

Evaluation of Comparative efficacy of *Gokshura Taila Matravasti* Versus *Ashwagandha Taila Matravasti* in the Management of *Katigraha* (Pain and Stiffness in the Lower back): A Randomized Controlled Trial

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Abstract-

Background: Nowadays, low back discomfort is a significant health issue. This might be the result of developing poor posture and lifestyle choices. A quick look through the Ayurvedic classics reveals numerous words used to describe the illness. Lower back pain is a symptom rather than a disease and can be brought on by a number of underlying conditions that range in severity. Although the source of the majority of LBP is unknown, non-serious muscle or skeletal problems such sprains or strains are assumed to be the primary culprits. Acharya Vagabhta mentioned in Ashtang Hrudya that in *Katigraha*, *Madhura* or *Amla Dravyas Kalka* or *Kwath* can be mixed with *Taila* or *Ghrta* to give *Anuvasan vasti*. **AIM:** Evaluation of Comparative efficacy of *Gokshura Taila Matravasti* Versus *Ashwagandha Taila Matravasti* in the Management of *Katigraha* (Pain and Stiffness in Lower back). **OBJECTIVES:** To assess the effect of *Gokshura Taila Matravasti* on *Ruja* (pain) and *Stambha* (stiffness) in *Katigraha* (pain and stiffness in lower back). To assess the effect of *Ashwagandha Taila Matravasti* on *Ruja* (pain) and *Stambha* (stiffness) In *katigraha* (pain and stiffness in lower back). To Compare the efficacy of *Gokshura taila Matravasti* with *Ashwagandha taila Matravasti* in *Ruja* and *Stambha* in management of *Katigraha* (pain and stiffness in lower back). **Methodology:** - in this study, total of 60 patients will be divided into two groups. In group A *Ashwagandha Taila Matra Vasti* will be administered in dose form of 60 ml for 9 days after. Same will be used for the other 30 patients i.e. group B with *Gokshura Taila Matra Vasti*. Result: The result will be assessed on baseline of objective parameters and data will be compared after treatment. **Conclusions-** Will be based on observations and results obtained.

Keywords – *Katigraha*, Pain and Stiffness in Lower Back, *Ashwagandha*, *Gokshura*, *Ashwagandha Taila Matra Vasti*, *Gokshura Taila Matra Vasti*.

INTRODUCTION

Ayurveda is an ancient Indian health science practiced for thousands of years. "Ayurveda" literally means "Knowledge of Life." It is more than simply, healthcare is a comprehensive approach to living a healthy lifestyle. Panchakarma is a unique disciplinary of Ayurveda that focuses on cleaning and detoxification. *Katigraha* is the condition

that *Ruja* and *Stambha* characterize due to the vitiation of *Vata* in the *Katipradesha*. *Katigraha* was regarded as a different ailment meant by Acharya Sharangdhara in *Nanatmaja Vatavyadhi* [1]. In *Gadanigraha*, *Lakshana* of *Katigraha* is described as the vitiation of *Vata Dosha* [2]. The most frequent disease is *katigraha*. It is one of the *Nanatmaja Vatavyadhi*, which is a lumbar area ailment. Even

though this disease is not Life-threatening, it has a significant impact on the daily activities of those who suffer from it. *Acharya Charka* mentioned, *trikashula* as an *aptarpanjanita roga* and also *trikapradesha* pain in *gudagat Vata Lakshana* [3]. In *Ashtanga Hrudaya*, *Acharya Vagbhata* listed *Katigraha* as a symptom of vitiation of *pakvshaya vata*[4]. *Katigraha* is a *Shosha* Predominant *Vyadhi* with a *Sthambha Shula*. As *Acharya Sushruta* stated, *Shula* cannot be formed without *Vata* vitiation [5]. According to *Gada Nigraha*, pain is caused by stiffness, caused by *Sama* or *Nirama* *Vayu* movement into *Kati*, implying the presence of *Dhatu Khsayatmaka Marga Avarodhaka* type of *samprapti*[6].

