsha*(Haemorrhoids). This clinical study was performed on 30 patients in a single group with *Apamarga Tikshna Pratisarniya Kshara* and

Dantyarishta on each patient selected from the OPD of the Department of *Shalya Tantra*, *Patanjali Bhartiya Ayurvedigyan Evam Anusandhan Sansthan*, Haridwar. Assessment was done before and after treatment by the subjective and objective parameters. For statistical analysis, Wilcoxon signed rank test, Paired t test and Friedman's Test were used. There are four

Subjective criteria i.e. bleeding per rectum, prolapse of pile mass, pain in anal region and constipation on which highly significant relief of *Apamarga Tikshna Pratisarniya Kshara* and *Dantyarishtha* has been found. Out of 30 patients, 25 patients i.e. 83.33 % were complete improvement followed by 05 patients i.e. 16.66% were marked improvement after the completion of the course as well as follow up period.

KEYWORDS: *Arsha, Constipation, Bleeding per rectum, Apamarga Tikshna Pratisarniya Kshara and Dantyarishtha*

INTRODUCTION

Ayurveda, known as "the science of life," has evolved in this nation from ancient times. Early humans adopted various approaches and therapies to address their health issues. These practices gradually evolved into a medical system known as *Ayurveda*. Among its branches, *Shalya Tantra* holds particular significance. This branch is characterized by its swift and effective nature, employing diverse methods such as *Yantra*, *Shastra*, *Kshara*, and *Agni* to achieve therapeutic outcomes. *Sushruta*, the author of the *Sushruta Samhita*, has made a substantial contribution to the field of surgery. This ancient text possesses its own distinctive originality and authenticity, enriching the foundation of modern medical expertise in the present era.

The *Sushruta Samhita* stands as the sole available *Ayurvedic* manuscript within the realm of surgical practice, enriched with comprehensive foundational surgical techniques and adjunctive measures. When it comes to the management of illnesses, it has been observed that there exist numerous ailments that prove challenging to address solely through conservative treatments. Among these, *Arsha* (piles) is one such serious condition that *Sushruta* has included in the *Ashta Mahagada*. The *Ashta Mahagada* outlines eight ailments—*Vatavyadhi*, *Prameha*, *Kushtha*, *Mudha Garbha*, *Arsha*, *Bhagandara*, *Ashmari*, and *Udara Roga*—as grievous diseases. This highlights the gravity of the ailment. Notably, even the World Health Organization (WHO) has designated November 20th of each year as "World Piles Day," underscoring the global prevalence of this condition and the considerable physical and mental distress it inflicts upon individuals.

NEED FOR STUDY

In accordance with traditional view points, the *Kshara Pratisaran* procedure is renowned for its profound therapeutic impact on *Arsha* (haemorrhoids). This underlines the necessity to

meticulously examine and analyze a compilation of literature from both *Ayurveda* and contemporary science to comprehensively elucidate the effects of *Kshara Karma* through clinical approaches. While limited research has been conducted on *Kshara* applications, the outcomes of these studies have demonstrated promising efficacy, further reinforcing the potential of these procedures.

WHY THIS TOPIC WAS SELECTED?

In modern perspective, there are various multi folded conservative treatment modalities are present with its own advantages and disadvantages. Therefore, there is an intense and persistent scope to find out a simple treatment for preventing these diseases without side effect. Hence, keeping this thing in view, *Apamarga Tikshna Pratisarniya Kshara* for local application and *Dantyarishtha* for oral use have been selected for manage this debilitating disorder of *Guda Arsha* (Haemorrhoids).

AIMS AND OBJECTIVES

1. To explore literature about the *Guda Arsha* in *Ayurvedic* classics and Haemorrhoids in modern medical literature.
2. To evaluate the efficacy of *Apamarga Tikshna Pratisarniya Kshara* (locally) and *Dantyarishtha* (orally) in *Guda Arsha* (Haemorrhoids).
3. To introduce a simple, safe, cost-effective, complication free, less irritant and best alternative modality in the management of *Guda Arsha*.

