



Research Article

COMPARATIVE CLINICAL STUDY ON THE EFFECT OF SARJARASADI MALAHARA AND VIPADIKAHARA GHRITA-TAILA IN THE MANAGEMENT OF VIPADIKA

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ABSTRACT

Vipadika is one among the several types of skin disorders elaborated by Ayurveda. A randomized open comparative clinical study was done on 30 no of patients diagnosed as *Vipadika* at V.Y.D.S. Ayurveda Mahavidyalaya, Khurja. They were divided into two groups. In Trial group (TG) 15 cases treated with *Sarjarasadi Malahara* and in Control group (CG) 15 cases treated with *Vipadikahara Ghrita-taila*.

The percentage of improvement was 95.13%, 96.79%, 96.15%, 86.68%, 95.13%, 94.57% in *Vipadikahara Ghrita-taila* and 87.19%, 84.39%, 73.53%, 90.91%, 87.19%, 76.65% in *Sarjarasadi Malahara* in respect to *Panipaada Sphutanam* (cracks of hands and feet), *Vedana* (pain), *Kandu* (itching), *Daha* (burning sensation), total number of cracks, total length of cracks. The statistical adjudication with suitable parameters shows that both drugs were extremely/very significant on subjective and objective parameters among both groups. The overall clinical effect of therapy shows that, 73.33% and 33.33% patients get maximum improvement, 26.67% and 53.33% get moderate improvement, 0% and 6.67% get mild improvement with *Vipadikahara Ghrita-taila* and *Sarjarasadi Malahara* respectfully.

Defining to the benefits assessed both the drugs were found capable to enforce relief, but based on percentage of improvement and overall result, it can be concluded that *Vipadikahara Ghrita-taila* was more effective than *Sarjarasadi Malahara*.

INTRODUCTION

Skin is given due importance since time immemorial owing to the aesthetic value conferred upon skin, complexion and beauty by the society. Any sicknesses of skin become a great dispute for an individual in the civilization. Ayurveda designates most of the skin diseases under the umbrella term of *Kustha roga* and has pointed at its multifactorial aetiology.

Vipadika is one among the 11 types of *Kshudra Kustha* characterized by *Panipada Sphutana* (fissures in palms and soles) and *Tivravedana* (severe pain), *Daha* (burning sensation)^[1,2].

Maharshi Vagbhata^[3] has also explained similarly with one more symptom as red patches over palm and sole. Because of the excessive friction or pressure over the skin *Vata* gets vitiated locally. Due to increase in the *Ruksha* nature of *Vata* the skin gets dry and becomes thickened. This results in the cracks. The condition may further worsen due to the absence of personal hygiene.

According to contemporary science, various disorders can cause cracked skin like hyperkeratosis palmo-plantaris, palmoplantar psoriasis, anhidrosis, dermatitis, diabetic neuropathy, eczema, hypothyroidism, psoriasis, cold weather, excessive exposure to hot water, detergent chemicals and low humidity etc^[4]. The pH of healthy skin is slightly acidic, exposure to many commercial cleansers and hand soaps like substances with an alkaline pH also contribute to interruptions of skin integrity. A homeostatic repair mechanism is stimulated, when the skin integrity is disturbed, that causes the rapid repair of barrier function. Continued exposure to alkaline

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substances will slow down repair by inhibiting normal skin acidity when there is continued exposure to unfavourable environmental factors. Cracked skin is often kicked off by a vicious cycle of events starting off as a minor, but leading to painful deep cracks. Plain old dry skin can lead to scaling, which cause itchiness leading to scratching. This scratching can cause inflammation and tears of skin that leads to more irritation and pain by becoming fissures^[5].

Local application is essential part in the management of any kind of dermatological ailments. It provides highest drug concentration at the site of action. Ayurveda elaborates various local applications (*Kusthahara Lepa*, *Vipadikahara Lepa*) for the management of *Vipadika*^[6]. Among those, in this present study *Sarjarasadi Malahara* was selected for trial. It is medicated oil mentioned in *Bhaisajya ratnavali Kustha roga chikitsa-Vipadika chikitsa* chapter indicated for management of *Padasphutana*. It was applied as external application. To compare the efficacy of the trial drug, the well-known external application preparation *Vipadikahara Ghrita-taila* was selected. It is medicated oil mentioned in *Charaka Samhita, Kushta chikitsa* chapter as a treatment for five types of skin diseases such as *Vipadika*, *Charma kushta*, *Eka kushta*, *Kitibha* and *Alasaka*.

