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A COMPARATIVE CLINICAL STUDY OF AGNIKARMA SHALAKA IN THE MANAGEMENT OF BAHYA ARSHA W.S.R TOEXTERNAL SKIN TAG.

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Abstract:

Introduction: *Arshas* is considered as one of the *asthamahagadaroga* by *Acharya Susruta* for which different methods of management such as *Bheshjakarma*, *ksharkarma*, *Shastrakarma* *Agnikarma* and *Raktamokshana*. The approach of *Agnikarma* has been mentioned in the context of disease as *Arsha*, *Arbuda*, *Bhagandar*, *Sira*, *Snayu*, *Asthi*, *Sandhigata Vata Vikaras* etc.in which pain is a predominant symptom. *Agni karma* can be ideating as ancient pain treatment tool. *Arshais* an extremely common problem reported since many years with prevalence rate that is highest among all the anorectal disorders. But in *Ayurveda* fourfold according to chronicity *Agnikarma* procedure seems to be more effective in clinical basis in the management of *Arsha*.

Materials and Methods: It's an open randomized parallel trial group. A total 40 patients were selected randomly with the symptoms were divided in two groups, and in each group 20-20 patient were treated with *Tamrashalaka* and *panchadhatu shalaka* respectively. With that diseased group *Excision of Bahyaarsha* was done.

Result: Both group had given remarkable improvement by the *Agni karma* procedure which was carried out throughout the study. This shows that *agni karma* acts very well for the management of *Arsha*.

Conclusion: *Agnikarma* by *TamraShalaka* gives better symptomatic relief than *panchadhatushalaka* in the management of *BahyaArshw.s.r to External skin tag*.

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Key Words: *Agnikarma*, *Arsha*,
Tamra Shalaka, *Panchadhatu*
Shalaka.

- Thermal Cautery is more powerful than caustic alkali, successfully unable in diseases which are not amaniable to medicines; surgical treatments and caustic alkalize and gives no rooms for the disease to reunite /reoccurrence.

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||A.H.Su.30/40||³

- The *Agni karma* stands pioneer among all para- surgical techniques according to *acharya sushruta* and *vagbhata* because of its qualities apunarbhava (no relapse), sterilization (*nirjivanakarma*) property, haemostatic active, cursitive properties and its effects on *doshas*.
- *Agni karma* is better than medicinal therapy, surgical treatment and *kshar karma* due to the following reasons.
- Those diseases that cannot be cured back to health by medicines, surgery and *kshar karma* is healed by *Dahan Karma* or Cauterization.
- There is no failure in treating by *Agni karma* (cauterization), which can sometimes be noticed in medicines, *kshar karma* and operation regarding certain diseases.

Among surgical disorders elaborated in the ancient ayurvedic surgical text, piles/haemorrhoids/Arsha is selected for the present clinical study.

- The term “Haemorrhoid” derived from the Greek words *Haima* means “blood” and *Rhoos* means “flowing” blood to ooze and the term “Piles” is derived from the Latin word which means “a ball”/Pillo. The etiology is still a matter of conjecture. The age-old factors enumerated as hereditary, laxative of external sphincter, anal infection, as principal cause and chronic constipation is the co-existing factor in majority of the patients.
- As per “Surgery of The Anus Rectum and Colon” Goligher, the incidence of haemorrhoids at least 50% of the people over the age of 50 years have some degree of haemorrhoidal symptoms and estimated men are to be effected roughly twice as women. The prevalence rate of this disease is 4.4% in ten million people. The faulty food habits and sedentary life style of modern man increase the incidence rate.

||John Goligher Edition: 5th vol: 1 2001||⁴

- *Arsha* is considered as one among the *Ashtamahagada's* by *Acharya Sushruta*

||Su.Su.33rd/4||⁵

- Management of *Arsha* such as *Bheshaja Karmas* (Conservative management), *Kshar karma* (*Caustic Alkali*), *Agni Karma* (Cauterization) and *Shastra Karma* (Sharp Instruments).

||Su.Chi.6th/3||⁶

Dahanopakarna(Instrumental/materials used for Agnikarma)

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||Su.Su.12th/4||⁷

The following are the means of burning such as-

- *Pippali*, goat's feaces, cows tooth, arrow, rod, *jambavaustha* (a wick-shaped instrument made of stone) and other metallic instruments, and also honey, jaggery and fatty substances. Among them,
- *Pippali*, goats feaces, cows tooth, arrow, rod, are applicable in diseases located in skin,
- *Jambavaustha* and other metallic instruments are indicated in those located in muscle
- While honey, jaggery and fatty substances are useful in those affecting blood vessels, ligaments, joints and bones.