AYURVEDIC REVIEW

Arsha could be traced in the *Vedic* literature as this disease has been described as ‘*Durnam*’ in ‘*Atharvaveda*’. Hymans related to *Garbh Dosha Nivarana* indicate affection of pudendal organ with “*Durnam*” in pregnant ladies. *Acharya Sushruta* has narrated it in the *Astamahagadas*. *Acharya Charka* has also devoted a chapter to this entity. He has explained vividly the medical management. *Acharya Vagbhata* has also mentioned about the disease in the best sum from *Acharya Charka* and *Acharya Sushruta* compendia, later on, *Chakradatta*, *Rastarangini*, *Madhava* have described.

MODERN REVIEW

Acharya Sushruta was the first specialist who portrayed the detailed writing with respect to the careful procedure in the administration of haemorrhoids. Ancient Egyptian, Greeks, Hebrews and Indians referred to Haemorrhoids in their writings. It is coded as Hammurabi in Babylon

in 2250 BC and in the Papyrus of Eber in about 1500 BC. In 19th century Verneuil (1855), Daret (1879) marked the birth of proctology with anatomically based and physiological reasoned hypothesis on haemorrhoid formation. Piles are certainly one of the common ailments that trouble mankind since long. In this regard, different views are noted. It is difficult to obtain any accurate idea of their incidence, but clinical experience suggests that many people of both sexes suffer from haemorrhoids. Treatments for haemorrhoids vary in their cost, risk and effectiveness. Haemorrhoids have been treated by various methods. Depending on their stage, haemorrhoids currently benefit from wide therapeutic possibility ranging from standard hygiene and dietetic rules to surgery.

Two Measures are highlighted for the Management:

1-Preventive Measures 2-Curative Measures

DRUG REVIEW

Apamarga Kshara

Drug name	Botanical name	Family	Part used
<i>Apamarga</i>	<i>Achyranthes aspera</i>	Amaranthaceae	<i>Kshara of Apamarga plant</i>

Mode of Action of *Apamarga*

Drug name	Rasa	Guna	Vipaka	Veerya	Prabhava
<i>Apamarga Plant</i>	<i>Katu, Tikta</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Katu</i>	<i>Usna</i>	<i>Kapha- Vatashamaka, Kaphapittasansodhana</i>

Dantyarishhta

Content Name	Rasa	Guna	Vipaka	Veerya	Indication
<i>Danti</i>	<i>Katu</i>	<i>Guru, Tikshna</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphapittahara</i>
<i>Chitraka</i>	<i>Katu</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka, Pittavardhaka</i>
<i>Bilva</i>	<i>Kashaya, tikta</i>	<i>Laghu, Ruksha</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka</i>
<i>Agnimantha</i>	<i>Tikta, Katu, Kashaya, Madhura</i>	<i>Ruksha, Laghu</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka</i>
<i>Shyonaka</i>	<i>Madhura, Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka</i>
<i>Patala</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Katu</i>	<i>Usna</i>	<i>Tridoshshamaka</i>
<i>Gambhari</i>	<i>Tikta, Kahsaya, Madhura</i>	<i>Guru</i>	<i>Katu</i>	<i>Usna</i>	<i>Tridoshshamaka</i>
<i>Brihati</i>	<i>Katu, Tikta</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka</i>
<i>Kantakari</i>	<i>Tikta, Katu</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Katu</i>	<i>Usna</i>	<i>Kaphavataashamaka</i>
<i>Gokshura</i>	<i>Madhura</i>	<i>Guru, Snigdha</i>	<i>Madhura</i>	<i>Sheet</i>	<i>Vatapittashamaka</i>
<i>Shalaparni</i>	<i>Madhura, Tikta</i>	<i>Guru, Snigdha</i>	<i>Madhura</i>	<i>Usna</i>	<i>Tridoshshamaka</i>
<i>Prishnaparni</i>	<i>Madhura, Tikta</i>	<i>Laghu, Snigdha</i>	<i>Madhura</i>	<i>Usna</i>	<i>Tridoshshamaka</i>
<i>Haritaki</i>	<i>Panchrasa (Except Lavana), Kashaya Pradhana</i>	<i>Laghu, Ruksha</i>	<i>Madhura</i>	<i>Usna</i>	<i>Tridoshhara</i>
<i>Vibhitaki</i>	<i>Kashaya</i>	<i>Ruksha, Laghu</i>	<i>Madhura</i>	<i>Usna</i>	<i>Tridoshhara, but mainly kaphashamaka</i>
<i>Amalaki</i>	<i>Panchrasa (Except Lavana), Amla Pradhana</i>	<i>Guru, Ruksha, Sheet</i>	<i>Madhura</i>	<i>Sheet</i>	<i>Tridoshhara but mainly Pittashamaka</i>

