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"A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF VAMANA KARMA WITH IKSWAKU AND MADANAPHALA IN THE MANAGEMENT OF PREDIABETES"

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ABSTRACT

Prediabetes is one of the major healthcare issues in the present times owing to its impact on the quality of life and risk of diabetes mellitus and other micro and macro-vascular diseases. It is a state of intermediate hyperglycemia which is a reversible state from where an individual can progress to diabetes or revert to normalcy. The reversal is majorly by employing diet modification, lifestyle management and timely detoxification and rejuvenation therapy to repair the impaired metabolism. . Prediabetes according to the Ayurvedic perspective falls under the umbrella of *Santarpanottha Vikara* and can be understood as the premonitory stage of *Prameha* i.e. *Purvaroopa* or a clinically reversible stage with good prognosis i.e. *Kaphaja Prameha*. *Prameha* is *Kapha Pradhana Tridhoshaja Vyadhi* and *Shodhana* is the main line of treatment in such conditions, particularly *Vamana*. Considering these, comparative clinical study aimed to assess the effectiveness of *Vamana Karma* using *Madanphala* (group A) and *Ikshvaku* (group B) in prediabetes management. Procedural and disease-specific parameters (FBS, PPBS, HbA1c) were evaluated. Following intervention, both groups exhibited a significant reduction in blood glucose levels. Group A demonstrated superior outcomes, with a mean reduction in FBS by 11.7 mg/dl, PPBS by 19.9, and HbA1c by 0.32, all statistically significant ($p < 0.05$).In conclusion, both interventions proved effective, but *Madanaphala* emerged as a preferable choice for *Vamana* compared to *Ikshwaku*, considering both *Rogagnatha* and *Karmukata*. This study highlights the potential of Ayurvedic approaches, emphasizing tailored treatments for prediabetes to mitigate its impact on individuals' well-being.

KEYWORDS: Prediabetes; *Kaphaja Prameha; Vamana; Madanaphala; Ikshwaku*

INTRODUCTION:

Pre-diabetes is an intermediate state of hyperglycemia considered to be an at risk state with chances of developing diabetes [1]. It is a condition in which the blood sugar level is higher than normal but not high enough to be considered diagnostic of diabetes[2]. People identified with prediabetes are at a higher risk for developing diabetes with a conversion rate of 5-10% and other micro and macro vascular disorders. Lifestyle risk factors for developing prediabetes include overweight, sedentary lifestyle and other metabolic disorders.From an ayurvedic point of view, metabolic syndrome and prediabetes can be considered as a *Santarpanottha Vikara*. Early stages of metabolic syndrome is understood as *Medovaha Srotosudhti*. *Apathyanimittaja Prameha* can

be taken as a fully established metabolic syndrome[3,4]. Thus, Prediabetes according to ayurvedic perspective can be understood as premonitory stage of *Prameha* i.e *Purvaroopa* or a clinically reversible stage with good prognosis i.e *Kaphaja Prameha*.

As of 2019, globally around 422 million people suffered from diabetes-mellitus and 1.6 million deaths are directly attributed to diabetes each year [5]. According to an article published in 2023 about a cross sectional study carried out between 2008 and 2020, the overall prevalence of type 2 diabetes is 11% and that of prediabetes is 15.3% .The treatment cost of diabetes in an economically backward family may drain as much as 25% of the entire income for each person with diabetes. Diabetes-mellitus and its complications have a lasting impact on the quality of life of individuals which makes it important to curb this disease at an early stage.

In contemporary system of medicine, the treatment for pre-diabetes is at 3 levels-lifestyle management, pharmacotherapy and bariatric surgery. Lifestyle management mainly targets a weight loss of 7% my means of low fat diet and exercise whereas pharmacotherapy includes administration of oral hypoglycaemic agents [6].