In the present study, efficacy of *agni karma* in the management of *Bahya Arsha* by two distinct *shalakas* will be evaluated. ||Su.Su.12th /10||⁸

- The disease that is troubling the human beings since the time immemorial is the *arsha* because of its manifestation at the *gudabhaga*, the *moola* of the *shareera*. The *chirakarivyadhi* because of the *mamsapradooshana* presents with the *pratyatmalakshana* of *kilaka* or *ankura* at the *gudabhaga* when it becomes *drushya* (visible). This fetches the attention of the patients and troubles them with a range of interfering in his daily routines to even his sexual performance, thus becoming nightmare for him.

- As this study was to evaluate the role of *Agni karma* in *Bahya Arsha* w.s.r to External skin tag, the literary review was done to find out that the *vataja* and *kaphaja arsha* are indicated for the agni karma, when they present with more advanced signs like *karkasha*, *sthira*, *pruthu* and *kathina* because of which, the other *bahiparimarjana chikitsa* like *teekshana lepa* and *abhyanga* fail to shed of the *ankura*.
- Agni karma, applied with the heated *shalaka* upto the extent of *mamsadahana* should remove these *shuskarsha* (*vataja / kaphaja*) and should not allow them to reoccur, if done properly according to classics. This advantage of the *agni karma* as non-recurrence of the *ankura*, should relieve the patient from the hell of suffering.

AIM AND OBJECTIVES

Aim:

- To evaluate the efficacy of two different *Agni karma Shalaka* [*Tamra & Panchadhatu Shalaka*] in the management of *Bahya Arsha* w.s.r. to External Skin tag. So, this study was taken up with an aim to evaluate

Objectives:

- The effect of agni karma in the *bahya arsha* with regards to their removal, early ambulation and less expensive for the patient and ultimately the non recurrence of the removed *arshankura*.

MATERIALS AND METHODS

- Among the 4-fold treatment of the *arsha*, the present study was planned to explore the efficacy of the *agni karma*. So before taking up the clinical study, the thorough evaluation is made regarding the study design, selection of patients depending upon the inclusion / exclusion criteria; the instrument to be used for the *agni karma* and the criteria to be taken up to assess the effect of therapy as following.
- Open Comparative Clinical study was planned on ***Agnikarma (with Tamra & Panchlohashalaka as per clinical group) in the management of Bahya Arsha*** w.s.r to External skin tag.

Hypothesis

Null Hypothesis{Ho}

- Agnikarma by *TamraShalaka* is not effective in the management of *BahyaArsha* with External skin tag.

Alternative Hypothesis{H1}

- Agnikarma by *TamraShalaka* is effective in the management of *BahyaArsha* with External skin tag.

Study Design:

- 40 numbers of Patients were randomly divided in the following groups for Clinical study.

Group A (Trial group):

- 20 number of patients of *Bahyaarsha* was treated with *Tamrashalaka*

Group B (Control group) :

- 20 number of patients of *Bahyaarsha* was treated with *Panchlohashalaka*

Inclusion Criteria

- *Vataja* and *kaphajaarsha*
- Patients irrespective of the Sex& Occupation for the study of *BahyaArsh* with External Skin tag.
- Patient's age group between 15 to 60 years.

Exclusion Criteria

- *Sahaja arsha*
- *Pittaja* and *Raktaja arsha*
- Patient suffering from severe systemic diseases like Tuberculosis, Diabetes Mellitus etc.
- Patient group of age below 15years and above 60years.
- Hb% below 10%.
- Patient suffering from HIV, HBsAg will be excluded.
- Patient who are not ready to sign in written consent form.

Diagnostic Criteria:

- *Bahyaarsha* were diagnosed clinically by the following *laxanas*

<i>Vataja Gudankura</i>	<i>Kaphaja Gudankura</i>	<i>V-K Gudankura</i>
Appearance -Resembles <ul style="list-style-type: none"> • <i>Soochivat</i> • <i>Teekshnagra</i> • <i>Kadambapushpa</i> • <i>Tundikeri</i> • <i>Bimbi</i> • <i>Karakandu</i> • <i>Kharjura</i> • <i>Karpasiphala</i> 	Appearance – Resembles <ul style="list-style-type: none"> • <i>Kareerabeeja</i> • <i>Panasabeeja</i> • <i>Gostana</i> • <i>Mahamoolayukta</i> 	Mixed signs and symptoms of <i>Vataja</i> and <i>Kaphajaarsha</i>
Colour: <ul style="list-style-type: none"> • <i>Shyava varna</i> • <i>Aruna varna</i> 	Colour: <ul style="list-style-type: none"> • <i>Pandu varna</i> 	
On touch : <ul style="list-style-type: none"> • <i>Shuska</i> • <i>Kathina</i> • <i>Sthira</i> • <i>Karkasha</i> • <i>Prathu</i> • <i>Vishputita</i> 	On touch : <ul style="list-style-type: none"> • <i>Mrudhu</i> • <i>Shlakshna</i> • <i>Guru</i> • <i>Sthira</i> • <i>Pichhila</i> • <i>sparshapriya</i> 	