MATERIALS AND METHODS

For the clinical study, patients were selected from the OPD and IPD of Shalya Tantra Department Patanjali Bhartiya Ayurvigyan Evam Anusandhan Sansthan, Haridwar.

Type of study: open prospective study.

Level of study: O.P.D. and I.P.D. level.

Sample size: 30 patients were taken for the open study.

Inclusion Criteria

- Patients with age ranging from 18 to 60 years.
- The patients having complaints of I and II, III degree internal hemorrhoids were taken for the study after screening.
- Patients willing to undergo trial and ready to give informed and written consent.

Exclusion criteria

- Patients below the age of 18 years.
- IV degree internal pile.
- Pregnancy
- Congenital deformity
- Known case of Carcinoma
- Known case of Tuberculosis
- Known case of Heart disease
- Rectal prolapse
- Patients suffering from systemic diseases such as HIV, Ulcerative colitis, Crohn's disease, Cirrhosis of liver, Diabetes mellitus and Carcinoma of rectum were excluded from this study.
- External thrombosed pile
- The associated condition like Fistula-in-ano, were excluded from this study.

Follow Up

Patient was taken for Follow up after a week, then onwards once in 15 days for the next 2 months. The follow up period was of 02 months and 07 days.

1st visit: 07 days after the completion of treatment

2nd visit: 15 days after 1st visit

3rd visit: 15 days after 2nd visit

4th visit: 15 days after 3rd visit

5th visit: 15 days after 4th visit

PROCEDURE OF APAMARGA KSHARA PRATISARANA

PURVAKARMA PRADHANA KARMA PASHCHAT KARMA

CRITERIA FOR ASSESSMENT

Subjective Parameters Objective Parameters

OBSERVATION

In this present clinical study, 30 patients of *Guda Arsha* were registered. All 30 patients are completed the full course of trial and the whole course of therapy. So, the present data are analysed on the basis of total 30 patients.

While taking diet into consideration there were two groups were observed vegetarian and mixed diet. It was observed in the study that maximum numbers of patients were taking mixed diet 19 (63.33%) and 11 (36.66%) patients were habituate to taken vegetarian diet.

While considering the bowel habitat, it was found in the study that maximum numbers of patients were constipated bowel habitat i.e. 25 (83.33%) and 05 (16.66%) patients were irregular bowel habitat.

While considering the Working nature, it was found in the study that maximum numbers of patients were 23 (76.66 %) have given the history of sedentary life style. While 04 (13.33 %) patients were having long standing nature of work and 03 (10%) were having physical labourer.

RESULTS

Effect on symptoms of Bleeding per rectum

In this study, we have used Wilcoxon Signed Rank test to test efficacy of the drug. The initial median rank of bleeding per rectum observed was 1 before treatment, which was brought down to 0.00 after treatment. The percentage of relief after treatment was 88%. We can observe that P value is < 0.001 i.e. less than .001. Hence, we can conclude that the efficacy of drug was Highly Significant.

