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## **“A COMPARATIVE CLINICAL STUDY ON THE MANAGEMENT OF BAHYA ARSHA (EXTERNAL HAEMORRHOIDS) WITH SUVARCHIKADI LEPA & PIPPALYADI LEPA” A-RESEARCH ARTICLE**

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### **1.ABSTRACT**

Arsha is as old as mankind being an abnormal to routine life. Arsha does not cause any threat to life but troubles a lot, so it is included in one of the Astha Mahagadas by Sushruta. This disease is largely confined to the Guda.(Anus) The management of piles has been a common problem for surgeon and proctologist ever since this disease was recognized as separate entity, Sushruta was the first surgeon who described certain para surgical and surgical procedures. The present available treatment measures are oushadha, shastra, kshara & agni karmas. Local external application is described by Sushruta. Hence a clinical study is planned to evaluate and efficacy of “Suvarchikadi lepa” in the management of arshas. In this study sample size of 30 patients were selected by simple random sampling methods, in the therapeutic effects are analyzed by using the **Subjective parameters** like **1) Pain, 2) Discomfortness. Objective parameters 1) Pruritis 2) colour changes 3) size of pile mass**. The duration of treatment has a 7 days and clinical assessments were done in **3<sup>rd</sup> 5<sup>th</sup> & 7<sup>th</sup> days interval**. At the end of the study, the “Suvarchikadi lepa” has shown significantly beneficial result in sustainable manner.

**KEYWORDS:** ayurveda; arshas; haemorrhoids; suvarchikadilepa, pippalyadi lepa.

## **2.INTRODUCTION**

1. Haemorrhoid is the commonest condition among the ano-rectal diseases in day to day practice in terms of incidence. A statistical data has proclaimed that approximately, 50% of the populations over the age of 50 years are suffering from haemorrhoids. The ratio of occurrence of haemorrhoids in males and females is 2:1 respectively.
2. Haemorrhoid is a disease which is very specific to human race only due to its erect posture. In this era of fast running life the chance of occurrence of haemorrhoid is very high and is found more in persons who are prone to the usage of incompatible foods and low roughage diet, suppression of natural urges, sedentary life-style, alcoholism, worry, tension, depressions, and in table-top professionals. Other contributing factors include pregnancy, ageing, chronic constipation or diarrhoea and some other ano-rectal diseases.
3. Bahyars has is commonly found in the present population. It causes agonizing pain to the patient; patients feel it like a growth or foreign body. If it is left untreated it increases in size causes obstruction in the anal canal which in turn leads to constipation and the complaints will aggravate. Many a times the bahyarsas will get infected and causes many complications.
4. The modern modalities of treatment for haemorrhoids are sclerotherapy, Rubber band ligation, cryosurgery, infrared photo coagulation, staple techniques, haemorrhoidectomy have their own limitations. It requires special training skills and equipments for their performance. Hence, it leaves a scope to find out a remedial measure to easy cure of disease and free from complication.
5. Under the above circumstances, there is a need to find out a new innovative and simpler procedure that which ideally suits in offering the relief the sufferers from the disease. In this regard, Acharya Sushruta, the pioneer in the field of surgery, described 4 principal therapeutic measures in the management of *Arshas* i.e. Bhesaja chikitsa, Ksharakarma, Agnikarma and Shastrakarma.
6. This classification clearly denotes that, Sushruta has emphasized (first and foremost) more on medicinal and para-surgical procedures then has laid importance to surgery. The conservative treatment advised by Acharya Sushruta for the treatment of Arshas including oral medications and number of lepas, **local applications which are simple, effective and least invasive. Lepas can also be used in the persons who have fear to undergo surgery.**

7. Some of the cases of haemorrhoids are clear indication for surgery, but it is not advisable due to old age and presence of systemic diseases such as carcinoma of rectum, portal hypertension, DM, etc., **This study is aimed for nonsurgical management of piles.** The local application of “suvarchikadi lepa” was selected to prove their efficacy according to the textual references. The pile masses supposed to be shed off but this was not observed in entire study. But however, regression of masses and disappearance of masses were seen.
8. Considering the above facts, an effort is made scientifically compare the therapeutic effect of suvarchikadi lepa on Bahyarhas.
9. In the present study a plan has been made to find out efficacy of suvarchikadi lepa.
10. These patients were classified according to age, sex, marital status, occupation, socioeconomic status, associated complaints, chief complaints, position of hemorrhoid, degree of hemorrhoids, and results were observed and recorded regularly on 0, 3<sup>rd</sup> 5<sup>th</sup> and 7<sup>th</sup> day. The external application of “suvarchikadi lepa” for piles is safe and effective even though it is not eradicated completely but shown significant results in relieving the symptoms brought the patient to the state of palliative therapy without surgery and its complications.