In Ayurveda, *Shodhana Chikithsa* is indicated in *Prameha* and its *Poorvaroopa* because of *Bahudoshavastha* and *Shodhana* line of management can help break the pathogenesis and prevent or delay the onset of the disease[7]. *Prameha* is caused due to vitiation of *Kapha Pradhana Tridhosha* which in turn vitiates the *Medadi Dhathu* leading to increased *Kledata* in the *Shareera*. *Shodhana* is the main line of treatment in such conditions and owing to the predominance of *Kapha*, *Meda* and *Kleda*, *Vamana* has been selected as the treatment modality[8]. *Ikshwaku-Kalpa* is compared with *Madanaphala* for *Vamana* as it is more *Teekshna*, *Kaphagna* and is specifically indicated in *Prameha*[9].

MATERIALS AND METHODS

SOURCE OF DATA

- Subjects were selected from OPD and IPD of Government Ayurveda Medical College and Hospital, Mysore and Government Hi-Tech Panchakarma Hospital, Mysore.
- Special camps was conducted for the purpose
- Diabetic camps held in other organisations were attended to select subjects.

METHOD OF COLLECTION OF DATA:

A. SCREENING:

- A screening proforma was prepared with all aspects of history, signs and symptoms of pre-diabetes
- Laboratory investigations were performed to arrive at the proper diagnosis.

B. DIAGNOSTIC CRITERIA[10]

- HbA1c: 5.7-6.4%
- FBS: 100-125mg/dl

C. INCLUSION CRITERIA

- Subjects aged between 25-55 years, irrespective of gender.
- Subjects fulfilling the diagnostic criteria
- Subjects fit for *Vamana Karma*

D. EXCLUSION CRITERIA

- Known case of diabetes, hypertension, ischemic heart disease, hyperthyroidism
- Pregnant & Lactating women
- Any other systemic illness

STUDY DESIGN:

A comparative clinical trial with pre and post-test design

PLAN OF STUDY:

- SAMPLING: Purposive sampling
- Sample size: Total sample size consists of 40 subjects, 20 in each group
- Intervention: The subjects are divided into 2 groups. Group A is subjected to *Vamana Karma* with *Madanaphala*, and Group B is subjected to *Vamana Karma* with *Ikswaku*.

DURATION:

- Duration : 30 days
- Follow up: 1 month

PLAN OF INTERVENTION:

- Group A is subjected to *Vamana Karma* with *Madanaphala*, and Group B is subjected to *Vamana Karma* with *Ikswaku*.

Table no 01:Plan of Intervention

Poorvakarma	• *Deepana Pachana* with *Trikatu Churna* 3 gms twice daily before food, with *Ushna Jala*, till the attainment of *Nirama Lakshana* . • *Shodhananga Snehapana* with *Dhanvantara Gritha* in *Arohana Krama* until *Samyak Snigdha Lakshanas* are obtained.	
	***Vishrama Kala*: (Day before *Vamana*)**	*Sarvanga Abhyanga* with *Murchitha Tila Taila* followed by *Sarvanga Swedana*(*Bashpa Sweda*) The subject is advised to consume *Kapha Utkleshakara Ahara*.
	On the day of *Vamana*:	*Sarvanga Abhyanga* with *Murchitha Tila Taila* followed by *Sarvanga Swedana*(*Bashpa Sweda*)
Pradhana Karma	**GROUP A** ● *Akanta Pana* with *Yavagu/Ksheera* ● *Vamana Karma* with *Madanaphala Churna +Saindhava+ Madhu* (10gm+2gm+qs) ● Administration of *Vamanopaga Dravya*(*Yashtimadhu Phanta/Saindhava Jala*)	**GROUP B** ● *Akanta Pana* with *Yavagu/Ksheera* ● *Vamana Karma* with *Ikswaku Beeja Churna+ Saindhava+Madhu* (10gm+2gm+qs) ● Administration of *Vamanopaga Dravya*(*Yashtimadhu Phanta/Saindhava Jala*)
Paschath Karma	• *Mukha Prakshalana* • *Dhumapana* • *Samarjana Krama* for 3-7days as per *Shuddhi*	