AIM AND OBJECTIVES

- **Primary Aim:** To assess the effect of *Sarjarasadi Malahara* in the management of *Vipadika*.
- **Secondary Aim:** To review the literature related to the disease "*Vipadika*" from Ayurveda as well as modern point of view.
- **Objective:** To compare the clinical efficacy of *Sarjarasadi Malahara* with controlled group (*Vipadikahara Ghrita-taila*) in the management of *Vipadika*.

MATERIAL AND METHODS

Study Type- Randomized open clinical comparative study

Sample Size- 30

Place of Study- V.Y.D.S. Ayurveda Mahavidyalaya, Khurja.

Study Design- Among the selected *Vipadika* patients, 30 no of patients fulfilling the inclusion criteria were randomly selected for clinical study. They were divided into two groups (TG, CG).

- ◆ In T.G.- 15 cases managed with *Sarjarasadi Malahara* as external application.
- ◆ In C.G.- 15 cases managed with *Vipadikahara Ghrita-taila* as external application

Selection Criteria for Patient- Cases of *Vipadika* were randomly selected as per diagnostic criteria

irrespective of sex, caste, occupation, socio-economical status etc.

Diagnostic Criteria- Diagnosis was considered according to presence of clinical features of *Vipadika* i.e. *Panipada Sphutanam* (cracks of hands and feet), *Tivra-vedana* (severe pain), *Kandu* (itching), *Saraag* (reddish discoloration), *Pitika* (papule)

Inclusion Criteria

- ◆ Patients who fulfil the diagnosis criteria i.e. presenting with classical signs and symptoms of *Vipadika*
- ◆ Age – Between 16 years and 60 years.
- ◆ Sex – Both sex
- ◆ Agreed for giving consent after making aware of the merits/demerits of the trial.
- ◆ Agreed for investigations (if needed) before inclusion into the trial and after completion of trial.
- ◆ Agreed for follow up for assessment and clinical evaluation.

Exclusion Criteria

- ◆ Age group < 16 yrs and > 60 yrs.
- ◆ Patients suffering from hemolytic, bleeding disorders, hereditary problems
- ◆ Patients suffering from any other major systemic disorders like diabetic mellitus, HIV etc.
- ◆ Associated with other forms of skin diseases.
- ◆ Lactating and pregnant women.
- ◆ Not agreed for giving consent/investigations/follow up

Lab Investigations

- ◆ Routine examination of blood
- ◆ Random Blood Sugar
- ◆ Any other necessary investigations to rule out exclusion criteria

Selection of Drug

Sarjarasa Malahara^[7]

- **Ingredients-** *Sarja rasa* (resin of *Shorea robusta*), *Saidhava lavana*, *Guda*, *Madhu*, *Guggul*, *Gairika*, *Ghrita*, *Siktha*
- **Dose-** Approximately 0.5cm smear thick over the affected area covering uniformly.
- **Route of Administration-** *Lepa* (external application)
- **Time of Administration-** Twice daily (morning & evening)

Vipadikahara Ghrita-taila^[8]

- **Ingredients-** *Jivanti*, *Manjistha*, *Darvi*, *Kampillaka*, *Paya* (cow milk), *Tuttha*, *Ghrita*, *Tila Tila*, *Sarjarasa*, *Madhuchichst* (bees wax).

- **Dose-** Approximately 0.5cm smear thick over the affected area covering uniformly.
- **Route of Administration-** *Lepa* (external application)
- **Time of Administration** - Twice daily (morning & evening)



Trial Period (Duration of Treatment)- 30 days

Follow Up- Every 10th day during trial period and once after 15 days of completion of trial.

Pathyapathya- Strict advise to maintain foot hygiene

OBSERVATIONS

Observation on Demographic Data- Presented in Tabular and Graphical presentation.