### **3.OBJECTIVES OF THE STUDY**

1. This study is aimed for non-surgical management of piles. The local application of “suvarchikadi lepa” was selected to prove their efficacy according to the textual references.
2. The treatment for arshas in modern science is surgery which is having its own limitations. Different types of treatments advocated as the line of treatment, among Bhesaja chikitsa, lepa is a simple technique which is least invasive, cost- effective and can be employed in patients who fear for surgery.
3. To study the disease Bahyarshas in detail.
4. To assess the effect of Suvarchikadi lepa on Bahyarshas.

### **4.MATERIALS & METHODS- METHODOLOGY:**

#### **MATERIALS & METHODS**

##### **Material used**

suvarchikadi lepa, shalaka/kurcha (probe, spoon), sterile cotton pads.

## MATERIALS

- Suvarchikadi lepa and Pippalyadi lepa.(drugs)
- Shalala/kurcha (probe, Spoon) Sterile cotton pads. disposable gloves.

### 1) SUVARCHIKADI LEPA DRUGS-

अर्शसां पातनार्थं सुवर्चिकाद्यं लेपः-

अर्शसां पातनार्थं सुवर्चिकाद्यं लेपः-

“सुवर्चिका बिडं दन्ती भल्लातकमथो वचा

चित्रकोऽर्कस्त्रिकटुकं स्नुहीक्षीरेण पेपेयेत्

एतदालेपनं श्रेष्ठमर्शसां क्षारसंमितम्

दहयते सप्तरात्रेण पुंस्त्वं च न विनश्यति” ॥ (गद.निग्रह. ४/११०-१११)

Suvarchikadi lepa is mentioned by maharshi shodala-in Gada nighara text.Suvarchikadi lepa drugs contains –Suvarchika lavana, Bida Lavana,danti Beeja Churna, Bhallatakabeeja (shodhita), Vachachurna, Chitrakachurna, Arkapatra, Trikatu churna (shunti, maricha, pippali). lastly Yava kshara.

### 2) PIPPALYADI LEPA DRUGS-

पिपल्यादि लेप

पिप्ली सैन्धव कुष्ठं शिरीषस्य फलन्तथा।सुधादुग्धार्कदुग्धैर्वा लेपोअयं गुदजं हरेत्। ( भैषज्यरत्नावली-अर्शोधिकार.९/१०)

- Pippali,
- kustha,
- Shireesha Beeja,
- Saindhava lavana and
- Snuhi ksheera.

## METHODS:

The patient was made to lie on the table in lithotomy position, and then suvarchikadi

lepa and Pippalyadi lepa are applied by sterile spoon on external pile masses. The total duration of the treatment is 7 days, the lepa is applied locally on Arsha ankura daily after defecation. and the assessment will be on alternate day. The quantity of the drug depends upon the size of arsha ankura.

Intention of this study was mainly to assess the efficacy of suvarchikadi lepa & pippalyadi lepa with indigenous drugs (suvarchikadi lavana, bida lavana, danti, chitrka, bhallataka etc.) in the management of Bahya arshas. In the present study Bahya Arshas were selected for suvarchikadi lepa & pippalyadi lepa according to random sampling method. Following points were observed during and after the therapy:

#### **Method of preparation of the drug-**

1. The suvarchikadi Lepa is prepared by taking equal quantity of suvarchika lavana, bidalavana, danti mula churna, Vacha, chitraka, etc, drugs in churna form, and given bhavana by Snuhi ksheera, and lastly yava kshara is added. The prepared lepa is applied over arsha and within seven days the arsha falls out.
2. The pippalyadiLepa is prepared by taking equal quantity of pippli mula, kusta, sheerisha beeja drugs in churna form, and given bhavana by Snuhi ksheera, The prepared lepa is applied over arsha and within seven days the arsha falls out.