ASSESSMENT CRITERIA

Objective parameter

FBS
PPBS
HBA1C

ASSESSMENT SCHEDULE

- Pre-test – 0^{th} day (Before intervention)
- Post-test- 1^{st} assessment- after 7 days of *Vamana Karma*
  - 2^{nd} assessment- 1 month after 1^{st} follow up

OBSERVATIONS AND RESULTS

1. Fasting Blood Glucose

In group A, the mean reduction in FBS value from before treatment to 1^{st} follow up is 17.4. With p value of 0.00, this reduction is highly significant. The mean reduction from before treatment to 2^{nd} follow up of 11.30 unit is not very statistically significant with a p value of 0.054. But this value is quite close.

In group B, the mean reduction from before treatment to first follow up is 22.70. This reduction is statistically significant with a p value of 0.00. The mean reduction from before treatment to 2^{nd} follow up is 12.30. This too is statistically highly significant with a p value of 0.00

Overall reduction in FBS value is statistically highly significant with a p value of 0.00. However, the

difference in reduction between the two groups is not statistically significant with a p value of 0.658.

Table no 02: FBS values in subjects before and after treatment

FBS VALUES	Groups		Total
	Group A	Group B	
Before treatment	120.4	122.4	121.4
1st follow up	103.0	100.0	101.5
2nd follow up	109.1	110.4	109.7

2. Post Prandial Blood Glucose

In group A, the mean reduction in PPBS value from before treatment to 1st follow up is 34.40. This result is statistically highly significant with a p value of 0.00. The mean reduction in PPBS values from before treatment to 2nd follow is 28.50 and with a p value of 0.00, this reduction too is statistically highly significant.

In group B, the mean reduction in PPBS values before treatment and 1st follow up is 15.20. This result is statistically highly significant with a p value of 0.01. The mean reduction from before treatment to 2nd follow up is 11.30 and this result too is statistically highly significant with a p value of 0.01.

Overall, there is a significant improvement in the PPBS values before and after treatment and this result is statistically highly significant with the p value of 0.00

The difference in mean reduction between the two groups is also is statistically significant with a p value of 0.008. This indicates that the reduction in PPBS was higher in group A than in group B.

Table no 03: PPBS values in subjects before and after treatment

PPBS VALUES	Groups		Total
	Group A	Group B	
Before treatment	169.8	144.8	157.3
1st follow up	135.4	129.6	132.5
2nd follow up	141.3	133.5	137.4

3. HBA1C

In group A, the average HBA1c value before treatment was 6.05 which reduced to 5.66% after 1 month.
In group B, the average HbA1c value before intervention was 5.94%, reduced to 5.69% after a month.
Overall, an average HBA1C of 5.99% reduced to 5.67% after 1 month

Table no 04: HBA1C values in subjects before and after treatment

HBA1C VALUES	Groups		Total
	Group A	Group B	

Before treatment	6.05	5.94	5.99
After treatment	5.66	5.69	5.67

4. OVERALL RESULTS

In terms of procedure, clinically *Madanaphala* yielded better *Shuddhi* in terms of *Maniki Shuddhi*, *Pittanta Lakshana* and *Kale Pravrutti*, with *Vegas* commencing on their own in an average of 15.3 minutes. With *Ikshwaku*, the upside was the ease of *Vamana Karma*, which produced more number of *Vegas* with less discomfort. However, none of these differences were statistically significant.

