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ROLE OF RAJAHPRAVARTINI VATI IN THE MANAGEMENT OF PRIMARY DYSMENORRHOEA (KASHTARTAVA) – A CLINICAL STUDY

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ABSTRACT

Dysmenorrhoea is the most common Gynaecological problem with painful menstruation due to increased levels of prostaglandins in the menstrual fluid, this results in uterine pain, nausea, vomiting, backache, diarrhoea, giddiness, syncope and fainting. In *Ayurveda* it is explained in terms of "*Kashtartava*", which is clinical entity characterized by pain and difficult expulsion of *Aartva* (Menstrual Blood) due to upward movement of *Raja* (Menstrual Blood), through *Pratiloma Gati* (Movement in reverse direction) of *Apana Vayu* and subsides after expulsion of *Artava*. Formation of *Artava* (Menstrual Blood) takes place during entire month, due to continuous filling of *Garbhashaya* through small capillaries, which is brought into *Yoni* and makes it to discharge outside every month by *Vayu*. The whole mechanism depends upon the proper functioning of *Apana* and *Vyana Vayu* where in *Apana Vayu* is responsible for *Raja Pravritii* while *Vyana Vayu* is accountable for blood circulation. In clinical intervention study, purposive randomly selected 40 patients were equally divided into 2 groups i.e. Group A (Trial Group) and Group B (Control Group). In Trial Group *Rajahpravartini Vati* in dose 250 mg twice a day and in Control Group Placebo

(Roasted wheat flour) 2 Capsule twice a day were advised for treatment, drug administration was started from 21st day of LMP to next 3 days of menstrual cycle for duration of consecutively 3 menstrual cycles.

It was found that average percentage of relief was higher in group A i.e. 71% while in group B i.e. 43.10%.

Keywords: Primary dysmenorrhea, Kashtartava, Agni

INTRODUCTION

Women's health is the primary factor to be considered for wellbeing of family, society and culture. Any physical or mental disorder disturbs her educational, social and economic life. The menstruation is considered as a landmark of homeostatic condition of reproductive system, when it is associated with unbearable pain and hampers daily activities it hells life during the menstruation is known as dysmenorrhea. Adolescence is a period of transition from childhood to adulthood and is characterized by a spurt in physical, endocrinal, emotional and mental growth, with a change from complete dependence to relative independence. Dysmenorrhoea is the most common Gynaecological problem with painful menstruation of sufficient magnitude so as to incapacitate day to day activities, which can be classified into Primary and Secondary. Primary dysmenorrhoea occurs in ovulatory cycle hence it makes its appearance a few years after menarche at least 6 - 12 months after painless periods. It is most intense on the first day of menses and progressively lessens with menstrual flow. Primary dysmenorrhoea is widely prevalent, more than 70% of teenagers and 30 – 50% of menstruating woman suffer from varying degree of discomfort. The common cause of primary dysmenorrhoea is increased levels of prostaglandins in the menstrual fluid, which results in uterine pain, nausea, vomiting, backache, diarrhoea, giddiness, syncope and fainting.² In Ayurveda it is explained in terms of "Kashtartava", which is a Tridoshaja Vyadhi with predominance of Vata, especially Apana and Vyana Vayu. It is not individual disease, but there are many diseases, in which it is described as a symptom and found in various Yonivyapad viz. Vatala, Udavarta and Paripluta.