The whole procedure can be explained in the followings lines as:

- a. Purva Karma
- b. Pradhana Karma
- c. Pashchat Karma.

#### **A. Purvakarma:**

1. A patient who was considered fit for procedure was prepared accordingly.
1. Patients were counselled and explained about the procedure in order to Make them mentally aware about the events of treatment.
2. Written Consent of the patients taken.
3. Patient after through examination-

Group 1: patients were made to lie down and exposed pile masses Then the patients were taken to pradhana karma.

Group 2: same as above group 1.

### **B. Pradhana karma-**

The patient is made to lie on the table in lithotomy position, and then suvarchikadi lepa and pippalyadi lepa are applied by sterile spoon on external pile masses in individual groups of 15 patients respectively. The total duration of the treatment is 7 days, the lepa is applied locally on Arsha ankura daily after defecation and the assessment will be on alternate day. The quantity of the drug depends upon the size of arsha ankura.

### **C. Pashchata karma**

In both the groups immediately after completion of procedure patients were advised to keep the area dry, clean, avoid exertion, and unwholesome diet. During the procedure, patients were carefully observed for any untoward complications.

### **SOURCES OF DATA**

The present open clinical study was conducted on 30 patients on the basis of simple randomised sampling procedure. Patients of bahya arshas were selected according to the signs and symptoms, and a case proforma was prepared. Patients were selected from O.P.D. & I.P.D. of shalya tantra department.

## **5. SELECTION CRITERIA**

### **INCLUSION CRITERIA**

1. Diagnosed cases of Bahya Arsha.
2. 16-60 years of age group irrespective of sex.
3. Patients unwilling for surgery
4. Discomfortness.

### **EXCLUSION CRITERIA**

1. External Thrombosed pile mass.
2. Patients having systemic pathology - malignancies, ulcerative colitis, crohnsdisease, Cirrhosis of liver and Diabetes mellitus.

### **ASSESSMENT CRITERIA:**

### **SUBJECTIVE CRITERIA**

1. Pain

## **OBJECTIVE CRITERIA**

2. Pruritis.
3. Size of pile mass.
4. Colour changes.
5. Discomfortness.

## **STUDY DESIGN**

A total number of 30 patients were randomly selected for the study. They were divided into 2 groups of each 15 patients.

### **GROUP 1- (TRIAL GROUP)**

15 patients were treated with **Suvarchikadi lepa** daily once for 15 minutes for 7 days, after defecation.

### **GROUP 2(CONTROL GROUP)**

15 patients were treated with **Pipplyadi lepa** daily once for 15 minutes for 7 days, after defecation.

#### **➤ Assessment-**

Both groups of Patients were assessed on day 0, 3<sup>rd</sup>, 5<sup>th</sup>, and 7<sup>th</sup> day. The progress will be noted in a specially prepared case sheet. The observations will be analyzed on the basis of assessment parameters (subjective and objective) the results will be statistically evaluated for its significance by t-test.

**Pathya:** All patients will be advised to follow soft light diet, fiber diet,

#### **FOLLOW- UP:**

- Follow up was done on 15<sup>th</sup> & 30<sup>th</sup> day of treatment.

## **GRADING OF PARAMETERS ACCORDING TO SEVERITY**

### **1.Pain: (VAS scale) Or MRC grading.**

Grade 0 – Nil or no pain

Grade 1 – mild pain during defecation.

Grade 2 – moderate pain during & after defecation. Grade 3 – sever pain during defecation and difficulty in sitting and walking.

## **2.Size of the pile mass (circumfrenial length)**

Grade 0 – complete regression of the pile mass. Grade 1 – 0.5cm -2 cm

Grade 2 – 2.1cm -4 cm

Grade 3 – 4.1cm -6 cm

## **3.Colour change of the pile mass:**

Grade 0 – normal skin colour Grade 1 – Blackish

Grade 2 – Reddish black Grade 3 – pale/ reddish brown

## **4.Itching/pruritis:**

- Grade 0 – No pruritus.
- Grade 1 – Mild pruritis.
- Grade 2 – Moderate pruritis.
- Grade 3 – Sever pruritis.