Lower back pain is not an illness but rather a symptom that can be caused by a variety of underlying issues of varying degrees of severity. Most LBP has no known etiology; however, it is thought to be caused by non-serious muscle or skeletal disorders like sprains or strains. Obesity, smoking, pregnancy weight gain, stress, poor physical condition, lousy posture, and poor sleeping can all contribute to LBP [7]. Low back discomfort is one of the most common issues nowadays. Low back pain (L.B.A.) affects 60–85 percent of adults at some point during their life; Even while the symptoms are modest and temporary in the vast majority of people, with 90% of them disappearing within six weeks, the impact on quality of life and cost implications are significant for those with intractable symptoms, chronic low back pain, defined as pain that lasts longer than three months, affects 15–45 percent of the population [8] as *Acharya Charaka* stated that when there is vitiation of *Vata dosh* to pacify it there is no other treatment than *Vasti chikitsa*. *Vasti* is called *Ardha chikitsa* that's is half of the other treatment [9].

प्रवाहणे गुदभ्रंशे मूत्राघाते कटिग्रहे॥५१॥ मधुराम्लैः शृतं तैलं घृतं वाऽप्यनुवासनम्। *A.H.Chi.9/51*,

In *Katigraha*, *madhura* or *amla dravyas Kalka* or *kwath* can be mixed with *taila* or *ghrita* to give *Anuvasan vasti* [10]. *Anuvasan vasti* is useful in *Vata Kapha dosha* pacification *Acharaya Vagbhata* in *Ashtanga Hrudaya* mentioned the *Matra Vasti* and its dosage related to *Anuvasan Vasti*[11], and personal fit for *Matravasti*. It is beneficial to pacifies all *Tridosha's* iTridosha's on regular basis [12]. *MatraVasti* strengthens and excretes waste from the body easily. *Sneha vasti* is a form of *Matra Vasti*. It

has received high recognition for its vast and multi-faceted application. *Matra vasti* is half the dose of *Anuvasana vasti*, which is half of three *pala* or twelve *tolas*. As a result, the *Matra Vasti* dose is 12 *pala* or six *tola* (approximately 72 grammes). According to *Charaka* and *Vagbhata*, the quantity of *Matra Basti* should be equivalent to the amount of *Hrisva Sneha matra* (minimum dosage of oral consumption of *Sneha*) [13]. *Acharaya Vagbhata* has also described the timing, dosage, and duration of *matrabasti*. *Acharya Charak* in *VimanSthan* and *Vagbhat* in *Sutra Sthan* mentioned, *Ashwagandha* and *Gokshura* in the *Madhura Skanda*, among *Shad Skanda* [14][15], with their properties that acting upon vitiated *vatadi doshas* [16]. *Madhura Dravya* has *Vata-soothing* effects, making them useful in *Katigraha*. *Gokshura* has its anti-inflammatory, analgesic, and antispasmodic actions [17]. *Vatahara* drugs, in combination with *Snigdha Dravya* (*Tila Taila*), which contains *Madhura Guna* generate *vatahara* property benefits the *Katigraha*[18]. Thus, the goal of this study is to compare the efficacy of *Ashwagandha tail* with *Gokshura taila* in the management of *Katigraha* (pain and stiffness in the lumbar region).

Need of Study

Now a days, the working pattern has changed to long-term sitting work, which is more common, which leads to pain and stiffness in the lumbar region. Many young populations do strenuous workouts in gym, which directly or indirectly causes pain and stiffness in the lumbar region. Exercise, physiotherapy, rest, and NSAIDs and analgesics are all used to relieve pain temporarily for low back pain and stiffness. Still, long-term relief is required in this approach in *Ayurveda Vasti chikitsa* (therapy) provide permanent relief of *katigraha* (pain and stiffness in the lower back). *Acharya Charak* in *Viman Sthan* and *Acharya Vagbhat* in *Chikitsa Sthan* mentioned, *Ashwagandha* and *Gokshura* in the *Madhura Skanda*[14][15]. *Gokshura* has its anti-inflammatory, analgesic, and antispasmodic actions; hence to widening the scope of treatment for *Katigraha*, *Gokshura* is chosen for intervention in *katigraha* (pain and stiffness in lower back[19]). *Vatahara* drugs in combination with *Tila Taila*, which have *tikshna*, *vyavayi*, *sukshma*, *vatashamak guna*, generate *vatahara* property that benefits the *katigraha* (pain and stiffness in the lower back) [20]. Single drug *Gokshura* is widely available and more productive, multidrug

formulation is more costly than single drug; hence to widen the efficacy of *Gokshura*, it is chosen for study.