In terms of reduction in blood glucose levels,

- In group A, the mean reduction in FBS levels was 11.3mg/dl. The mean reduction in FBS levels in group B was 12.3. However, this difference is not statistically significant.
- In group A, the mean reduction in PPBS levels was 28.5mg/dl. The mean reduction in PPBS levels in group B was 11.3mg/dl. The difference in mean reduction in PPBS values across the 2 groups is 17.2 and the p value is highly significant suggesting the reduction was better with *Madanaphala*.
- With respect to HbA1c levels, in group A, the mean reduction was 0.39%. The mean reduction in HbA1c levels in group B was 0.25%. The difference between the two groups is statistically significant at a p value of 0.055 indicating *Madanaphala* is a better drug for *Vamana* in prediabetes.

DISCUSSION

Discussion on this study is dealt in three domains;

- Procedural action
- Drug action
- Action of *Vamana* on prediabetes

PROCEDURAL ACTION:

Snehapana: During *Snehapana*, as only *Gritha* is administered, there is acceleration of fat utilisation in the absence of carbohydrates. This action promotes mobilisation of fatty acids from the adipose tissue. Here, the administered medicine contains micromolecules of medicine and macromolecules of fat. During the digestion, the medicinal micromolecules are absorbed.

Swedana: After *Snehapana*, *Abyanga* and *Swedana* is carried out. It is proven that *Abhyanga* stimulates lymphatic drainage, helps in water loss and *Swedana* helps in burning calories. Overall, this process causes hemo-concentration, i.e. increased concentration of cellular components in the blood.ultimately, this causes liquification of *Doshas*.

Vamana: In *Vamana*, the body fluids are removed from the upper route. The GI tract is lined by mucous membrane which has a dual nature of absorption and secretion. During *Vamana*, the cellular fluid is drained into the interstitial fluid which is drained into the vascular compartment, from there it is drained into the gastric tract for elimination. Thus, *Vamana* creates a biochemical alteration in the gastric mucosa thereby draining out body fluids which has dissolved toxins and biochemicals in them.

DRUG ACTION:

Trikatu Churna is composed of *Shunti*, *Maricha Pippali*, which is *Deepana*, *Shleshmahara* and *Medoghna*. *Prameha* is a *Vyadhi* which primarily involves *Kapha* and *Meda* in its *Samprapthi*. The *Phalashruthi* of *Trikatu Churna* also includes *Prameha*.

Dhanvantara Gritha is selected as the drug of choice for *Snehapana*. It is mentioned in *Prameha Adhikara* of *Ashtanga Hridaya*. Most of the drugs in *Dhanvantara Gritha* possess *Katu Tiktha Rasa*, *Laghu Ruksha Guna*, *Ushna Veerya and Katu Vipaka*. It is *Tridoshahara*, *Deepana*, and *Kapha-Medhohara*. Owing to these properties, in addition to causing *Dosha Utkleshana*, it also targets the specific dhatus and helps in appropriate elimination of vitiated *Kapha* and *Kleda*. The contents of *Dhanvantara Grita* include, *Patha*, *Hareetaki*, *Gokshura*, *Punarnava*, *Yava*, *Vidanga* etc. *Vidanga* has been enumerated in numerous formulations for *Kaphaja Prameha* in over 15 ayurvedic texts. *Patha* has been proven effective in the management of diabetes through experimental in-vivo models.

Haritaki possesses hypolipidemic and immunomodulatory properties, thus helpful in diabetes. *Yava* is rich in beta-glucans, which are effective in lowering serum cholesterol and regulating blood glucose levels.

Murchitha Tila Taila was selected for the purpose of *Sarvanga Abhyanga*. It has both *Brumhana* and *Karshana* properties.*Tila Taila* has *Ushna Teekshna Guna* by virtue of which it traverses through the *Anu Srotas* and does *Medakshapana*. In addition, majority of the drugs are *Kaphamedahara*. Thus it was selected for *Sarvanga Abhyanga* during *Vishrama Kala.*

Vamaka: *Madanaphala* and *Ikshvaku* are the drugs chosen for *Vamana Karma*.