The word Artava has two meaning viz. Antah Pushpa (Ovum) & Bahir Pushpa (Menstrual Blood). In the present context, it can be inferred as Bahir Pushpa (Menstrual Blood only). Formation of Artava (Menstrual Blood) takes place during entire month, due to continuous filling of Garbhashaya through small capillaries, which is brought into Yoni and makes it to discharge outside every month by Vayu. The whole mechanism depends upon the proper functioning of Apana and Vyana Vayu where in Apana Vayu is responsible for Raja Pravritii while Vyana Vayu is accountable for blood circulation. Kashtartava (Primary Dysmenorrhoea) is a clinical entity characterized by pain and difficult expulsion of Aartva (Menstrual Blood) due to upward movement of Raja (Menstrual Blood), through Pratiloma Gati (Movement in reverse direction) of Apana Vayu and subsides after expulsion of Artava. The probable mode of pathogenesis may be due to Margavarodha and Dhatu Kshaya. The vitiated Vata by Ruksha, Sheeta, Sukshma properties spread through Rasavaha Srotasa and leads to Rasavaha, Raktavaha and Artavavaha Srotodushti. Dosha - Dushya Sammurchhana takes place in Garbhashaya. Due to vitiation of Vyana and Apana Vayu the Akunchana and Prasarana Kriya of Garbhashaya does not take place properly, the state exactly that of dysrhythmia of uterine muscles, which will hinder in proper flow of menstrual blood leading to Kashtartava. As per the knowledge of treatment available in modern medical science for dysmenorrhoea is only analgesic, antispasmodic and hormone therapy all these are having their own side effect and dependency toward the medication for most of the time every month, whereas in Ayurveda several drug are indicated in the context of Yonivyapad these drugs are herbo-mineral compound and safe without causing side effect among that Rajahpravartini Vati containing Kaseesa (Ferrous Sulphate), Tankan (Borex), Kumari (Aloevera) and Hingu (Ferula Foetida), is the most common drug used by the gynecologist in day today practice for such condition.³

Hypothesis:

- ✓ Null hypothesis: H₀: *Rajahpravartini Vati* will be effective in the management of Primary Dysmenorrhoea (*Kashtartava*)
- ✓ Alternate hypothesis: H_{a:} Rajahpravartini Vati will not be effective in the management of Primary Dysmenorrhoea (Kashtartava)

Material and Methods:

Patients having the symptoms of Primary Dysmenor-rhoea (*Kashtartava*) were purposive randomly selected (total 40 patients) for the study from O.P.D. and I.P.D. of Pt. Khushilal Sharma Government (Autonomous) Ayurveda College and Institute, Bhopal. A clinical evaluation of patient was done in special Performa by collecting the data through information obtained by history, Physical examination and laboratory investigations. The drugs required for clinical study were prepared in the department of *Rasa Shastra* and *Bhaishajya Kalpana* of this Institute. The ethical clearance was obtained by the Institutional Ethics Committee (IEC) in its meeting dated 27th May 2017.

Study Design: Purposive Randomly selected patients were equally divided into 2 groups i.e. Group A (Trial Group) and Group B (Control Group). Group A patients were given *Rajahpravartini Vati* (250 mg) and in Group B patients were given placebo (Roasted wheat flour-250mg) twice a day with lukewarm water after taking meal for 3 Consecutively menstrual cycles. Drug was started from 21st day of LMP to next 3 days of menstrual cycle along with *Nidan Parivarjana* in both groups.

Drug Profile: Rajahpravartini Vati: The ingredients of Rajahpravartini Vati are Kaseesa (Ferrous sulphate), Tankan (Borex), Kumari (Aloe) and Hingu (Ferula foetida) in equal quantity.⁴

Criteria for Diagnosis: The diagnosis of Primary Dysmenorrhoea (*Kashtartava*) was based on the symptoms described in *Ayurvedic* classics as well as modern literatures.

Criteria for Selection of Patient:

Inclusion Criteria:

- ✓ Patients who had chief complaint of painful menses for at least 3 or more cycles.
- ✓ Pain along with scanty blood flow.

- ✓ Pain along with average amount of blood flow.
- ✓ Age group between 12 30 years.

Exclusion Criteria:

- ✓ Patient not fulfilling the inclusion Criteria.
- ✓ Patients below 12 years and above 30 years.
- ✓ Married woman
- ✓ Patients with chronic illness like Tuberculosis, Hypothyroidism, Hyperthyroidism, Severe Anaemia, Diabetes mellitus, AIDS, Syphilis etc.
- ✓ Patients taking Oral Contraceptive Pills.
- ✓ Urinary Tract Infection (UTI)
- ✓ Any Pelvic pathology Fibroid, Adenomyosis, PID, Endometriosis, DUB, PCOD, Carcinoma.
- ✓ Patient who refused to give written consent for participation in the research study.

