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TO EVALUATE THE EFFICACY OF INDIGENOUS COMPOUND IN *RAKTAPRADARA* w.s.r DYSFUNCTIONAL UTERINE BLEEDING

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ABSTRACT

Any abnormality in *Rutuchakra* (menstrual rhythm) leads to excessive and irregular uterine bleeding is known as *Raktapradara* or Dysfunctional Uterine Bleeding (DUB).The main ingredients of indigenous compound churna are *SHUNTHI* and *BHARANGI*. *SHUNTHI* which is *vata- kaphahara, dipana, bhedana, raktashodaka, sophahara*, possess significantly antioxidant properties, an effective supplement for heavy menstrual bleeding and act as *raktapittahara* and anti-inflammatory in action. *Bharangi* is *kapha- vatahara, jvarahara, kasahara, raktadoshahara and amapacana.* In present study 30 patients were selected that fulfilled the criteria of diagnosis and consented for the study. After completion of three consecutive cycles, treatment was withdrawn and net follow up was taken again after interval of one month to know any recurrence of sign/symptoms. The parameters selected for the study were Duration of menstrual flow, Amount of menstrual bleeding, consistency, intermenstrual cycle, backache, pain in abdomen and haemogram.53.33% patients had moderately improved after third follow-up. The trial drugs are significant in the management of *Raktapradara*.

Keywords: *Raktapradara, SHUNTHI, Bharangi*.

INTRODUCTION

Raktapradara indicated the excessive and irregularity of menses.[1,2] in the female the reproductive system has a great importance and any disease in this system will seriously affect her health and happiness and also it proves to be a great discomfort. *Raktapradara* is one amongst the extensive range of occurrence. Any abnormality in *Rutuchakra* (menstrual rhythm.[3,4]) leads to excessive and irregular uterine bleeding which is known as "*Raktapradara*" in classical text.

Various treatments prescribed in modern medicine like hormone therapy, antiprostaglandins and antifibrinolytic agents etc. have not

proved their definite efficacy inspite of high price and side effect, and lastly hysterectomy may lead to hormonal imbalance and psychological upset in young fertile women.Keeping this in mind it was thought to dive in the ocean of treasure of ayurvedic medicine to find a remedy for it, which will be gentle, non – hormonal, practical, safe, and effective alternate in the management of DUB. So, we have selected *SHUNTHI* and *Bharangi* which not only cures *raktapitta, pradara*, but is *balya* and *brumhana*. They are gentle, non-hormonal, practical, safe and effective in the management in management of *ra*.[4,5]

The amount of *Arthava* is increased due to increase in following factors-

- Increase in *rasa dhatu* (increased *kapha*)
- Increase in *pitta dhatu* (increased *pitta*)
- Increased movement of *rasa* and *rakta* towards uterus (increased *vata*)

The main ingredients of indigenous compound churna are *SHUNTHI* and *BHARANGI*. *SHUNTHI* which is *vata- kaphahara, dipana, bhedana, raktashodaka, sophahara. SHUNTHI* possess significantly antioxidant properties and probably helps to inhibit gastric mucosal damage. *SHUNTHI* is as effective as Mefanamic acid and ibuprofen in relieving pain in women with primary dysmenorrhea. It is an effective supplement for heavy menstrual bleeding and act as *raktapittahara* and anti-inflammatory in action.

Bharangi is *kapha- vatahara, jvarahara, kasahara and raktadoshahara,amapacana, anulomana,Raktashodaka, sothahara, krmighna, dahaprasamana, raktotklesaka, vranapacana, granthisamana.*

SHUNTHI and *bharangi* have properties to cure disorders of blood and menstrual cycle due to *kashaya rasa, pitta nasaka and shula hara* properties and so used in treating *raktapradara* as described in various *granthas* like *Rajnighantu, Shaligrama nighantu* and *Bhavaprakasha nighantu* etc.

OBJECTIVES OF THE STUDY

1. To study *Raktapradara* as per Ayurveda and modern.
2. To evaluate the efficacy of indigenous compound in the management of *raktapradara.*
3. To find out simple, economical, best possible and non-hormonal therapy for DUB.