Research Question:

Whether *Gokshura Taila Matra Vasti* is more productive than *Ashwagandha Taila Matra Vasti* in the management of *Katigraha* (Pain and stiffness in the lumbar region)?

Hypothesis

Alternate Hypothesis

Gokshura Taila Matra Vasti is more efficacious than *Ashwagandha Taila Matra Vasti* in the Management of *Katigraha* (pain and stiffness in the lower back).

Null Hypothesis

There is no significant difference between the efficacy of *Gokshura Tail Matra Vasti* and *Ashwagandha Taila Matra Vasti* in the Management of *Katigraha* (pain and stiffness in lower back).

PICO MODEL:

1.	P	Diagnosed case of <i>Katigraha</i>
2.	I	<i>Gokshura Taila Matra Vasti</i>
3.	C	<i>Ashwagandha Taila Matra Vasti</i>
4.	O	Relief in <i>Ruja</i> and <i>Stambha</i> in <i>Katigraha</i>

AIM AND OBJECTIVES:

AIM:

Evaluation of Comparative efficacy of *Gokshura Taila Matravasti* Versus *Ashwagandha Taila Matravasti* in the Management of *Katigraha* (Pain and Stiffness in Lower back).

OBJECTIVES:

1. To assess the effect of *Gokshura Taila Matravasti* on *Ruja* (pain) and *Stambha* (stiffness) in *Katigraha* (pain and stiffness in the lower back).
2. To assess the effect of *Ashwagandha Taila Matravasti* on *Ruja* (pain) and *Stambha* (stiffness) In *katigraha* (pain and stiffness in the lower back).

3. To Compare the efficacy of *Gokshura tail Matravasti* with *Ashwagandha tail Matravasti* in *Ruja* and *Stambha* in the management of *Katigraha* (pain and stiffness in the lower back).

RESEARCH GAP ANALYSIS

S. No.	Author	Journal name and year	Title	Conclusion	Remark
1.	KP DF, Thakar AB, Shukla VD.	Ayu. 2013 Jan 1;34(1):36-41.	Clinical efficacy of Eranda Muladi Yapana Basti in the management of Kati Graha (Lumbar spondylosis).	<i>Eranda Muladi Yapana Basti</i> yields better results in pacifying pure <i>Vataja</i> or <i>Vata Kaphaja</i> type of <i>Kati Graha</i> .	1. Duration of <i>Yapan Vasti</i> is more than <i>Matra Vasti</i> . The contents of <i>Yapan Vasti</i> are <i>Gokshura tail Matra Vasti</i> . 2. In <i>Pitta Prakriti</i> , patients symptoms may aggravates due to ingredients containing <i>Ushna Virya</i> property of <i>yapan vasti</i>
2.	Tripathy R, Namboothiri P, Otta S.P. Open label comparative	International Journal of Ayurveda and Pharma Research June 2016	a clinical trial of Dvipanchmooladi Taila and Ksheerbala Taila MatraVasti in the management of low back ache.	It is established that <i>Dvipanchmooladi tail Matra Basti</i> efficiently reduces pain, stiffness	Patients were selected between 30-60 yrs of age, but now a days in the current scenario, <i>Katigraha</i> affecting early adulthood.
3.	Bhende SV, DadaraoParwe S, Patil M, Waigi R..	International Journal of Ayurvedic Medicine, Vol II (2),310-313, December 2020	Evaluate the effectiveness of Madhura and Amla Dravya Matravasti in <i>Katigraha</i>	Both <i>Madhura Dravya</i> and <i>Amla Dravya</i> show improvement in <i>Katigraha</i> . Comparing the percentage wise relief, <i>Amla Dravya (ChinchaTail)</i> <i>Matravasti</i> seems to be more effective on overall symptoms of <i>Katigraha</i> .	<i>Gokshura</i> has a wide range of efficacy than <i>Chincha</i> , sample size for comparative effectiveness was small, with 15 in each group
4.	Bhende SV, Parwe S.	International Journal of Ayurvedic Medicine. 2020;11(2):310-	Role of Ashwagandha Taila Matrabasti in the Management of <i>Katigraha</i> .	<i>Matrabasti</i> with <i>Madhura Dravya (Ashwagandha tail)</i> effective in reducing symptoms of <i>Katigraha</i>	1. In compare with <i>Ashwagandha</i> , <i>Gokshura</i> has properties like an anti-inflammatory, antispasmodic, and analgesic. 2. <i>Gokshura</i> is more easily available than <i>Ashwagandha</i>