Criteria for Assessment of Therapy: The assessment was done on subjective and objective parameters noted on 10th day (AT1), 20th day (AT2) and 30th day (AT3) of after treatment where initial sign and symptoms was taken as 1st day (i.e. B.T.). The obtained results were analyzed with the use of Wilcoxon signed rank method to check the significance of subjective parameters and paired 't' test for objective parameters. Comparison of efficacy will be done using Mann-Whitney test in subjective parameters and unpaired t-test in objective parameters. Statistical analysis on the percentage of improvement in each parameter will evaluate by the formula: Average BT- Average AT * 100/ Average BT.

Scoring Pattern Adopted for Assessment

Assessment criteria for Subjective parameters

Panipaada Sphutanam (Cracks of Hands and Feet)

- G₀ – Normal foot/palms
- G₁ – Roughness is present and felt by touching but not by visualizing
- G₂ – Excessive visible roughness and leading to slight cracks
- G₃ – Roughness leading to cracks and fissures

Vedana (Pain on Numeric pain scale)- Instruct the patient to point to the numbers to indicate how much pain they are currently feeling.

- G₀ – Absence of pain/no pain (0 mark on scale)

- G₁ – Mild pain that can easily be ignored (1 - 3 mark on scale)
- G₂ – Moderate pain that cannot be ignored, interferes with function and needs treatment from time to time (4 to 6 mark on scale)
- G₃ – Severe pain that is present most of the time demanding constant attention (7 to 10 marks on scale)

Kandu (Itching)

- G₀ – No itching
- G₁ – Mild itching (only aware of itching when relaxing)
- G₂ – Moderate (sometime disturb the sleep and day time activity)
- G₃ – Severe (constant itching, frequent sleep disturbance)

Daha/Raga (Burning Sensation at the affected site)

- G₀ – No burning at the affected site
- G₁ – Mild burning sensation at the affected site but bearable nature comes occasionally
- G₂ – Moderate burning sensation at the affected site present all over the day: requires some measures for relief (water)
- G₃ – Severe burning sensation at the affected site: Requires some medical applications but may remain throughout the day

Assessment criteria for objective parameters

Number of cracks (total cracks of hands and feet)

- G₀ – No crack
- G₁ – 1-10 crack
- G₂ – 11-20 crack
- G₃ – > 20 crack

Total length of cracks

- G₀ – Absent
- G₁ – < 10mm
- G₂ – 10-20 mm
- G₃ – > 20 mm

Overall assessment of the therapy - It was noted after treatment upon the subjective and objective parameters in view of percentage of improvement classify as follows

- ◆ Maximum improvement - > 75% improvement
- ◆ Moderate improvement - > 50% to 75% improvement
- ◆ Mild improvement - > 25% to 50% improvement
- ◆ Unsatisfactory - Negligible (\leq 25%) improvement

OBSERVATIONS

Table 1: Statistical analysis showing the effectiveness of Trial drug

Sign & Symptoms	Mean Score			Mean diff.	± S.D.	± S.E.	w-Value	p - Value	Significance
	B.T.	A.T.							
<i>Panipaada Sphutanam</i> (Cracks of Hands and feet)	2.73	AT1	2.40	0.33	0.49	0.13	15	0.0625	Not quite significant
	2.73	AT2	1.20	1.53	0.52	1.00	120	0.0001	Extremely significant
	2.73	AT3	0.13	2.60	0.63	0.16	120	0.0001	Extremely significant
<i>Vedana</i> (Pain on Numeric pain scale)	2.21	AT1	1.86	0.36	0.50	0.13	15	0.0625	Not quite significant
	2.21	AT2	0.93	1.29	0.61	0.16	91	0.0002	Extremely significant
	2.21	AT3	0.07	2.14	0.66	0.18	105	0.0001	Extremely significant
<i>Kandu</i> (Itching)	2.60	AT1	2.20	0.40	0.52	0.16	10	0.125	Not significant
	2.60	AT2	1.10	1.50	0.53	0.17	55	0.002	Very significant
	2.60	AT3	0.10	2.50	0.53	0.17	55	0.002	Very significant
<i>Daha</i> (Burning Sensation at the affected site)	2.50	AT1	2.17	0.33	0.52	0.21	3	0.5	Not significant
	2.50	AT2	0.67	1.83	0.75	0.31	21	0.0313	Significant
	2.50	AT3	0.33	2.17	0.75	0.31	21	0.0313	Significant
Number of cracks (total cracks of hands and feet)	2.73	AT1	2.40	0.33	0.49	0.13	15	0.0625	Not quite significant
	2.73	AT2	1.20	1.53	0.52	1.00	120	0.0001	Extremely significant
	2.73	AT3	0.13	2.60	0.63	0.16	120	0.0001	Extremely significant
Total length of cracks	2.47	AT1	2.20	0.27	0.46	0.12	10	0.125	Not significant
	2.47	AT2	1.20	1.20	0.46	0.12	120	0.0001	Extremely significant
	2.47	AT3	0.13	2.33	0.62	0.16	120	0.0001	Extremely significant