MATERIALS AND METHODS

The main ingredients of indigenous compound churna are *SHUNTHI* and *BHARANGI*. In this study both ayurvedic and modern subjective and objective parameters of assessments were included. Besides, the results of the clinical study have also been scrutinized from both ayurvedic as well as modern point of view, to arrive at important conclusion.

Source of Data:

The present clinical study was conducted at P.G. Department of PrasutiTantra of N.K.J. Ayurvedic Medical College and Post Graduate Center, Bidar. 30 patients who required management of *raktapradara* were selected from inpatient and outpatient department of Shree Siddharudha Charitable Hospital in Bidar. Being a clinical study patients were selected on

simple randomized sampling grounds after proper investigations and physical examination according to selection criteria.

Sample size: 30 Patients were selected according to inclusion criteria, patient fulfilling above criteria.

Sample Procedure: Patients are thoroughly examined and diagnosed before selection. Only those patients fulfilling below inclusion criteria are selected. Sample size: 30 patients will be selected.

Single blind study: 30 Patients will be administered *SHUNTHI* and *bharangi* churna 5 gm BD with *Tandulodaka* as *Anupana* for a period of three months.

Follow up – patients were followed regularly once in a month and specific attention was paid to note their menstrual history, changes in symptoms, psychological status.

INCLUSIONCRITERIA:-

1. Age group from 16 to 40 years females.
2. Complaints of excessive bleeding per vagina

EXCLUSION CRITERIA:-

1. Patient on hormone replacement, Depo-Provera, or Norplant in last three months.
2. Patient has intrauterine device.
3. History of systemic and metabolic disorders.
4. Patient with a previously diagnosed bleeding disorder.
5. Complaints of bleeding per vagina more than 6 pad/day
6. Acute pelvic inflammatory diseases.
7. Fibroid uterus.
8. Tubercular endometritis.
9. Pelvic endometritis
10. Carcinoma of the cervix and endometrium.
11. Uterine polyp.
12. Threatened or spontaneous or incomplete abortion or ectopic pregnancy.

Trial procedure: Each case of trial group was registered for the study. A specially designed Research Case Sheet which contains details about her personal data, obstetric data, gynaec data and any surgeries (myomectomy), data and examination etc. was prepared.

Criteria of Assessment:

A) Subjective Parameters :

TABLE 1: Duration of Menstrual Flow:

DAYS	GRADE
<5 Days	0
6-7 days	1
8-9 days	2
>9 days	3

TABLE 2: Amount Of Blood Loss: Pads /day

<3 pads / day	0
3 to 4 pads / day	1
4 to 5 pads / day	2
5 to 6 pads / day	3

TABLE 3: Interval Of Menstrual Cycle:

28 to 30 days	0
20 to 27 days	1
15 to 19 days	2
<15 days or irregular	3

TABLE 4: Consistency:

Normal	0
Thick	1
Thin	2
With clots	3

TABLE 5: Pain Abdomen (Acc. To MRC Grading):

Absent	0
Mild	1
Moderate	2
Severe	3

TABLE 6: Back Ache:

Present	1
Absent	0

B) Objective parameters :

TABLE 7: Hb%:

Normal (>11 gm%)	0
Mild (9-11 gm%)	1
Moderate (7-9 gm%)	2

Laboratory Investigations:

Following investigations were carried out in the patients to rule out any organic or systemic disease.

1. USG
2. Blood Investigation: CBP, RBS, ESR, CT, BT, TSH (If Required).

Statistical Analysis:

The information collected on the basis of observation were analyzed using appropriate statistical test (Paired‘t’ test) was used for parametric data) to evaluate the significances at different levels i.e. at 0.05, 0.01and 0.001 levels.

TABLE 8: Showing t-test values.

Insignificant or Not significant (NS or NQS)	p>0.05
Significant (S)	p<0.05
More or very Significant	p<0.01
Highly or Extremely Significant	p<0.001

The obtained results were interpreted as follows-

Result:

After completion of treatment in the Trial group patients were assessed at monthly intervals for 3 months. Data obtained from the parameters of assessment, before & after the therapy was utilized to evaluate the overall effect of therapy.