Katigraha is an issue that affects a large number of people. Aging, trauma, a sedentary lifestyle, and a lack of exercise are all potential causes of this condition. In this previous year, there is a complete change in work mode, due continue long time sitting work problems related with lumbar region increases such as pain and stiffness. *Sneha Vasti* form of *Matra Vasti*. It has received high recognition for its vast and multi-faceted application. Many studies have been undertaken on *Katigraha* and *Matravasti*, but no comparative study on *Gokshura tail* and *Ashwagandha trial* has been conducted. As a result, the current research is being planned.

MATERIAL AND METHODS

Source of Data: Patients will be recruited from the O.P.D. and IPD of the *Panchakarma* of Mahatma Gandhi Ayurveda College, Hospital and Research Centre, Wardha, and from Peripheral Camps.

Sample size (Including sample size calculation):

Total Sample size: 60

Group (A): Control Group (30)

Group (B): Standard Group (30)

Sampling procedure: Randomization computer-generated table.

Type of Study: Interventional Study

Study design: Randomization standard control single blind superiority clinical trial.

Grouping & Posology:

Group	Sample size	Intervention	Dose	Procedure	Duration	Follow up
A	30	Ashwagandha taila	60ml	Matravasti	Nine days	Baseline on 0 th day 1 st follow up on the 10 th day 2 nd Follow up 28 th day
B	30	Gokshura taila	60ml	Matravasti	Nine days	The baseline on 0 th day 1 st 10 th day 2 nd Follow up 28 th day

Study Duration: 2 years.

Drug Collection/Authentication-

Raw medications would be obtained from trustworthy sources, identified and authenticated by the Department of Dravyaguna, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (Hirapur), Wardha.

- **Case Definition** -A diagnosed *Katigraha* subject with symptoms including *Ruja* (pain) and *Stambha* (stiffness) in *Katipradesha*, with having either gender between the ages of 20 to 60 years.

Data collection tools and process:

Inclusion criteria:

- A patient who are willing to give written informed consent.
- A *Katigraha* (pain and stiffness in the lower back) diagnosis with clinical symptoms ranging from 6 months to a year and no neurological deficit.
- *Katigraha* (pain and stiffness in the lower back) patients range in age from 20 to 60 years [21].
- Patients who are fit for the *Matravasti* procedure [22].

Exclusion criteria

- Myelopathy is associated with lumbar and other spinal disc disorders.
- Patients with a neurological condition [23].
- Traumatic Patients.
- Pregnant Women and Lactating mother.
- Patient is linked to both simple and complicated fractures.
- Patients with anorectal diseases [24].

Details of Drug Preparation-

Gokshura tail and *Ashwagandha taila* will be prepared in the Dattatrya Rasashala of Mahatma Gandhi Ayurveda College, Hospital & Research Centre using standard operating procedures.

Sr. No.	Dravya	Latin name	Rasa	Guna	Virya	vipaka	Doshghnata
1	Gokshura (panchanga)	Tribulus Terrestris	Madhura	Guru Snigdha	Sheeta	Madhura	Vatapitahara
2	Ashwagandha (Mula)	Withania somnifera	Kashaya, Tikta, Madhura	Laghu, Snigdha	Ushna	Madhura	Kaphavataasha

3	<i>Tila taila</i>	Sesamum Indicum .linn	<i>Madhur, Tikta</i>	<i>Madhur, Tikta</i>	<i>Sheeta</i>	<i>Madhu</i>	<i>Tridosh ahara</i>
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smoke, dust, etc. collect the necessary materials for *Vasti*, such as a table, medicine, and material for *Abhyanga* and *Mrudusweda*.

The subjects were told to arrive after eating a light diet of less than 3/4 of their usual amount (neither to *Snigdha* nor to *Ruksha*) and digesting their last meal properly.