Investigations: ESR, Hb%, USG (if required)

Criteria for Assessment:

- ✓ The patients were assessed on the basis of clinical presentation and relief found on the cardinal symptoms before treatment and after treatment. A grading pattern to assess the subjective feature and the clinical symptoms viz. Shula (Pain), Artava Praman (Amount of blood flow), Yathochitkal Darshanam (Interval of menstruation), Artavaasrava Avadhi (Duration of flow), Prasek (Nausea), Chardi (vomiting), Vibandha (Constipation), Shrama (Fatigue), Aruchi (Anorexia) etc.
- ✓ Which so ever presented by the patients was graded into (0-3) scale on the basis of severity, before and after completion of therapy.
- ✓ Hematological Investigations
- The information gathered on the basis of observations were subjected to statistical analysis in terms of mean (x) standard deviation (S.D.) and standard error (S.E.) in subjective criteria, Wilcoxon test and Mann-Whitney is a non-parametric test which was applied for paired and unpaired data respectively; whereas objective criteria t-test is parametric test which was applied for paired and unpaired data respectively.
- ✓ The obtained results were interpreted as: Insignificant-p > 0.05, Significant-p < 0.01, Highly significant-p< 0.001, Extremely significant-p< 0.0001.

✓ Overall therapy was classified as No Improvement - < 25%, Mild Improvement - 25 < 50%, Moderate Improvement- 50 < 75%

Markedly Improvement - 75 < 100%, Cured-100%.

Grading Pattern for Cardinal Symptoms Severity of Pain:

Criteria	Grading
Menstruation is not painful and daily activity unaffected	0
Painful Menstruation, mildly affecting daily activities	1
Painful Menstruation, affecting daily activity required Analgesics.	2
Severe excruciating pain associated with painful crises agonizing look compelling her to stop day to day	3
activity	

Duration of Pain:

Criteria	Grading
No pain	0
24 hours / 1 day	1
48 hours / 2 days	2
72 ours / 3 days	3

Radiation of Pain:

Criteria	Grading
No Radiation	0
Radiation present	1

Artava Praman (Amount of Blood Flow Per Day Assess Number of Sanitary Pad):

Criteria	Grading
2– 3 Pads / day	0
1– 2 Pads / Day	1
Spotting / 1 pad / day	2
Spotting	3

Yathochitkal Darshanam (Interval of Menstruation):

Criteria	Grading
21 – 35 Days	0
36–40 Days	1
41 – 45 Days	2
Above 45 days	3

Artavasrava Avadhi (Duration of Flow):

Criteria	Grading
Duration of menses 3 – 7 Days	0
0 – 2 Day	1
Only Spotting	2

Prasek (Nausea):

Criteria	Grading
Absent	0
Present	1

Chardi (Vomiting):

Criteria	Grading
Absent	0
Present	1

Vibandha (Constipation):

Criteria	Grading
No Constipation	0
Frequency once in a day	1
Frequency of alternate day and patient feels difficulty in defecation	2
Patient can't pass stool without any medication	3

Shrama (Fatigue):

Criteria	Grading
No Fatigue	0
After heavy work, relieved soon & tolerate	1
After moderate work relieved later & tolerate	2
After little work relieved later	3

Aruchi (Anorexia):

Criteria	Grading
Absent	0
Present	1

Observation and Result: In this study, following observations were found in menstrual cycle and cardinal features. **Table 1:** Menstrual Cycle and Cardinal Features

Cycle	Group A	Group A		Group B	
	No. of Patient	Percentage	No. of Patient	Percentage	
Regular Cycle	9	45	16	80	
Irregular Cycle	11	55	4	20	
Severity of pain	20	100	20	100	
Duration of pain	20	100	20	100	
Radiation of pain	11	55	15	75	
Amount of blood flow	20	100	20	100	
Interval of menses	20	100	20	100	
Duration of flow	20	100	20	100	

Table 2: Cardinal Features

Symptoms	Group A		Group B	Group B		
	No of patients	Percentage	No of patients	Percentage		
Nausea	10	50	5	25		
Vomiting	7	35	2	10		
Constipation	13	65	8	40		
Fatigue	18	90	11	55		
Anorexia	15	75	12	60		

Effect of Therapy: Response of therapy on various clinical features in group A, treated with Rajahpravartini Vati orally by applying Wilcoxon matched pairs signed ranks test.