Table 2: Statistical analysis showing the effectiveness of Control drug

Sign & Symptoms	Mean Score			Mean diff.	± S.D.	± S.E.	w-Value	p - Value	Significance
	B.T.	A.T.							
<i>Panipaada Sphutanam</i> (Cracks of Hands and feet)	2.6	AT1	2.47	0.13	0.35	0.09	3	0.5	Not significant
	2.6	AT2	1.27	1.33	0.62	0.16	105	0.0001	Extremely significant
	2.6	AT3	0.33	2.27	0.96	0.25	105	0.0001	Extremely significant
<i>Vedana</i> (Pain on Numeric pain scale)	2.13	AT1	2.00	0.13	0.35	0.09	3	0.5	Not significant
	2.13	AT2	1.00	1.13	0.52	0.13	105	0.0001	Extremely significant
	2.13	AT3	0.33	1.80	0.68	0.17	120	0.0001	Extremely

									significant
<i>Kandu</i> (Itching)	2.83	AT1	2.67	0.17	0.39	0.11	3	0.5	Not significant
	2.83	AT2	1.75	1.08	0.79	0.23	45	0.0039	Very significant
	2.83	AT3	0.75	2.08	1.31	0.38	45	0.0039	Very significant
<i>Daha</i> (Burning Sensation at the affected site)	2.75	AT1	2.50	0.25	0.46	0.16	3	0.5	Not significant
	2.75	AT2	1.13	1.63	0.52	0.18	36	0.0078	Very significant
	2.75	AT3	0.25	2.50	0.53	0.19	36	0.0078	Very significant
Number of cracks (total cracks of hands and feet)	2.6	AT1	2.47	0.13	0.35	0.09	3	0.5	Not significant
	2.6	AT2	1.27	1.33	0.62	0.16	105	0.0001	Extremely significant
	2.6	AT3	0.33	2.27	0.96	0.25	105	0.0001	Extremely significant
Total length of cracks	2	AT1	1.93	0.0667	0.26	0.07	1	0.9999	Not significant
	2	AT2	1.00	1.00	0.53	0.14	91	0.0002	Extremely significant
	2	AT3	0.47	1.533	0.916	0.236	78	0.0005	Extremely significant

Table 3: Showing the Incidence of Patients According to the % of Improvement After Treatment in Both Groups

Sign & symptoms	AT	% of improvement	
		C.G.	T.G.
<i>Panipaada Sphutanam</i> (Cracks of hands and feet)	AT1	12.20	5.13
	AT2	56.09	51.27
	AT3	95.13	87.19
<i>Vedana</i> (Pain on Numeric pain scale)	AT1	16.13	6.25
	AT2	58.08	53.12
	AT3	96.79	84.39
<i>Kandu</i> (Itching)	AT1	15.38	5.88
	AT2	57.69	38.23
	AT3	96.15	73.53
<i>Daha</i> (Burning Sensation at the affected site)	AT1	13.33	9.09
	AT2	73.32	59.09
	AT3	86.68	90.91
Number of cracks (total cracks of hands and feet)	AT1	12.20	5.13
	AT2	56.09	51.27
	AT3	95.13	87.19
Total length of cracks	AT1	10.81	3.33
	AT2	48.64	50.00
	AT3	94.57	76.65