Detail of drug preparation:[25]

<i>Gokshura tail proportion 1:4:16</i>	<i>Ashwagandha taila proportion 1:4:16</i>
1 part of <i>Gokshura kalka</i>	1 part of <i>Ashwagandha kalka</i>
4 part of <i>Tila Taila</i>	4 parts of <i>Tila Taila</i>
16 parts of water	16 parts of water
Make a <i>Kwath</i> of all material and heat	Make a <i>Kwath</i> of all material and heat
Reduce till all water content get evaporated	Reduce till all water content gets evaporated

The coarse powder of the *Kalka dravya* will be taken in *khalva yantra* and triturated with little quantity of water till we obtain *Kalka*.

Now, *Tila taila* will be taken in a clean wide-mouthed stainless-steel vessel, and placed over a mild fire.

Then, *kwatha* and water followed by *Kalka* will be added and processed with frequent stirring.

Then, as soon as all the *Sneha siddhi lakshanas* are attained, the hot tail will be filtered into a clean stainless-steel vessel.

Then, after the *taila* is cool down, it is packed and preserved in appropriate airtight containers for further therapeutic use.

Procedure for *Matra vati* [26]:

The procedure of *Matravasti* is divided into three stages such as *Purvakarma*, *Pradhan karma*, and *Pashchat karma*.

1. *Purvakarma* (Pre-procedural preparation):

Sambar Sangraha: for *Matravasti*, choose a room with good lighting, free from air,

➤ *Trikatu Churna* 3gm T.D.S. was used for three days in the condition of the *Saamata Deepan* and *Pachan* before beginning the *Matravasti* procedure.

➤ Local *Abhyanga* with *Tila taila* was performed with lukewarm oil over the abdomen, buttocks, and thighs for 5-10 minutes, followed by *Mrudu Swedan*.

2. *Pradhankarma* (Procedural preparation) :

➤ After the *Purvakarma* was completed, the subject was advised to lie down on the *Vasti* table in a left lateral position, with the left leg straight and the right leg flexed at the knee and hip joints.

➤ The patient must keep his left hand below his head at all times. In an enema syringe, 60 cc of lukewarm oil was injected. Rubber catheter with lubricant spread on it, attached to an enema syringe.

➤ Rubber catheters were inserted into the anus up to 4 inches after the air in the enema syringe was removed. While inserting the catheter and the oil, the subject was instructed to take a deep breath and not shake his body.

3. *Pashchatkarma* (Postprocedural preparation):

➤ Following the administration of *Vasti*, the subject was instructed to lie down in a supine position with hands and legs freely spread over the table.

➤ Then gently tap over the hips, soles, elbows, and palms to allow the *Matravasti* to spread throughout the body and be retained for the required time.

- After a while, the subject was advised to get up from the table and rest in his bed and not to sleep throughout the day.
- The retention time of *Vasti* should be noted.

Observations:**Samyak yoga Lakshana- (C.si.1/44) [27]**

1. *Sa Anila Sa Purisha Sneha Pratyagamana*
1. *Raktadi Buddhi-Indriya Prasada*
2. *Svapnanuvruti*
3. *Laghuta*
4. *Bala*
5. *Srushtasca*
6. Absence of *Daha*

Ayoga Lakshana- (C.si.1/45) [28]

1. *Adha Sarira Ruja*
2. *Udara Ruja*
3. *Prushta Ruja*
4. *Parsva Ruja*
5. *Ruksha Gatrata*
6. *Ruksha Svara*
7. *Purusha Sanga*
8. *Mutra Sanga*
9. *Vata sanga*

Atiyoga Lakshana- (C.si.1/46) [28]

1. *Hrillasa*
2. *Moha*
3. *Klama*
4. *Sada*
5. *Murccha*
6. *Vikartika*

Sneha Vasti Vyapada & their management: - (C.si.4/25) [29]