Materials: -

- Anorectal examination table
- Spot light

- *Tamra* and *Panchloha* with round tip
- Allies forceps
- Different drums with sterile cotton gauze pieces, sterile drapes etc
- Tray with sterile gloves of different size
- Tray containing sterile syringe
- Bottles of *Shatadhautghrita/ Yastimadhughrita/ Mahanarayanataila* etc and antiseptic lotion.
- Anaesthetic drugs (Inj.Lignocaine 0.2% plain)

Methodology:

- Agni karma with the help of *Tamra* or *Panchlohashalaka* as per clinical group was done in a single sitting, for the *chedana* of *bahya arsha*.

Pre-operative procedure (Common for both groups)

The following instructions were advised before application of *agni karma*:

- Written informed consent was taken
- Patients were asked to maintain proper local part preparation and general hygiene.
- Administration of Tetanus toxoid.
- Soap water enema to clean bowel to avoid contamination during surgery.
- Sensitivity test (with Inj.Xylocaine 2% plain)

Operative procedure (Common for both groups)

- Patient was put into lithotomy position after the spinal anaesthesia on the lithotomy table.
- Part is painted with Betadine and Spirit followed by drapping.
- Infiltration of local analgesic with Inj Plain 2% of lignocaine, was done
- After achieving proper analgesia and relaxation, manual anal dilatation was done upto 4 fingers lubricated with local analgesic jelly.
- Now the external pile mass was held in allies forcep and gentle traction was applied to make the base like a pedicle, of the pile mass.
- Now the heated round tip of *Tamra* or *Panchlohashalaka* is applied at the base of the pedicle and moved across the base of the pile-mass to exert *pratisarana*
- Type of agnidahana till the fibres of corrugator cutis ani are seen.

- Thus the *sudagdhavrina* possessing blackish discoloration is applied with *ghrita* or *madhu* and rectal pack is applied.
- The same method is applied to the other external piles also at the same sitting. But the order of application of *Agni* is followed in the clockwise position starting from the 11 o'clock, when there are multiple masses.

Post-operative: (Common for both groups)

- *Agnikarma* itself doesn't require much post-operative care.
- After Operative management of *Agnikarma* it was be treated as a *Sadyo-Vrana*.
- *HaritakiChurna* 1tsp with 1 tsp *Guda* at Early Morning on Empty Stomach
- *Avagaha Sweda*
- Local application with *Madhu* and *Ghrita*.
- Patients were allowed to do normal routine works.
- High nutritional light diet, green leafy vegetables *takrasevana* and *ushnajalapana*, fruits.

Avoid

- Consumption excessive use of coffee, tea and alcohol, spicy fried food, constipating diet, riding, cycling, prolonged sitting, excessive indulgence in coitus etc.

Follow-Up

- Weekly Once Up to one month

Assessment Criteria

- Subjective Parameters is assessed by Self gradation in BT and AT

Subjective

- Pain
- Burning sensation

Subjective Parameter

- Pain is assessed by VAS Scale pain score Index
- Absent of mass

Discussion on results:

- As the main complaints of the patients were the presence of the *arshankura* and Pain, the effect of therapy was mainly concentrated on these signs and symptoms.
- Since the pile mass (*arshankura*) were completely excised with heated *TamraShalaka* and *Panchlohashalaka* as per clinical group in a single sitting, their absence is not considered for the statistical evaluation as all of the 20 patients in each group were devoid of the masses after the procedure.
- Pain and Burning sensation were considered for the statistical evaluation as they were more of subjective types and they need sometime for their resolution.
- Even though it was an observational study the assessment of change in the intensity of the post-operative pain and burning sensation was made to draw some of the conclusions regarding the time taken for subsiding of the Burning sensation and wound healing.

Effect of therapy on pain (ruja)

In Group A

- Majority of the patients (85%) who had complained of pain with the mean score of **2.65**, were relieved off their pain by **80 %** after the treatment indicated with the mean score of **0.8**, which is statistically significant ($p<0.001$).

In Group B

- Majority of the patients (85%) who had complained of pain with the mean score of **2.5**, were relieved off their pain by **70 %** after the treatment indicated with the mean score of **1.2**, which is statistically significant ($p<0.001$).
- Among them majority of the patients had pain due to *kaphavritavata* and remaining patients had pain because of *vid avritavata*. The relief might have been achieved because of the local effect of *agnikarma* in relieving the *margavarodha* to *apanavata* by the *mamsankurachedana* and systemic effect of *agni* in liquefying the *kapha* to take out the *avarana* to *vata*, thus subsiding the aggravated *vata* to relieve the pain..