Table 4: Comparison of effects on different parameters of both drugs

Symptom	Group	No of pts	Means	Mann-Whitney (U value)	p-Value	Remark
Panipaada Sphutanam (Cracks of hands and feet)	C.G.	15	2.6	93	0.3676	Not significant
	T.G.	15	2.267			
Vedana (Pain on Numeric pain scale)	C.G.	14	2.143	77	0.1824	Not significant
	T.G.	15	1.8			
Kandu (Itching)	C.G.	10	2.5	50	0.494	Not significant
	T.G.	12	1.833			
Daha (Burning Sensation at the affected site)	C.G.	6	2.167	18	0.4273	Not significant
	T.G.	8	2.5			
Number of cracks (total cracks of hands and feet)	C.G.	15	2.6	t=93	0.3676	Not significant
	T.G.	15	2.267			
Total length of cracks	C.G.	15	2.333	t=58	0.0125	Significant
	T.G.	15	1.533			

Table 5: Overall clinical Effect of therapy

Clinical effect of therapy	Overall Effect of therapy			
	C.G.		T.G.	
	f	%	f	%
Maximum improvement (> 75%)	11	73.33	5	33.33
Moderate improvement (>50 - 75%)	4	26.67	8	53.33
Mild improvement (>25 - 50%)	0	0	1	6.67
Unsatisfactory (≤25%)	0	0	1	6.67

DISCUSSION

Vipadika is one among the 11 types of *Kshudra Kustha*. *Vipadika* is prevalent commonly in society. It hinders a person’s daily activities due to crack and pain in hand and foot. Ayurveda gave more priority to external application than internal (*Shamana*) therapy in *Vipadika*. *Acharya Charaka* has categorically mentioned the different categories of external applications like *Kusthahara Lepa*, *Vipadikahara Lepa* etc. Therefore local application is essential part in the management of any kind of dermatological ailments. It provides highest drug concentration at the site of action. In Ayurveda, it is mentioned that, role of external application (*Lepa*) in *Kustha* is as important as internal medication. Keeping all this in mind, the *Sarjarasadi Malahara* was chosen as a need of the hour. *Vipadikahara Ghrita-taila* is a known and effective medicine in treating *Vipadika* chooses for comparison of effect.

Probable Mode of Action of Trial and Control Drug: The compositions in both the drugs are approachable lieu of principles of treatment of *Vipadika*.

On Rookshata: The herbs like *Jeevanti*, *Go-Ghrita*, *Tila Taila* and *Madhucchista* having *Snigdha Guna* which might have helped to control *Vata* and for the prevention of *Rukshata* and *Kharasparsha* in *vipadika*. This type of lubrication helps for moistening and softening of skin.

On Kandu: *Kandughna* property of *Tuttha* and *Daruharidra*, *Krimigna* property of *Manjista*, *Kampillaka*, *Tuttha* and *Sarjarasa*. *Vishagna* property of *Sarjarasa*. *Kaphagna* property of *Manjista*, *Daruharidra*, *Kampillaka*, *Sarjarasa*. *Kapha lekhana* property of *Tuttha* and *Kapha nissaraka* property of *Jeevanti moola* may help to subside the itching.

On Sphutana: *Vrana shodana* and *Vranaropana* properties of *Daruharidra*, *Kampillaka*, *Tila taila*, *Sarjarasa* and *Manjista*, *Rasayana* property of *Godugdha*, *Snigdha guna* of *Jeevantimoola*, *Godugdha*, *Goghrita*, *Tila taila* and *Madhucchista* might have reduced and cured the symptom *Sphutana* of *Pani* and *Pada*.

On Vedana: *Vedana sthapaka* action of *Kampillaka*, *Tila taila* and *Sarjarasa* might have subsided the symptom *Vedana*.

On Srava: The *Sthambaka* action of *Sheeta Veerya* of *Sarjarasa*, *Kashaya Rasa* and *Sandhaneeya* property of *Tila taila*, *Sheeta veerya* of *Jala*, *Go-dugdha*, *Go-grita* and *Jeevanti moola* might have been cured the symptom *Srava*.

On Daha: The *Pitta Shamaka* properties of *Manjista*, *Jeevanti moola*, *Daruharidra*, *Go-dugdha* and *Go-ghrita* might have subsided the symptom *Daha*.

❖ **The demographic data in this study reveals that** Maximum numbers of patients i.e. 13 (43.33%) were observed between the age group of 51 -60 years, 21 (70%) were males, 12 (40%) were farmers, 21 (70%) were received irregular treatment, 11 i.e., 36.67% have *Tridosaja prakruti*, 13 (43.33%) of the patients were in *Vishmagni* group, 15 (50.00%) were of *Krura kostha*.