## **6. DISCUSSION**

- The clinical study has been discussed under the following headings.
- Review of literature.
- Observation & results.
- Mode of action of formulation.

### **1.Discussion on review of literature**

Arsha is the disease of yore, vivid description is available in almost all ayurvedic classics.

The disease arsha can be very conveniently compared to the disease haemorrhoids described in modern science,. bahya arsha can be compared to external haemorrhoids. The external haemorrhoids can be correlated with the arsha having laxanas like karkasha, stira, prithu, Katina,. Sravi type of arsha can be considered as bleeding haemorrhoids. Acharya sushruta the father of surgery described various types of arshas like sahaja jatasyottaraja, kalaja in detail. The prime etiopathogenic factor of arsha is mandagni i.e.hypofunctioning of diesgestive enzymes, which in turn leads to constipation, prolonged contact of accumulated excretory material to gudavali results in development of arsha. About chikitsa of arsha-

Sushruta, described four therapeutic measures in the management of arsha, Bhesaja chikitsa, (medical management), Kshara karma (Caustic cautery), agni karma (thermal Cautery), and

Shashtra karma (surgery). With different conditions of the arshas. These measures in definite order are suggestive of similar methods to be preferred first. Haemorrhoids which are not chronic, having mild aggravation of doshas, symptoms and complication are treatable with medicines. In medicinal treatment our acharyas have explained number of lepas for arshas in different samhitas like Gada Nigraha, Bhaishjya Ratnavali, Yogaratnakar, Chakradutta, etc.

## **2. Discussion on Drug review-**

When physician has proper knowledge of drug, he can use visha as a medicine, so it is very important to have the proper knowledge of drug. In our various ayurvedic samhitas narrated various measures like local abhyanga, avagaha, lepa, varti, etc preparations for those patients who are not fit for surgery & fear for surgery. So an attempt was made to study one of those measures i.e. The lepana karma on bahya arshas relieves edema, stiffness, itching, pain etc. This method which is simple, safe, harmless, easy to perform, economic and devoid of complications was taken for the study.

The suvarchikadi lepa formulations as mentioned in various texts. Method of collection of drug and their active properties & quantity of drug used for the treatment & specific indications are followed. Discussion on those arshas having the involvement of vata and kapha origin, the treatment must be done with kshara karma. (Su.chi.6/5) & the pile masses which are prolapsed and are of impurity then those should be treated without instrument. (Su.chi6/7) Various Lepa preparations are mentioned in samhitas, the suvarchikadi lepa is one amongst them. (gada nigraha II<sup>nd</sup> part 4/110-111) The lepana karma on bahya arshas relieves edema, stiffness, itching, pain and vitiated blood will be drained out. (Cha.chi14/59).

## **3. discussion on effect of therapy on parameters:**

In the present study, the effect of the therapy was assessed on each sign and symptom of Arshas, being scored before and after treatment and were assessed statistically for the level of significance.

**1. Effect on pain:** - Pain was reduced by 78.37% in Group A & 52.63% in Group B. Both the groups showed improvements with significance p-value of <

0.05. Severity of pain in both the groups is mainly due to pravrudha vata and kapha doshas. In external pile mass the main pathology for pain is the combination of dilatation of venous plexus, thrombosis and inflammation.

The application suvarchikadi lepa on Bahya Arshas in Group A has resulted in reduction of

pain when compared BT and AT. This may be due to the drug formulation suvarchikadi lepa mainly acts as vatagna & shulanashaka. The ingredients, such as Bhallataka, Snuhi, Shunti having shothahara property. The treatment with pipplyadi lepa to external pile mass in Group B has also showed improvement in reduction of pain due to its vedanasthapaka and shothahara properties of Snuhi and sheerish.

**2. Effect on pruritis:** - It showed significant reduction in Group A up to 80.55% & in Group B up to 55.26%. Results of both the groups were significant p-value of < 0.05.

In pruritis itching & redness of external anal region occurs due to the vitiated vata, kapha dosha. the drug danti, chitraka, having specific action on kandu & shotha.

In Group B- the drug shirisha, kusta having the action mainly kandugna properties have reduced the pruritis in Bahya Arshas.