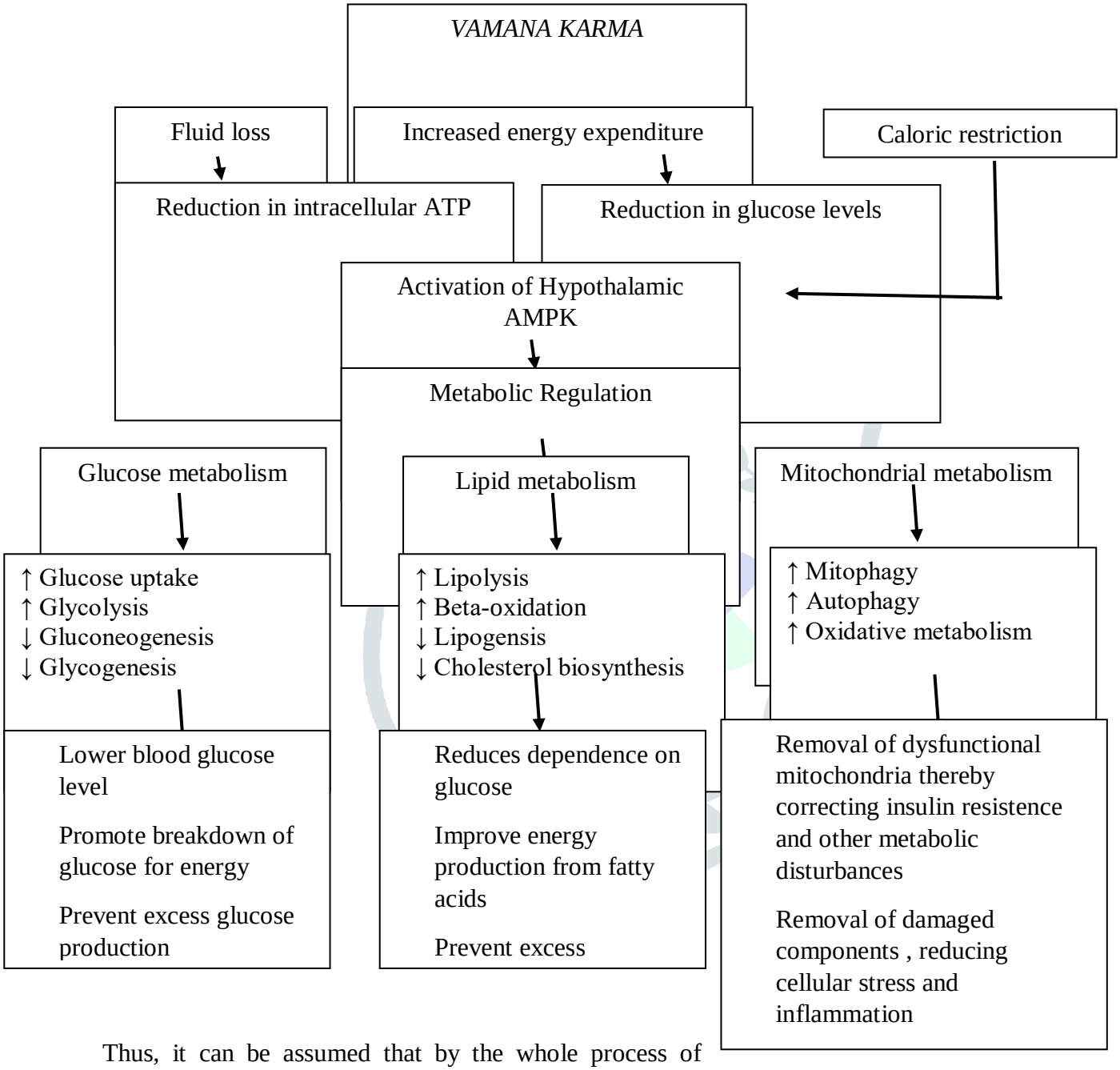
Madanaphala: *Madanaphala* possesses *Madhura Tikta Rasa, Laghu Ruksha Guna, Katu Vipaka, Ushna Veerya* and is *Kapha-Vatahara, Chardaneeya* and *Lekhana*. It is indicated in diseases like *Jwara, Gulma, Prameha* etc. *Madanaphala* is often the first choice of drug for *Vamana* irrespective of the disease condition because of its *Anapayi* property. Numerous research work has been done to study the pharmacognostical properties of *Vamana*. The bioactive fraction of *Madanaphala* is said to have immunostimulant activity. *Vamana* with *Madanaphala* has given excellent results numerous *Kaphaja Vikaras* like *Tamaka Shwasa*, diabetes, hypothyroidism etc. It has Dumetorinin A, B, C, & D, randialic acid. Anti-viral, anti-fungal, anti- allergic, anti-inflammatory, analgesic properties.