TABLE 9: Showing % relief

Cured	100% relief
Marked improved	75 to 99 % relief
Moderate improved	50 to 74 % relief
Mild improved	25 to 49 % relief
No improved	Less than 25 %

Statistical analysis of:

1) Subjective parameters:

The result will be statistically assessed by employing some non-parametric tests.

2) Objective parameters :

Within the groups (intra group comparison)

If the observations are paired type (dependency) then to test significant difference between two dependent means or paired means we may use paired “t” test.

The test statistics

$$t = \frac{\bar{d}\sqrt{n}}{s}$$

Where $\bar{d} = \sum \frac{d}{n}$

d= difference between before treatment values and after treatment values

n= no. of observations

s= standard deviation of the difference degrees of freedom. =n-1

Between the groups (Intergroup comparison)

For testing the significant difference between two independent means' t' test may be employed.' F' test may be employed if needed. Where

F = $\frac{S1^2}{S2^2}$ S1=variation in the first group

S2= Variation in the second group.

The 't' test may be employed

t = $\frac{\bar{X}-\bar{Y}}{S\sqrt{\frac{1}{n1}+\frac{1}{n2}}}$

Where $\bar{X} = \sum\frac{X}{n1}$ x = the first group

$\bar{Y} = \sum\frac{Y}{N2}$ Y = the second group

S = pooled standard deviation = $\sqrt{\frac{\sum(x-\bar{x})^2+\sum(y-\bar{y})^2}{n1+n2-2}}$

n1 = No. of observations in the first group

n2 = No. of observations in the second group.

Degree of freedom = n1+ n2 - 2

OBSERVATIONS AND RESULTS

General Observations:

TABLE 10: Age Wise Distribution of 30 Patients

AGE	TRIAL GROUP	%
16-30	12	36.66
30-40	18	63.33

In the present study of 30 patients, 36.66 % belong to the age group between 16-30 years & 63.33 % between 30-40 years.

TABLE 11: Showing Socio Economical Status Wise Distribution of 30 Patients

Class	Trial Group	%
Lower class	16	53.33
Middle class	10	33.33
Upper class	04	13.33

Table shows that in the present study 53.33% patients belonged to Lower class followed by 33.33% patients of Middle class and the rest 13.33% belonged to upper class.

TABLE 12: Showing Occupation Wise Distribution

Occupation	Trial Group	%
Business	04	13.33
Housewife	18	60
Service	02	6.67
Student	06	20

Table shows that in the present study Maximum No. of patients 60% were housewives followed by 20% patients who were students the rest 6.67% patient were in service and 13.33% in business.

TABLE 13: Marital Status Wise Distribution of 30 Patients:

Married	20	73.33
Unmarried	10	26.66

Table shows 73.33% of patients were married whereas rest of the patients (26.66%) was unmarried in the present trial.

TABLE 14: Showing Psychological Status Wise Distribution

Psychological	Trial Group	%
Good	10	33.33
Agitated	12	40
Dull	08	26.66

Table shows that out of 30 patients most of the patients (40%) had agitated or stressed, followed by 33.33% of patients having good and 26.66 % of patients having dull psychological status.

TABLE 15: Showing *Deha-Prakriti* Wise Distribution

DehaPrakriti	Trial Group	%
Kapha-Vataja	14	46.66
Pitta – Kaphaja	10	33.33
Vata-Pittaja	06	20

Table shows that out of 30 patients most of the patients (46.66%) had Kapha-Vataja Prakriti followed by 33.33% of patients had Pitta-KaphajaPrakriti and 20% of the patients had Vata-Pittaja Prakriti.

TABLE 16: Showing Parity Wise Distribution of 30 Patients.

Parity	Trial group	%
Nulliparous	12	40
Primipara	02	6.66
Multipara	16	53.33

Table shows that in the present study maximum patients (53.33%) were Multiparous followed by Nulliparous (40%) and only 6.66% of patients were Primiparous.

TABLE 17: Showing Duration of Cycle Wise Distribution

Duration of cycle	Trial group	%
Grade-0	04	13.33
Grade-1	10	33.33
Grade-2	08	26.67
Grade-3	08	26.67

Table shows that in the present study maximum patient having grade-1(33.33%) followed with grade-2(26.67%), grade-0(13.33%) and grade-3(26.67%).