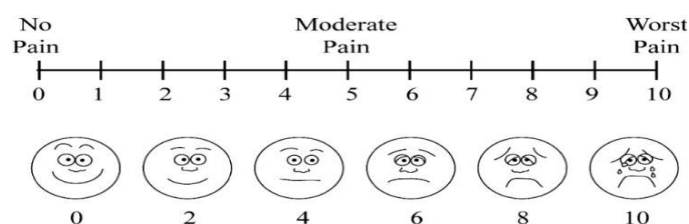
1. **Vata Vruta Sneha- management- Rasnadi tikshan Vasti, Rasnadisidha tail Anuvasana Vasti**
2. **Pitta Vruta Sneha – management- Vasti with swaadu- tiktadravyas**
3. **Kapha Vruta Sneha – management- Teekshna Vasti**
4. **Anna Vruta - management- Pachana with katu and Lavanavhurna and kwatha, Mrudu virechana, Amaharakriya**
5. **Purisha Vruta- management- Sneha, Sweda, Varti, Shyamabilwadi Siddha Niruha and Anuvasana Vasti**
6. **Abhukta Vruta- management- Niruha & Anuvasana vasti prepared with gomutra, syama, trivrit, yava, kola, and kulattha should be given.**

Assessment criteria**(1) Ruja (Pain) (VISUAL ANALOG SCALE)**

The patient will be asked to rate their experience of pain using numbers from 0 (being no pain) to 10 worst pains.

Table no.1**Scoring pattern for assessment of subjective parameters**

a) Shoolain Kati (Pain):	Grade 1 - No Pain
	Grade 2 - Minor Pain
	Grade 3 - Moderate Pain
	Grade 4 - Severe Pain
b) Sthambha in Kati(Stiffness):	Grade 0 - Normal movement
	Grade 1 - 0 to 25% Restricted
	Grade 2 - 25% to 50% Restricted
	Grade 3 - 50% to 75% Restricted
	Grade 4 - 75% to 100% Restricted



Schober's Test is a "physical examination used in physical medicine and rehabilitation and rheumatology to measure the ability of the patient to flex lowerback^[30] .

Table no.2: Overall Assessment of Clinical Response:

Sr	Overall Assessment	Clinical Response
1	Complete remission	100% relief in signs and symptoms and walking without any pain were considered complete remission
2	Marked Improvement	75-99% relief in signs and symptoms
3	Moderate Improvement	50-74% relief in signs and symptoms
4	Mild Improvement	25-49% relief in signs and symptoms
5	Unchanged	No change in signs and symptoms

Range of motion of lumbar spine:

Range of Motion	Normal
Flexion	60°
Extension	25°
Left lateral Flexion	25°
Right lateral Flexion	25°

Investigations:

1. X-ray lumbosacral spine will be done only to rule out the exclusion condition.

ANALYSIS PLAN

A] Drug Analysis

Raw medications would be obtained from trustworthy sources, identified and authenticated by the Department of *Dravyaguna*, Mahatma Gandhi Ayurveda College, Hospital & Research Centre, Salod (Hirapur), Wardha.

Data analysis (statistical methods)

The collected data will be analyzed with the help of an inferential statistical test.

Observation and result:

The results will be created using various charts, graphs, and tables based on data from the followup chart and other observations. To determine the relevance of the findings, do the following. Improvement in range of motion, pain, and stiffness after treatment will be noted as significant.

Discussion -

Ashwagandha is Analgesic, antiinflammatory, neuroprotective, immunoprotective effects hence it will be act on pain and stiffness in lower back^[31].

Gokshura have its anti-inflammatory, analgesic, and antispasmodic actions, hence to widening the scope of treatment for *Katigraha*, *Gokshura* is chosen for intervention in *katigraha* (pain and stiffness in lower back)^[32]. *Vatahara* drugs in combination with *Tila Taila*, which have *tikshna*, *vyavayi*, *sukshma*, *vatahamak guna* generate *vatahara* property that benefits the *katigraha* (pain and stiffness in lower back)^[33]. Single drug *Gokshura* is widely available and more efficacious, multidrug formulation is more costly than single drug hence to widening the efficacy of *Gokshura* it is chosen for study.

It will be based on what has been observed, and the outcomes gained.

Scope of implications of the proposed study:

If *Gokshura Taila Matra Vasti* is efficacious in reducing lumbar pain and stiffness, then the clinical evidence with simple, easy use, safe, with widely efficacious, can be formulated for the management of *Katigraha* (pain and stiffness in the lower back).

Ethical consideration:

The study will start after clearance from, I.E.C. Mahatma Gandhi Ayurveda College Hospital and Research Centre Salod (H), Wardha, and C.T.R.I. registration.

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