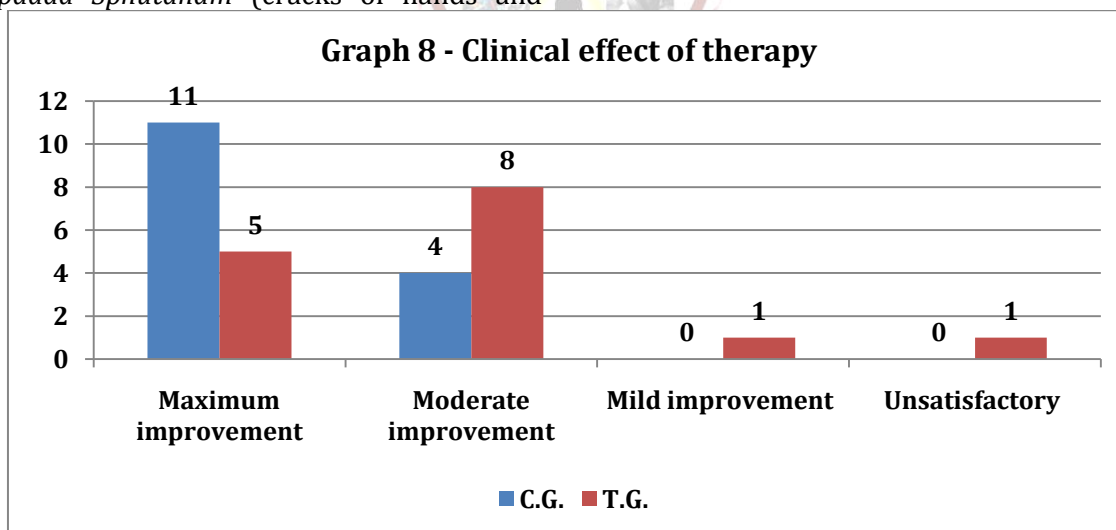
❖ **The clinical data in this study reveals that** all patients belonging to TG & CG were got relief, which has been critically assessed in the language of percentage. So far the improvement of cardinal sign symptoms in the present study, the percentage of improvement was 95.13%, 96.79%, 96.15%, 86.68%, 95.13%, 94.57% in *Vipadikahara Ghrita-taila* and 87.19%, 84.39%, 73.53%, 90.91%, 87.19%, 76.65% in *Sarjarasadi Malahara* in respect to *Panipaada Sphutanam* (cracks of hands and

feet), *Vedana* (pain on numeric pain scale), *Kandu* (itching), *Daha* (burning Sensation at the affected site), number of cracks (total cracks of hands and feet), total length of cracks. This shows, the cases achieved more benefit by *Vipadikahara Ghrita-taila* than *Sarjarasadi Malahara*.

❖ **The statistical adjudication with suitable parameters shows that** both drugs (*Vipadikahara Ghrita-taila* & *Sarjarasadi Malahara*) were extremely/very significant on subjective & objective parameters among both groups.

❖ **The comparison of effect of both drug in this study reveals that** the difference of effect of trial drug in C.G. and T.G. on various symptoms like *Panipaada Sphutanam* (cracks of Hands and feet), *Vedana* (pain on numeric pain scale), *Kandu* (itching), *Daha* (burning sensation at the affected site), number of cracks (total cracks of hands and feet), total length of cracks was not significant that means the relief provided by both group was nearly similar.

❖ **Overall clinical assessment of results shows-** Both the drugs derived improvement leading to maximum, moderate, mild and unsatisfactory having 73.33%, 26.67%, 0%, 0% by CG and 33.33%, 53.33%, 6.67%, 6.67% by TG respectively. However in the series of trial complete cure could not be achieved in any group.



CONCLUSION

Manifestation of *Vipadika* is irrespective of age, sex, occupation, but predominantly seen in between the age group of 51 -60 years (43.33%), males (70%), farmers (40%). *Vipadika* can occur among all *Prakrutis* but predominantly found in *Tridosaja Prakruti* (36.67%). The main conclusive impression as regards efficacy of the drug is that both drugs are found capable to enforce relief but *Vipadikahara Ghrita-taila* is more effective than *Sarjarasadi Malahara*.

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