**3. Effect on colour of pile mass:** - Normalcy of skin colour was established by 70 % in Group A and 48.78% in Group B. the test were significance p-value of < 0.05. the drugs of suvarchikadi lepa shows significant effect on inflammation. however inflammation get subsided colour change seen because of suvarchika the drug having properties like shothagna should be reached significant effect of change in the colour. In pipplyadi lepa the drug shirisha & snuhi having property of shothahara & vedanasthapaka, that may cause change in colour.

**4. Effect on size of pile mass:** - Pile masses were reduced by 70 % in Group A and 46.66% in group B the test showed no significance in both the groups.

There is mild changes in reduction of size of pile mass in both the groups.

## **6. Discussion on Observation and Results**

### **1. Age:**

It has been observed from the study that out of 30 patients maximum no. of patients i.e 9 (30%) were in between the age group 40 - 49 years (Adult) followed by 7 patients (23.33%) in the age group of 20-29 years, 7 patients (23.33%) in the age group of 30-39 years, and least of 5 patients (16.66%) in the age group 50-59 years. The present clinical study shows that the age group between 40- 49 years having busy lifestyle, considerable time of bike ride, stress and strain which may leads to impairment of digestive function.

### **2. Sex:**

In this study higher incidence (80%) was observed in males than females (20%). The reason

may be due to males involving in manual work and females due to their timid and shy nature don't present herself with anorectal complaints until and unless its severe.

### **3.Occupation:**

Incidence of occupational status revealed that 19(63.33%) patients were in service, 6(20%) patients were business persons, 3 (10 %) patients were students and 2(6.66%) housewives. This data suggests that most of the people in service group had prolonged sitting position which is the main etiological factor for arshas and other categories of occupations which is again contributing factor, hence these may be the reasons for this incidence.

### **4.Marital status:**

Maximum number of patients 24 (80%) were married and 6 (20%) were unmarried. No specific relation can be established from this observation.

### **5.Socio-economic condition:**

Maximum number of patients 24 patients (80%) were from middle class, 6(20%) of poor class. Prolonged sitting posture at work, mental strain, and the living standard of middle class, may be the reason for GI disturbances (Ama formation) and vata-kapha prakopa causing the above incidence.

### **6.Habits:**

Maximum number of patients 10 (33.33%)& 10(33.33%) were tobacco chewing & alcoholics, 4 (13.33%) patients were smokers and 6(20%) patients had no specific habits. As alcohol vitiates the tridosas and leads to mandagni. The smoking and tobacco chewing leads to vata prakopa, constipation, hard stool sets in thus this may be the reason for above incidence.

### **7.Ahara:**

In the present research work 19 (63.66%) of patients showed mixed food habits (i.e.veg & non veg type of diet) and remaining 11 (36.66)% patients were purely vegetarian. This shows that the patients with veg & non-vegetarian food habits were more prone to vitiation of tridoshas and initiation of etiological factors of the diseases than that of vegetarian food habits.

### **8.Intensity of pain:**

It was observed that 17 (56.66) patients were having severe intensity of pain, 10(33.33%) patients had moderate and 3(10%) had mild intensity of pain. Though the

onset of the disease is gradual in nature, prolapsed pile mass get inflamed easily due to contributory factors so in most of the patients who visited our OPD had sever intensity of pain.

### **9.Position of pile mass:**

Maximum of 18.07% patients had pile mass at 5 O clock, 16.86% of patients had at 3 O clock, 14.45% at 7 O clock, 10.84% at 11 O clock position and 24.09% at other positions. No specific conclusion can be drawn about the position because external haemorrhoidal plexus are grossly embedded.

### **8.CONCLUSION**

The review of literature and clinical study provides certain useful conclusions as follows.

1. Sushruta considered the disease Arsha as one of the Mahagada being it difficult to treat.
2. Management of haemorrhoids has become a problem to all the surgeons and proctologists even today due to many unavoidable draw backs and complications such as incontinence and recurrence, etc.
3. "Suvarchikadi Lepam" is curative, safe and effective in reliving symptoms in early stage of disease and also useful in patients who are unwilling for surgery.
4. "Suvarchikadi Lepam" helps in relieving agony and discomfort to the patients without hospitalization. Hence it may be a poor man's choice as it is easily available, more economical and effective.
5. So the use of "Suvarchikadi Lepam" is an ambulatory type of treatment which gives quick action and no side effects. Also can be used as a better alternative to surgery.