Table 3: Effect of Therapy in Group A (Trial Group)

Symptoms	Mean		MD	% Relief	SD	SE	p value	Results
	BT	AT						
Severity of Pain	2.30	0.25	2.05	82.6	0.604	0.135	p<0.0001	Extremely significant
Duration of pain	1.75	0.20	1.55	88	0.823	0.1846	p<0.0001	Extremely significant
Radiation of pain	0.9500	0.200	0.7500	78	0.4443	0.09934	p<0.0001	Extremely significant
Amount of blood flow	1.35	0.55	0.80	59.25	0.523	0.117	p<0.0001	Extremely significant
Interval of menses	1.03	0.40	0.90	69	0.447	0.100	p<0.0001	Extremely significant
Duration of flow	1.15	0.40	0.75	65.21	0.55	0.123	p<0.0001	Extremely significant
Nausea	0.95	0.150	0.80	84	0.410	0.0917	p<0.0001	Extremely significant
Vomiting	0.45	0.15	0.30	66	0.47	0.1051	p-0.0313	Insignificant
Constipation	1.15	0.30	0.85	73	0.489	0.1094	p<0.0001	Extremely significant
Fatigue	1.85	0.65	1.20	64	0.4104	0.0917	p<0.0001	Extremely significant
Anorexia	0.90	0.15	0.75	83	0.443	0.09934	p<0.0001	Extremely significant

Response of therapy on various clinical features in group B (Control Group), treated with Roasted wheat powder orally by applying Wilcoxon matched pairs signed ranks test.

Table 4: Effect of Therapy in Group B (Control Group)

Symptoms	Mean		MD	% Relief	SD	SE	p value	Results
	BT	AT						
Severity of Pain	1.95	1.05	0.90	46.15	0.552	0.123	p<0.0001	Extremely significant
Duration of pain	2.15	1.30	0.85	39.5	0.745	0.166	p<0.0002	Significant
Radiation of pain	0.650	0.30	0.35	53.84	0.489	0.109	p<0.0156	Significant
Amount of blood flow	0.80	0.65	0.15	18.75	0.5871	0.131	p-0.375	Insignificant
Interval of menses	1.05	0.50	0.55	52.38	0.604	0.135	p-0.0020	Significant
Duration of flow	0.60	0.30	0.30	50	0.4702	0.1051	p-0.0313	Significant
Nausea	0.550	0.40	0.15	27.27	0.366	0.0819	p-0.250	Insignificant
Vomiting	0.70	0.40	0.30	42.85	0.470	0.1051	p-0.0313	Significant
Constipation	0.60	0.30	0.30	50	0.470	0.1051	p-0.0313	Significant
Fatigue	1.65	1.05	0.60	36.36	0.6806	0.1522	p-0.0020	Highly Significant
Anorexia	0.55	0.35	0.20	36.36	0.4104	0.0917	p-0.0020	Highly Significant

Comparative Chart on Effect on Therapy on Cardinal Symptoms:

Table 5 A: Effect of Therapy on Cardinal Symptoms

Symptoms	Group A percentage	Group B percentage
Severity of pain	82.60	46.15
Duration of pain	88	39.5
Radiation of pain	78	53.84
Amount of blood flow	59.25	18.75
Interval of menses	69	52.38
Duration of flow	65.21	50

Table 5 B: Effect of Therapy on Cardinal Symptoms

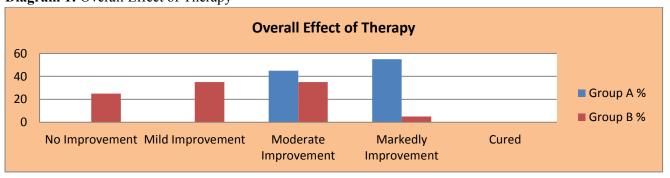
Symptoms	Group A percentage	Group B percentage
Nausea	84	27.27
Vomiting	66	42.85
Constipation	73	50
Fatigue	64	36.36
Aruchi (anorexia)	83	36.36

Overall Effect of Therapy:

Table 6: Overall Effect of Therapy

Result	Group A	Group A		Group B		
	No. of Patient	Percentage	No. of Patient	Percentage		
No Improvement	00	00	05	25		
Mild Improvement	00	00	07	35		
Moderate Improvement	09	45	07	35		
Markedly Improvement	11	55	01	5		
Cured	0	00	00	00		