TABLE 18: Showing Amount of Bleeding Wise Distribution

Amount of bleeding	Trial Group	%
Grade-0	0	0
Grade-1	04	13.33
Grade-2	06	20
Grade-3	20	66.67

Table shows that in the present study maximum patient having grade-3(66.67%) followed with grade-1(13.33%), and grade-2(20%)

TABLE 19: Showing Intermenstrual Cycle Wise Distribution

Intermenstrual cycle	Trial Group	%
Grade-0	12	40
Grade-1	14	46.67
Grade-2	02	6.67
Grade-3	02	6.67

Table shows that in the present study maximum patient having grade-0(40%) followed with grade-1(46.67%), grade-2(6.67%) and grade-3(6.67%)

TABLE 20: Showing menstrual blood consistency Wise Distribution

Consistency	Trial Group	%
Grade-0	0	0
Grade-1	10	33.33
Grade-2	06	20
Grade-3	14	46.76

Table shows that in the present study maximum patient having grade-3(46.76%) followed with grade-1(33.33%) and grade-2(20%).

TABLE 21: Showing Pain Abdomen Wise Distribution.

Pain	Trial Group	%
Grade-0	08	26.67
Grade-1	12	40
Grade-2	08	26.67
Grade-3	02	6.67

Table shows that in the present study maximum patient having grade-1(40%) followed with grade-0(26.67%), grade-2(26.67) and grade-3(6.67%)

TABLE 22: Showing Backache Wise Distribution

Backache	Trial Group	%
Grade-0	12	40
Grade-1	18	60

Table shows that in the present study patient having backache grade 0 (40%), followed with grade-1 (60%).

TABLE 23: Showing Hb% Wise Distributions of 30 Patients**.**

Hb (gm)	Trial Group	%
Grade-0	5.0	33.33
Grade-1	6	40
Grade-2	4	26.67

Table shows that in the present study maximum patient having grade-1(40%) followed with grade-0(33.33%), grade-2(26.67)

TABLE 24: Effectiveness of Trial Group:

SIGNS & SYMPTOMS	B.T. Mean ± S.E.	Follow Up	A.T. Mean ± S.E	df	T-Value	P-Value	Effectiveness %	Remark
Duration of menstrual flow	2.35 ± 0.128	AT1	1.4±0.13	14	1.87	>0.05	23.52	NS
		AT2	0.428±0.13		2.25	<0.05	50	S
		AT3	0.133±0.09		2.64	<0.05	67.64	S
Amount of blood loss	2.13 0.09	AT1	1.733±0.118		1.46	>0.05	18.75	NS
		AT2	1.13±0.09		2.34	<0.05	46.87	S
		AT3	0.6±0.130		2.42	<0.05	71.87	S
Constituency	2.2±0.10	AT1	1.66±0.125		1.54	>0.05	24.24	NS
		AT2	1±0		2.25	<0.05	54.54	S
		AT3	0.66±0.125		2.64	<0.05	69.69	S
Intermenstrual cycle	1.866±0.13	AT1	1.6±0.130		1.74	>0.05	14.28	NS
		AT2	0.933±0.118		2.42	<0.05	50	S
		AT3	0.8±0.144		2.64	<0.05	57.14	S
Backache	1.466±0.165	AT1	1.2±0.106		2.25	<0.05	18.18	S
		AT2	1±0.097		3.5	<0.05	31.81	S
		AT3	0.6±0.163		4.5	<0.05	59.09	S
Pain abdomen	1.533±0.165	AT1	1.2±0.106		2.64	<0.05	21.73	S
		AT2	1.066±0.066		3.5	<0.05	30.43	S

		AT3	0.666±0.125		5.24	<0.05	56.52	S
Hemoglobin percentage	2.133±0.13	AT1	1.6±0.130		1.87	>0.05	25	NS
		AT2	1±0		2.25	<0.05	53.125	S
		AT3	0.733±0.11		2.64	<0.05	65.625	S

Comparison between BT and AT Trial group:

1. **Duration Of Menstrual Flow**
   The mean score of the symptom which was 2.35 ± 0.128 before treatment reduced to 1.4±0.13 after first follow up, after second follow up it is reduced to 0.428±0.13, after third follow up the mean score of duration of menstrual flow was reduced to 0.133±0.09. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.
2. **Amount Of Blood Loss**
   The mean score of the symptom which was 2.13±0.090 before treatment reduced to 1.733±0.118 after first follow up, after second follow up it is reduced to 1.133±0.09, after third follow up the mean score of amount of blood loss was reduced to 0.6±0.130. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.
3. **Constituency**
   The mean score of the symptom which was 2.2±0.10 before treatment reduced to 1.66±0.125 after first follow up, after second follow up it is reduced to 1±0, after third follow up the mean score of constituency was reduced to 0.66±0.125. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.
4. **Intermenstrual Cycle**
   The mean score of the symptom which was 1.866±0.13 before treatment reduced to 1.6±0.130 after first follow up, after second follow up it is reduced to 0.933±0.118, after third follow up the mean score of intermenstrual cycle was reduced to 0.8±0.144. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.
5. **Back Pain**
   The mean score of the symptom which was 1.466±0.165 before treatment reduced to 1.2±0.106 after first follow up, after second follow up it is reduced to 1±0.097, after third follow up the mean score of backache was reduced to 0.6±0.163. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.
6. **Pain Abdomen**
   The mean score of the symptom which was 1.533±0.165 before treatment reduced to 1.2±0.106 after first follow up, after second follow up it is reduced to 1.066±0.066, after third follow up the mean score of pain was reduced to 0.66±0.125. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.

7. Hemoglobin Percentage

The mean score of the symptom which was 2.133±0.133 before treatment reduced to 1.6±0.130 after first follow up, after second follow up it is reduced to 1±0, after third follow up the mean score of depressed mood was reduced to 0.733±0.11. When these values were statistically analyzed, it showed that the drug was significantly effective with p value < 0.05.

TABLE 25: Overall Effect of Treatment

Result	Trial group					
	AT1		AT2		AT3	
	No. of pts	%	No. of pts	%	No. of pts	%
Cured (100%)	0	0	0	00	0	0
Marked improvement (75-99%)	0	0	00	0	4	26.66
Moderate Improvement (50-74%)	0	0	5	33.33	8	53.33
Mild improvement (25-49%)	2	13.33	10	66.66	3	20
No improvement (>25%)	13	86	00	0	0	0

In the present study overall effect of treatment showed that, in trial study after first follow up 13.33% had mild improved and 86% patients have no improvement,. After second follow up 66.66% had mild improvement and 33.33% patients had moderate improvement in trial group and after third follow up 20% patients had mild improvement, 53.33% had moderate improvement and 26.66% had marked improvement in trial group.

DISCUSSION

Raktapradara is a disease in which majority of women experience certain uncomfortable physical and psychological symptoms. Here, an attempt is made to evaluate the effect of *SHUNTHI* & *Bharangi* churna in the *raktapradara*.

Discussion on Clinical Study

Present study was planned to evaluate the clinical study of indigenous compound in the management of *raktapradara* in trial study. For the present study 30 patients were selected that fulfilled the criteria of diagnosis and consented for the study. After completion of three consecutive cycles treatment was withdrawn and net follow up was taken again after interval of one month to know any recurrence of sign/symptoms. The parameters selected for the study were Duration, Amount of menstrual bleeding, constituency, intermenstrual cycle, backache, pain and haemogram.

Discussion on General Observations

Incidence showing Age wise

Maximum number of patients were between the age group 30-40 Years (63.33 %) followed by the age group 16-30 Years(36.66%). This shows that *raktapradara* is found predominantly in the child bearing age. During reproductive phase of life family burdens, children and personal worries are higher. These might affect the personal life of women due to which menstrual cycle is disturbed and leading to *raktapradara*.

Incidence showing Socio-economic status wise

In the present study 53.33% patients belonged to Lower class followed by 40% patients of Middle class and the rest 6% belonged to Upper class. It may be implicated that the upper class being more aware of their health status and financially strong provide themselves with early treatment and have lesser incidence towards the disease. People of lower class are not having proper diet and hygienic environment. So the chances of malnutrition, anemia and other chronic health problems are higher in the lower class. This reflects their higher incidence in the study group. Middle class is the moderate income group, therefore they undergo lot of stress in many phases of day to day life and are less aware of their health status. We know that stress itself is a cause for many disorders.