Ikshvaku: *Ikshvaku* has *Tiktha Rasa, Laghu Ruksha Guna* and is *Vata-Pittahara*. It is a *Vamaka* and is indicated in conditions like *Visha, Udara, Gulma,* and *Meha. Ikahvaku Churna* contains phytosterols, flavonoids, tannins and saponins. *Ikshvaku* possesses *Shodhana, Bhedana* and *Kaphanissaraka* properties by virtue of which it does *Vishyandana* and *Vilayana* of *Baddha Kapha* and *Meda*, clears the obstruction in *Srotas* and aids normal movement of *Dosha*. The chemical constituents of *Ikshvaku* include cucurbitacin, palmitic acid, stearic acid, beta-glucosides. Cucurbitin is found to have emetic properties.Various studies have been done on *Vamanakarma* with different *Kalpa* of *Iskwaku* and has shown significant results.

ACTION OF *VAMANA* ON PREDIABETES:

The ultimate aim of carrying out *Vamana Karma* in prediabetes is to eliminate the toxins, correct the metabolism and bring about sustained normalcy of blood glucose levels.

Illustration No 01: Hypothetical mode of action of *Vamana* on prediabetes



Thus, it can be assumed that by the whole process of *Vamana*, starting from *Snehapana* to *Samsarjana*, the changes happening in the body will ultimately result in correction of metabolism thereby breaking the pathogenesis of prediabetes. However, these changes are not permanent and can only be sustained by means of diet and other lifestyle modification.

Thus, in the study, following the intervention, subjects were advised lifestyle changes in terms of diet and exercise which is the ultimate method to manage prediabetes and prevent the onset of diabetes.

CONCLUSION

Prediabetes is one of the major medical issues in the country considering its implications on the quality of life and economy.This condition is majorly caused due to metabolic impairment secondary to improper diet and lifestyle which includes lack of physical activity, day-sleep and unregulated use of sweets, dairy, meat and oily food.Family history of diabetes, history of gestational diabetes, PCOS, hypothyroidism, and obesity are major risk factors for prediabetes and diabetes mellitus. *Dushitha Kapha* and *Abaddha Meda* are major

pathological entities that circulate all over the body and lodge in the *Mutravaha Srotas*, producing both *Sarvadaihika* as well as *Mutra Sambandi* symptoms.

The procedure of Vamana was carried out safely in both the groups using Madanpahala in group A and Ikshwaku in Group B. There was overall significant reduction in FBS, PPBS, and HbA1c levels in all 40 subjects.The reduction in FBS level was more or less the same in both groups.The reduction in HbA1c and PPBS was better in *Vamana* with *Madanaphala* as compared to *Ikshwaku*.Among the two drugs, *Madanaphala* was effective in terms of *Swayam Pravrutti* and *Kalepravrutti* of *Vega*, *Maniki Shuddhi* and *Pittanta Shuddhi*. *Ikshwaku* yielded slightly more *Vegas* and produced less discomfort.

In conclusion, it can be said that *Madanaphala* proved to be a better choice of drug for *Vamana* in prediabetes both in terms of procedural ease as well as disease management.

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