### **9.RESULTS**

1. Clinical analysis showed that on 3rd day 13 patients had no improvement, whereas 2 patients had mild improvement.
2. On 5<sup>th</sup> day 8 patients had mild improvement, 6 patients had moderate improvement and no patients had maximum improvement.
3. On 7<sup>th</sup> day 3 patients had moderate improvement whereas 9 patients showed maximum improvement and 3 patient was completely cured.

**8.ASSESSMENT OF RESULTS:****TABLE NO.01. OVERALL CLINICAL ASSESSMENT OF RESULT:**

RESULT	GROUP-I A.T.			GROUP-II A.T.		
	3rd day	5th day	7th day	3rd day	5th day	7th day
<b>Cured 100%</b>	00	00	3 (20%)	00	00	2 (13.3%)
<b>Max. Improved 75 to 99%</b>	00	00	9 (60%)	00	00	4 (26.6%)
<b>Mod. Improved 50 to 74%</b>	00	6 (40%)	3 (20%)	00	4 (20%)	4 (26.6%)
<b>Mild Improved 25 to 49%</b>	2 (13.3)	8 (53.3%)	00	2 (13.3)	6 (40%)	5 (33.3%)
<b>Not Improved &lt;25%</b>	13	00	00	13	5 (33.3%)	00

**ASSESSMENT OF RESULTS:**

All the parameters were assessed statistically before and after treatment and follow up to assess the total effect of therapies.

- ◆ **Cure** – 100% free from cardinal sign and symptom, these are pain, prurits, size of pile mass, colour change of mass.
- ◆ **Max. Improvement** – >75% improvement of the above mentioned cardinal sign and symptom.
- ◆ **Moderate Improvement** – 50% to 74% improvement of the above mentioned cardinal sign and symptom.
- ◆ **Mild Improvement** – 25% to 49% improvement of the above mentioned cardinal sign and symptom.

- ◆ **No. Improvement** - <25% improvement of the above mentioned cardinal sign and symptom.

Grading & grouping according to the assessment criteria and measurement scale concerned to each item categorically differentiated the findings among the patients in the clinical study. And finally the assessment as a whole was presented in percent value.

In order to present the study in a scientific manner the statistical assessment of the result was done by using Paired t-test in consultation with Bio- Statistician.

**Table no.02.Overall clinical assessment of trial & control group result-**

GROUP A TRIAL GROUP						
B.T. Mean± S.E. 9.53±0.37	A.T. MEAN±S.E		T VALUE	P VALUE	EFFICACY	REMARK
	AT 1	8.86±0.29	2.86	<0.01	6.99%	HS
	AT 2	5.93±0.39	10.73	<0.01	37.76%	HS
	AT 3	2.4±0.38	16.00	<0.01	74.83%	HS
GROUP B CONTROL GROUP						
B.T. Mean±S.E. 9.8 ±0.26	A.T.Mean±S.E		T value	P value	efficacy	Remark
	AT 1	9.33±0.28	2.16	<0.05	4.76%	S
	AT 2	7.33±0.37	7.66	<0.01	25.17%	HS
	AT 3	4.8±0.48	12.07	<0.01	51.02%	HS

### **GROUP-A**

Clinical analysis showed that

**1) On 3<sup>rd</sup> day-** 13 patients had no improvement, where as 2 patients had mild improvement.

**2) On 5<sup>th</sup> day-** 8 Patients had mild improvement, 6 patients had moderate improvement and no patients had maximum improvement.

**3) On 7<sup>th</sup> day** - 3 Patients had moderate improvement where as 9 patients showed maximum improvement and 3 patient was completely cured.

## **GROUP -B**

Clinical analysis showed that

**1) On 3<sup>rd</sup> Day**-13 Patients had no improvement, whereas 2 patients had mild, and no patients showed neither maximum improvement nor were cured.

**2) On 5<sup>th</sup> Day**- 5 Patients had no improvement, 6 patients had mild improvement and 4 patients showed moderate improvement and no patients showed neither maximum improvement nor cure rate.

**3) On 7<sup>th</sup> Day**- Of treatment, 5 patients showed mild improvement, 4 patients showed moderate improvement, 4 patients shows maximum improvement, where as 2 patient showed completely cured.

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