Diagram 1: Overall Effect of Therapy



DISCUSSION

Discussion is an important aspect of that work to reach on any conclusion. It is important, as before establishing any theory, Discussion is the prior step to conclusion. Discussion is a process of re-examining oneself. It forms a base for conclusion. In spite of detailed classical study and experimentation in various ways, the result of that research adopted only after the proper reasoning of its observation. The findings and observations are evident by the discussion. It is most intense on the first day of menses and progressively lessens with menstrual flow. Dysmenorrhoea is one of the most common problems experienced by adolescent girls.⁵ Primary dysmenorrhoea is widely prevalent, more than 70% of teenagers and 30 – 50% of menstruating woman suffer from varying degree of discomfort. The severe incapacitating type which interferes with a woman's daily activities affects only about 5 - 15% of the population. Its prevalence is higher amongst the more intelligent and sensitive working woman both the local and systemic symptoms are apparently the result of increased levels of prostaglandins in the menstrual fluid. The exact cause of primary dysmenorrhoea is still obscured. Several theories are speculated for the etiology of primary dysmenorrhoea viz. the hormonal, the psychological, the nervous and the genetic and risk factors have been identified as possible etiopathological causes behind the condition. Hormones are hypothesized key, influencers for triggering menstrual pain and "higher levels of prostaglandins, leukotrienes, vasopressin, hormones and platelet-activating factor in menstrual fluid. These key elements make possible pelvic pain associated with arterial vasoconstriction, blood clot formation, menorrhagia, and increased uterine contractility. 6 In the pathogenesis of dysmenorrhoea progesterone, vasopressin and prostaglandins play an important role. Due to decrease level of progesterone and increase level of vasopressin production of prostaglandins which increase myometrial activity and result in the form of dysrhythmic uterine contraction followed by hypoxia, ischemia and pain. In 'Kashtartava' Tridosha are involved with predominance of *Vata*. The probable mode of pathogenesis may be due to Margavarodha and Dhatu Kshaya. In Charaka Samhita, it is clearly mention that *Vata* produces various disorders with respect to its various etiological factors. The vitiated Vata by Ruksha, Sheeta, Sukshma properties spread through Rasavaha Srotasa and leads to Rasavaha, Raktavaha and Artavavaha Srotodushti. Dosha - Dushya Sammurchhana takes place in Garbhashaya. Due to vitiation of Vyana and Apana Vayu the Akunchana and Prasarana Kriva of Garbhashava does not take place properly, the state exactly that of dysrhythmia of uterine muscles, which will hinder in proper flow of menstrual blood leading to Kashtartava. In Susruta Samhita, it is depicted that, "Dosha Avrita Margatvata Artavam Nashayati Striyah". The duration of cycle in an individual may vary from 21 to 35 days. However, on an average 28 days is counted for normal menstrual period.⁷ In the present study, it was observed that due to stressful condition the menses become irregular which may be physiological. Withdrawal of progesterone preceding menstruation probably causes break down of lysosomes and release of phospholypase A2 which act upon the phospholipids in the cell wall and produces large amount of arachidonic acid resulting in initiation of prostanoid cascade and the synthesis of various prostaglandins. 8 which is responsible for painful menstruation. It may be reduces due to Kumari component of drug, which possess anti-prostaglandin activity and helpful in releasing the pain. Another component of trial drug was *Hingu*, it has anti-spasmodic property and well known for Vatanulomana. 10 In the pathogenesis impaired Jatharagni which hinder Dhatwagni and result improper formation of *Dhatu* and *Upadhatu*. Artava is a Updhatu of Rakta and Rakta is formed after Rasa Dhatu.11 In group A, better result found in Amount of menstrual blood (Artava Pramana), Interval of menses and Duration of flow was due to synergetic effects of Hingu, Kaseesa and Tankana. These drugs optimized the metabolism of body thus leading to proper secretion of hormones in the body which finally regulate interval between menses. Hingu is a drug having Deepana and Pachana properties by which it metabolizes Aam and regulate the physiological process of Dhatu and Upadhatu formation. Kaseesa, which is an iron compound and Hingu and Kumari both drugs are known as Artava Janana. 12 by which it increases the amount of blood flow, this may be due to Nidana Parivarjana and Ayurvedic dietetics. During menstruation due to increase quantity of Prostaglandins, the tendency of nausea and vomiting appears. In Rajahpravartini Vati, Kumari is a drug having anti-prostaglandin. 13 property leads to decrease tendency of nausea and vomiting. Tankan is a drug having Shrotoshodhak property, clarifies the Sama Kapha whereas Kumari by its Pitta-virechaka property normalized Sama-Pitta. 14 Constipation is caused by Vitiation of *Vata* and *Kapha*, aggravation of Vata is due to Margaavrodha, which modifies the natural path of Apan Vayu. In group A, better result was seen due to synergetic effect of Kumari and Hingu. Hingu is well established drug for