Effect on symptoms of Prolapse of pile mass

The initial median rank of prolapse of pile mass observed was 2 before treatment, which was brought down to 0.00 after treatment. The percentage of relief after treatment was 90%. We can observe that P value is < 0.001 i.e. less than .001. Hence we can conclude that the efficacy of drug was Highly Significant.

Effect on symptoms of Pain in anal region

The initial median rank of pain in anal region observed was 2 before treatment, which was brought down to 0.00 after treatment. The percentage of relief after treatment was 91%. We can observe that P value is < 0.001 i.e. less than .001. Hence, we can conclude that the efficacy of drug was Highly Significant.

Effect on symptoms of Constipation

The initial median rank of constipation observed was 2 before treatment, which was brought down to 0.00 after treatment. The percentage of relief after treatment was 86%. We can observe that P value is < 0.001 i.e. less than .001. Hence, we can conclude that the efficacy of drug was Highly Significant.

Overall effect of the therapy

Sr. No	Result	No. of patients	Percentage
1	Complete improvement (Cured)	25	83.33
2	Marked improvement	05	16.66
3	Moderate improvement	00	00
4	Mild improvement	00	00
5	Unchanged	00	00

On the basis of the specific scoring pattern adopted, the total effect of therapy had been assessed. Out of 30 patients, 25 patients i.e. 83.33 % were complete improvement followed by 05 patients i.e. 16.66% were marked improvement after the completion of the course as well as follow up period.

DISCUSSION

Diet

Maximum number of patients i.e. 63.33% were having mixed diet and rest of 36.66% were vegetarians. These observation shows that mixed diet doesn't contain much fibrous food stuff and due to that constipation may occur and ultimately piles may be developed.

Bowel habit

Maximum 83.33% were reported constipated bowel habit and 16.66% had given history of irregular bowel habit. The constipation and hard stool demand more straining during the defaecation which increases the rectal pressure and formation of piles ultimately. This indicates that constipation which is the main cause of *Arsha*.

EFFECT OF THERAPY ON CLINICAL FEATURES

Effect of Therapy on Painful Defaecation

91% improvement was observed on 67th day(After Treatment). Painful defaecation might be taken care off due to *Ksharana*, *Pachana*, *Amahara*, and *Tri Doshahara* properties of *Apamaga Kshara*. In *Dantyarishta* formulation, the ingredients are- *Danti root*, *Chitaraka root*, *Brihthapanchmool*, *Triphala* etc. Almost all of these drugs are having the property of *Deepan*, *Pachana*, *Vatanulomana*, *ushna guna* hence will have *shulaprashamana* or the pain relieving activity and are said to be the best appetizers.

Effect of Therapy on Bleeding per Rectum-

On 67th day(After Treatment), 88% improvement was observed. This is might be happened due to the properties of *Kshara* such as *Stambhana*, *Pachana* and *Dahana* mentioned in the texts to achieve haemostasis.

Effect of Therapy on Prolapse of Pile Mass:-

90% improvement was found on 67th day(After Treatment). Prolapse of pile mass might be reduced due to *Vilayana*, *Shodhana*, *Shoshana*, and *Lekhana* properties of *Kshara*. Increased size of pile mass may be reduced by virtue of *Pachana*, *Vilayana*, *Shoshana*, *Lekhana* and *Amahara* properties of *Apamarga Kshara*.

Effect Of Therapy On Constipation:

86% improvement was found on 67th day(After Treatment). In *Dantyarishta*, Drugs like *Haritaki*, help to relieve the constipation and decrease the pressure on the pile masses.

Overall Effect of the Therapies:-

Out of 30 registered patients, 83.33 % patients were completely cured (>80% relief in complaints) while marked improvement was seen in 16.66% (50-80% relief in complaints) of patients.