Incidence showing Occupation wise:

Most of the women registered were house wives (63.33%). Household work, day sleep and stress may contribute to vitiation of *doshas*. They are more prone to emotional stress because they don't have any extra activity to engage their mind. So this psychological state may affect the artavautpatti. However, a wider and deep study is required to come to an exact conclusion.

Incidence showing Marital Status wise:

Incidence according to marital status showed that 73.33% were married and 26.66% were unmarried. This can be attributed to the fact that the incidence of the disease is influenced by sexual activeness and psychosocial problems related with marriage.

Incidence showing Psychological status wise:

Incidence in the present study showed that 53.33% were subjected to mental stress. One can say that, due to *krodha, chinta, tanava, rajogunavriddhi* occurs and thus increases the *vata*. Mainly due to above *nidana, vyanavayu* is vitiated and as mentioned in the book of gynaecology (Premavathi Tiwary,[10] Emotional stress, strain etc. affect hypothalamus and thus inhibiting the release of GnRH. It alters the normal Hypothalamo-Pituitary-Ovarian axis and thus produces some irregularities in the menstrual cycle.

Incidence showing Deha-Prakriti wise:

Incidence according to *prakriti* showed that the majority of patients (50%) were of *Kapha-Pittaja Deha Prakriti* followed by *Pitta-Kaphaja Deha Prakriti* (30%).

Incidence showing Parity wise:

Maximum No. of patients registered were multiparous (66.66%), this may be attributed to the fact that the state where the study was conducted has highest incidence of child marriage. Although a definite concept regarding the influence of parity cannot be drawn, it is believed that uterine congestion and susceptibility to infection of uterine cavity is more common in multiparous women.

Effect of treatment:

The assessment of the results was made by scoring the signs and symptoms. All the observations regarding the changes in the menstrual variables like the duration of bleeding, amount of bleeding, interval of cycle, constituency, backache, pain abdomen, and Hb% were assessed and The statistical evidence shows that there is a significant difference between BT and AT in I, II & III month.

Effect on Duration of menstrual flow:

When duration of menstrual flow were considered then 67.64 % got relief in trial group

after third follow up. This shows that trial group therapy showed moderate improvement.

Effect on Amount of blood loss:

When amount of blood loss were considered then 71.8 % got relief in trial group after third follow up.

Effect on Constituency:

When constituency were considered then 69.69 % got relief in trial group after third follow up.

Effect on Intermenstrual cycle:

When intermenstrual cycle were considered then 57.14 % got relief in trial group after third follow up.

Effect on Backache:

When backache were considered then 59.09 % got relief in trial group after third follow up.

Effect on Pain abdomen:

When pain abdomen were considered then 56.5 % got relief in trial group after third follow up.

Hemoglobin percentage:

When Hemoglobin percentage were considered then 65.62 % got relief in trial group after third follow up.

Overall effect of therapy:

The present study shows that the *SHUNTHI* and *bharangi* in *raktapradara* helps in reducing the symptoms, and trial group shows moderate improvement.

CONCLUSION

The following conclusions are made after carrying out the present study.

- DUB/*Raktapradara* is the commonest disorder found in between 16 to 40 years of age.
- The impairment of the H-P-O axis resulting in ovulatory cycles lead to menorrhagia, without involving any other organic or systemic pathology.
- Modern Medicine offers hormonal treatment and surgical therapy.
- The contents of the drug selected for the present study i.e. *SHUNTHI* and *BHARANGI* are *kaphavatashamaka*, *deepana*, *pachana*, *Raktashodaka*. It is hemostatic in action, anti-inflammatory, analgesic, antimicrobial, digestive & carminative, having hepatoprotective action& increases liver metabolism, which may normalize HPO axis and cure the disease.
- Significant effect of the trial drug is seen in three month period.
- Besides the medication by the trial drug, there is need of emotional support by their family members as a part of psychotherapy.
- The present study shows that the indigenous compound helps in reducing the symptoms, and showed moderate improvement.

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