Deepan, Pachan and Vatanulomana, thus remove obstruction from the natural path of Apana Vayu whereas Kumari is Tikta and Madhur in Rasa, Snigdha and Pichchil in Guna having Katu Vipaka, Sheeta Veerya and Bhedana in its Prabhava. It has Vata reducing, Kapha reducing, Pittasaraka properties by which it removes constipation. Fatigue is tiredness or lack of energy in the body it may be physical and mental. It is a common feature of anemia. In a cross-sectional survey done in five colleges of Bhavnagar, Raval CM et al. find out 489 college girls; 18.4% were having moderate to severe premenstrual symptoms. The symptoms commonly reported were Fatigue/ lack of energy, decrease interest in work and anger/irritability. 15

Probable Mode of Action: Hingu, Tankana, Kaseesa and Kumari are component of Rajahpravartini Vati. 16 Kaseesa helps in Rakta Dhatu Vriddhi, which improve the uterine blood circulation. Hingu has anti-flatulent and Deepana properties and counteracts spasmodic disorders and may probably suppress the secretion of progesterone hormone. 17 Kumari having Tikta Rasa and used mainly as purgative, improves digestion; the cathartic properties of aloes are attributed to the presence of a mixture of glycosides called, aloin. 18 Kumari also contains beeta-sitosterol and has the anti-prostaglandin activity. Cathartic property of this relives the obstruction in the pathways of Vayu, and there by relieves spasm. 19 In this study, it was observed that several psychological factors were found in the patients of Kashtartava, Kumari exerts calming and soothing effect on mind and works as a tranquillizer and a mild sedative, hence, it is found beneficial in mental stress, hypertension, insomnia and headache. Tankana is Garbhashaya sankochaka (improves the tonicity of uterine muscle) drug helps in normal harmonization during contraction. It may be due to the fact that "Rajahpravirtini Vati" has Katu, Tikta Rasa, Laghu, Snighdha and Tikshna Guna. Tikta Rasa and Tikshna Guna of drug clear the Srotoavarodha. Katu Vipaka and Ushna Virya pacify the reliever the Vata and it has Vatanulomana property which helps in normalizing the function of Apanvata.²⁰

CONCLUSION

The term Kashta denotes difficulty in Kashtartava, there is a difficulty in discharging menstrual blood because of vitiation of Vayu. Regulation of Vayu plays a key role in treating Kashtartava vis-à-vis Primary dysmenorrhoea. The menstrual rhythm depends upon the Hypothalamus-Pituitary-Ovarian function, whereas the amount of blood is depending upon the uterine condition. The endometrial, which is the seat of Artava especially Bahirpushpa undergoes a series of cyclical change in accordance with the influence of the hormone. The main aim of treatment is to remove the intermediary metabolites from Poshak Dhatus, the removal of Sang by Kapha is Margavarodha is main cause of Kashtartava. Subsequently to increase Dhatu nourish by Deepan, Pachana drugs by increase the Jatharagni and Dhatwagni Vyapara. As per pathogenesis, treatment of Kashtartava should be Vightan of Samprapti by Vatanulomak and Vatashamak Chikitsa. It was found that average percentage of relief was higher in group A i.e. 71% while in group B i.e. 43.10%. During the treatment, patients were advised to follow NidanParivarjan, which is also good principle of Ayurveda, strongly advocated by Acharya Sushruta "Sankshepataha Kriyayogo Nidana Parivarjanam", which is further proven in this study (Su. Ut. 1/25). Finally, it can be concluded that the drug taken for the clinical trial (Rajahpravartini Vati) was found very effective along with Nidan Parivarjan in alleviating the symptoms of Primary dysmenorrhea (Kashtartava).

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