SUMMARY

- In present study, patients belonging to Hindu community (100%), upper middle socio-economic status (63.33%) and from semiurban habitat (50%)were high.
- Excess intake of *Madhura Rasa* (56.66%), *Mandagni*(70%),constipated bowel habit (83.33%) and mixed diet (63.33%) person contributed in high percentage in this study.
- Maximum 76.66% patients were observed job of Sedantary nature.

- Among the various habits observed consumption of tea/smoking/alcohol was seen in this study i.e. 33.33% patients were addicted to tea, 10% patients were alcoholic. *Avar Vyayama Sakti* was observed in 53.33% patients.
- Out of 30 registered patients, all patients completed the trial, among them which, 83.33% patients were found completely cured, while marked improvement was seen in 16.66% of patients.
- The initial mean score of bleeding per rectum i.e. before treatment was 6.28. Its value was reduced up to 2.90 at Day 67(after treatment) with 88% of relief. It is evident that P value is less than 0.001. Here, we can conclude that effect observed is highly significant.
- The initial mean score of the prolapse of pile mass i.e. before treatment was 6.70. Its value was reduced up to 2.80 at Day 67(after treatment) with 90 % of relief. It is evident from the table that P value is less than 0.001. Here, we can conclude that effect observed is highly significant.
- The initial mean score of pain i.e. before treatment was 6.92. Its value was reduced up to 2.98 at Day 67 (after treatment) with 91 % of relief. It is evident from the table that P value is less than 0.001. Here, we can conclude that effect observed is highly significant.
- The initial mean score of constipation i.e. before treatment was 6.48. Its value was reduced up to 2.62 at Day 67 (after treatment)with 86 % of relief. It is evident from the table that P value is less than 0.001. Here, we can conclude that effect observed is highly significant.

CONCLUSION

The present study “**A Clinical Study To Evaluate The Effect Of *Apamarga Tikshna Pratisarniya Kshara And Dantyarishtha In Guda Arsha*(Haemorrhoids)**”was carried out. After a detailed observation and discussion on the observed data, the following conclusion has been drawn:

Apamarga Tikshna Pratisarniya Kshara showed that the symptoms of pain in ano, bleeding per rectum, and prolapse of pile mass are relieved.

No adverse effects were reported by any of the patients during the course of treatment.

Tikshna Apamarga Kshara Pratisarana can be performed by cost-effective manner. Complete treatment was found as not costly.

Kshara application needs very less instruments and only surface or local infiltration, no general anesthesia or spinal anesthesia is needed as required to carry out other surgical procedures.

No hospital stay is needed and procedure can be carried out on out patient basis or one day surgery. No complications like other surgical procedures are evident here.

Dantyarishta improves the function of *pachakagni* by improving the function of *pachakapitta* and *Samanvaya*. Simultaneously it improves the function of *Apanavayu* and relieves the *Vibandha*.

Dantyarishta also acts as *shothahara* and *Vednasthapana* drug. Its potency is enhanced by the process of fermentation. It becomes *Sukshma*, *Tikshna*, and *anulomana* which enhances the speed of absorption of the drug and fast acting property.

This formulation is easily storable and the shelf life is increased.

The dose becomes very less. It is more tasty than the *kwatha* preparation.

Further, the treatment is cost effective and devoid of side effects, so it can be applied in the community.

The follow up study shows that results achieved in the patients are effective and stable for a long time, no recurrence was noticed in the patients during the follow-up.

During Evaluation by Statistical data effect of *Apamarga Tikshna Pratisarniya Kshara* and *Dantyarishta* found as following:

Bleeding per rectum: It showed Highly significant(HS) relief of 88% with p value (<0.001).

Prolapse of pile mass: Data of prolapse of pile mass showed Highly Significant (HS) relief of 90% with p value (<0.001)

Constipation: It showed Highly Significant(HS) relief of 86% with p value (<0.001).

Pain in anal region: It showed Highly Significant(HS) relief of 91% with p value (<0.001).

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