Effect of therapy on Burning Sensation (daha) post-operatively

Group A

- The post-operative Burning Sensation immediately after the procedure (on 1st day) was more with the mean score of 2.55, during the defecation. *Daha* was there for 15 to 20 minutes and day by day *Daha* was reducing and on 7th day the Burning sensation is almost negligible with the mean score 0.15 and about 90% of relief from the pain which is also statistically

significant ($p < 0.001$). The increase in the pain immediately after procedure with the mean score of 0.8, which is statistically significant ($p < 0.001$) was reduced and due to the burning of tissue that results into necrosis. Patient's complaint of burning sensation that may be attributed to *Rakta* and *pittakopana* by *agni*. But application of medicated *ghrita* relieves the burning sensation by the *rakta* and *pittaprasadana* on in post-operative period.

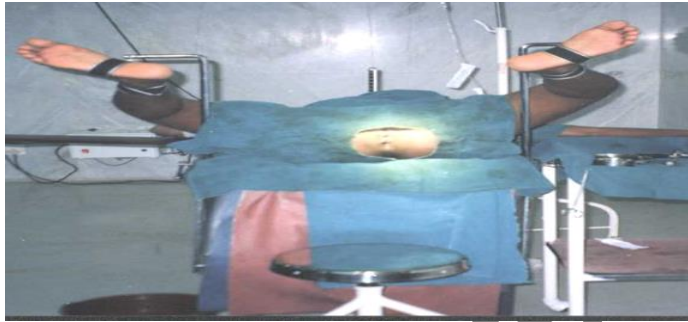
Group B

- The post-operative Burning Sensation immediately after the procedure (on 1st day) was more with the mean score of 2.60, during the defecation. *Daha* was there for 20 to 30 minutes and day by day *Daha* was reducing and on 7th day the Burning sensation is almost negligible with the mean score 0.30 and about 80% of relief from the *daha* which is also statistically significant ($p < 0.001$). The increase in the pain immediately after procedure was reduced with the mean score of 1.2, which is statistically significant ($p < 0.001$).
- And due to the burning of tissue that results into necrosis. Patient's complaint of burning sensation that may be attributed to *rakta* and *pitta kopana* by *agni*. But application of medicated *ghrita* relieves the burning sensation by the *rakta* and *pittaprasadana* on in post-operative period.
- Follow up Is done up to 1 month on post – operative 1st day, 7th day, 14th day, 21st day, 28^{th/30th} day to assess the pain (both the pathological and procedure induced), wound healing, relief from the associated complaint, complications of *agni karma* and recurrence of the *arsha*. This was noted with the help of the self- gradation of the assessment criteria in the Performa of case sheet of *arsha* designed for the study.

Overall effect:

- The overall effect of the therapy was drawn from the 30 days follow up in relation to the pain and burning sensation. At the end of the 30th day follow up, it was found that all the 20 patients in each group were free from the *arshankura*, pain, burning sensation and wound completely healed. This confirms that there is 100% cure i.e., complete remission in all the 20 patients in each group. Since, the complaints i.e. pain were secondary to the *arshankura* before the treatment, and after the treatment didn't reoccur as there was no recurrence of the *arshankura* because of the *agni karma* with *tamra* and *panchlohashalaka*. Thus, the study confirms 100% success.

Materials and Methods of Agnikarma



Lithotomy Table & Position



Materials



Before Procedure



Afret Procedure



Healed Wound

Conclusion

On the basis of the review of literature and observations made by this clinical study, which was conducted on the selected 20-20 patients in each group, the following conclusions can be drawn.

1. The *Nidana* that are mentioned for *Arsha*, remain same till today with little bit of modification like bike riding and distant travelling in place of *Prishtayana* etc.
2. *Arsha* that occur associated with the *Udara*, *Pandu* and *Kamala* etc, point towards the haemorrhoids secondary to the hepatic failure etc, systemic diseases.
3. *Agni karma* happens to be the ultimate treatment modality for the *Vataja* and *Kaphaja Arsha*, that present with *Kathina*, *Parusha*, *Sthira* and *Karkashalakshana*.
4. External piles most of the time, happen to be *Vataja* or *Kaphaja Arsha*. But *Vataja* or *Kaphaja Arsha* cannot be only external piles all the time.
5. Majority of the sufferers happen to be middle aged; married; non-vegetarian; males and of middle income group.
6. *Agni karma* is effective in removing the *Ankura* and its associated complaints with significant change in relief, most important being the non-recurrence of the *Ankura*.
7. From the result it is concluded that *TamraShalaka* much more effective than *Panchlohashalaka* with respect to early heating, faster conduction of heat and economical for acquiring. so null hypothesis is rejected and alternate hypothesis is accepted
8. But as the sample size is minimal (20 patients in each) and also the duration of study is short (1 months), the establishment of the obtained results requires the study on large number of sample with long term follow up, in multicentres.

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